



# Operator's Manual

## Ventilator NKV-330





## About This Manual

In order to use this product safely and fully understand all its functions, read this manual before using the product. Keep this manual near the instrument or in the reach of the operator and refer to it whenever the operation is unclear.

### Accompanying Documentation

The ventilator comes with the following manuals. Refer to the manual depending on your needs.

#### Operator's Manual (this manual)

Describes the operation and settings of the ventilator. Read this manual before use.

#### Administrator's Guide

For administrators. Describes how to install the ventilator and about the settings which only an administrator can change as well as providing information on maintenance and inspection of the ventilator. Read the Operator's Manual together with this guide.

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### Trademark

The company name and model name are trademarks and registered trademarks of each company.



The mark printed on the SD card that is used in this instrument is a trademark.

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This product stores personal patient information. Manage the information appropriately.

Patient names on the screen shots and recording examples in this manual are fictional and any resemblance to any person living or dead is purely coincidental.

The contents of this manual are subject to change without notice.

If you have any comments or suggestions on this manual, please contact us at: <https://www.nihonkohden.com/>



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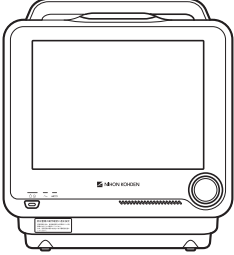
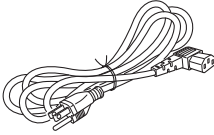

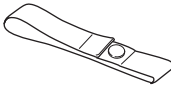
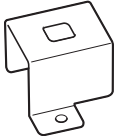

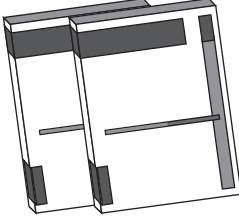
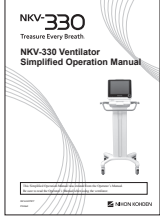

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# Unpacking

Check that all the items are included in the package. If there are any missing items, contact your Nihon Kohden representative.

The name and quantity are described under the illustration.

| NKV-330 and Other Packaged Items   |  |  |   |
|--|--|--|---|
| <br>NKV-330 ventilator (1)        | <br>AC power cord (1) | <br>Test breathing circuit (1) | <br>Cable binder (4)                 |
| <br>Power cord retaining bracket | <br>Screws (2)        | <br>Manuals (2)               | <br>Simplified operation manual (1) |
| <br>Certification (1)           |  |  |   |




For standard accessories such as the AC power cord and for consumables such as the breathing circuit and sensors, only use Nihon Kohden specified accessories and consumables to ensure the safety and performance of the ventilator.

For the “name and model” and “catalogue number” of the standard accessories, refer to “Standard Accessories and Options” (p. 16-31).





# Conventions Used in this Manual and Instrument

## Dangers, Warnings and Cautions

| Level  | Description   |
|--|---|
|  <b>DANGER</b>  | A danger alerts the user to a hazardous situation which causes death or serious injury.   |
|  <b>WARNING</b> | A warning alerts the user to possible injury or death associated with the use or misuse of the instrument.  |
|  <b>CAUTION</b> | A caution alerts the user to possible injury or problems with the instrument associated with its use or misuse such as instrument malfunction, instrument failure, damage to the instrument, or damage to other property. |

## Icons in this Manual

| Icon  | Description   |
|---|---|
|    | Gives additional information and suggestions.                             |
|  | Indicates related pages in this or other manuals which give more details. |

## Text Conventions in this Manual

| Style          | Description   |
|----------------|---|
| Main battery   | SB-831V lithium ion battery                                       |
| Backup battery | SB-330Z battery pack  |
| [XXX]          | Key on screen   |
| [XXX] tab      | Tab for changing windows  |
| [XXX] window   | Window displayed with a tab                                       |
| XXX window     | Window displayed with a key                                       |
| “XXX”          | Message on screen   |
| Main screen    | Screen that always shows patient information and control settings |
| Touch XXX      | Touch screen operation  |
| Select XXX     | Touch screen or knob operation                                    |
| <b>XXX</b>     | Hardware components   |



# Safety Standards

## Safety Standard Classification of the Ventilator

### Type of protection against electrical shock

Class I (during AC power supply operation)

Internally powered equipment (during internally powered operation)

### Degree of protection against electrical shock

SpO<sub>2</sub>, CO<sub>2</sub> connections:

Defibrillator-proof type BF applied part

Gas output:

Type BF applied part

### Degree of protection provided by enclosures

IP22 (Protected against solid foreign objects of

12.5 mm  $\phi$  and greater, Protected against vertically falling water drops when enclosure tilted up to 15°)

### Method of cleaning and disinfecting or sterilization

Equipment NOT suitable for sterilization

Degree of safety of application in the presence of FLAMMABLE ANAESTHETIC MIXTURE WITH AIR, OR WITH OXYGEN OR NITROUS OXIDE

Equipment not suitable for use in the presence of FLAMMABLE ANAESTHETIC MIXTURE WITH AIR, OR WITH OXYGEN OR NITROUS OXIDE

### Mode of operation

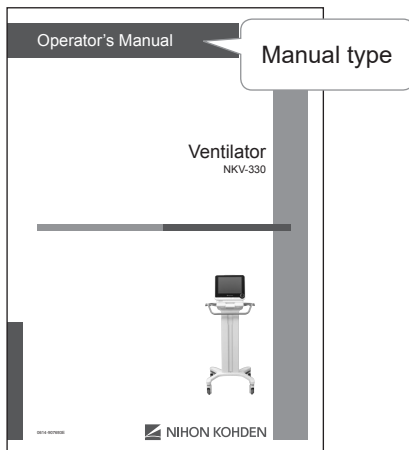
CONTINUOUS OPERATION

ME EQUIPMENT type

INDOOR MOBILE type



# Organization of the Manuals



The documentation for this device is divided into two manuals: the Operator's Manual and the Administrator's Guide.

This manual is the Operator's Manual.

The Administrator's Guide has the following content.

## Administrator's Guide

### 1 Installation and Connection

Explains about ventilator installation conditions, how to connect cables and power cord, how to install devices, and check items.

### 2 System Configuration Settings

Explains about settings on the SYSTEM CONFIGURATION window.

### 3 System Setup Settings

Explains about the password-protected settings on the SYSTEM SETUP window.

### 4 Maintenance and Inspection

Explains about how to do maintenance inspection of the ventilator. This should be done by a specialist in medical equipment and by following the procedures in this manual.

### 5 Factory Default Settings

Lists all the settings (items, details, default settings) that are described in this manual.



# 1

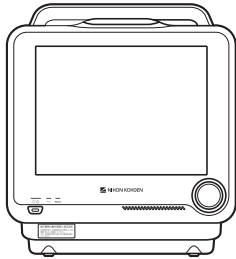
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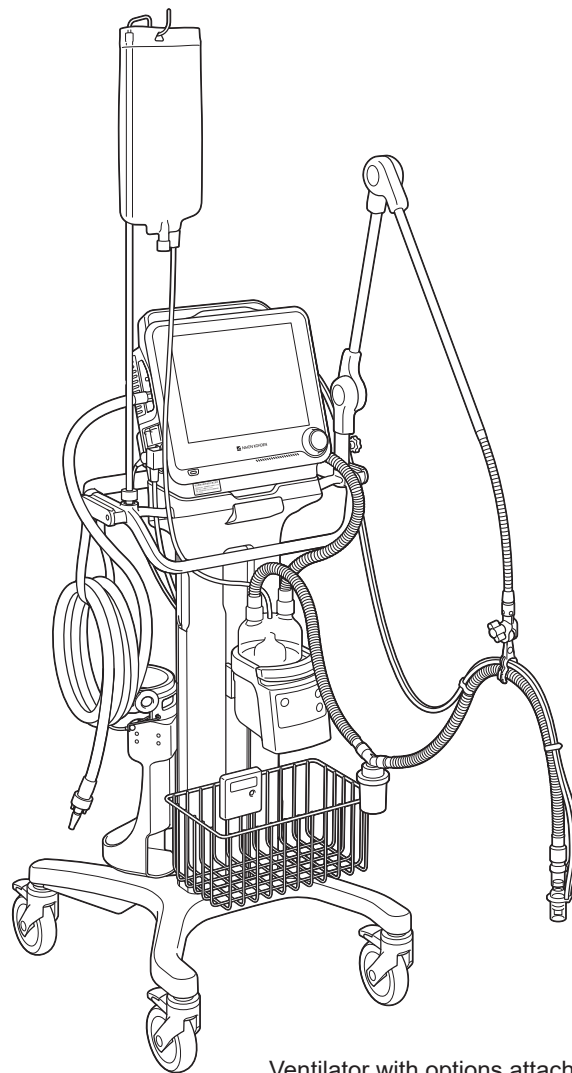


# Introduction

## Indications for Use



This ventilator uses positive pressure to provide ventilation and ventilatory assistance as well as oxygen administration to adult or pediatric patients who have spontaneous breathing but need mechanical ventilation (patients with a tidal volume of 100 mL or more). This ventilator can be used in the ICU, recovery room, ward or transport inside the hospital. This ventilator is intended for use by qualified medical personnel such as physicians, nurses, respiratory technicians.



Ventilator with options attached

# Functions

## Ventilation mode and oxygen therapy mode

The ventilator can operate in ventilation mode or oxygen therapy mode.

| Ventilation Mode   | Oxygen Therapy Mode                 |
|--|-------------------------------------|
| SPONT-PS, S/T, PCV <sup>1</sup> , PRVC <sup>1</sup> and PPV <sup>1</sup> | O <sub>2</sub> Therapy <sup>1</sup> |

<sup>1</sup> These can only be used when the corresponding setting is set to [On] in the “Ventilation Mode” settings on the System Configuration ► [Vent] window.



Refer to the following.  
Administrator's Guide:  
Section 2 “System Configuration Settings”

## Monitoring

The Main screen shows monitoring information such as numerics and waveforms.

This monitoring information appears based on airway pressure and flow measured by the pressure sensor and flow sensor and the inspiratory O<sub>2</sub> concentration measured by the O<sub>2</sub> sensor.

Furthermore, it displays useful information for safe respiratory management through use of its SpO<sub>2</sub> probe and CO<sub>2</sub> sensor.

## Alarms

The ventilator is equipped with alarms.

It notifies parameter measurement abnormalities and device abnormalities by displaying a message on the screen, sounding an alarm and blinking and lighting an alarm indicator.

## Review information display

The ventilator can save 72 hours of alarm history and operation history.

Saved monitoring information can be displayed with useful trend graphs and trend lists in order to ascertain trends in a patient's condition.

## Event logs

The ventilator can save more than 72 hours of alarm history and operation history.

The event logs make it possible to check past alarm information and operation information (such as changes in settings).

## Long-term data recording

The ventilator can store, numeric data<sup>1</sup> and event log for more than 1 year on an SD card.

<sup>1</sup> 1-min interval data

## External device interface

The ventilator can be connected to a nurse call system or an external device.

## Portability

The ventilator can operate on batteries for up to 2 hours. It can be mounted and unmounted to the optional cart with a single action, thus facilitating mobility during device transport within the hospital.



## User interface

The ventilator screen is operated by a touch screen and operation knob. In addition, it provides cabinet display and enables the screen layout to be customized.

---

## Measurement Parameters

The following parameters can be measured by the ventilator.



Measurable parameters differ depending on the ventilation mode. Refer to Section 6 “Factory Default Settings”.

## Waveforms

Airway pressure (Paw), flow, volume, plethysmogram (Pleth) and carbon dioxide partial pressure (CO<sub>2</sub>)

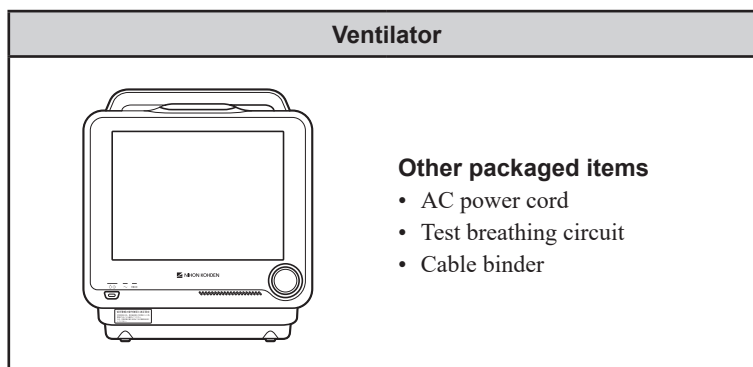
## Measurement values

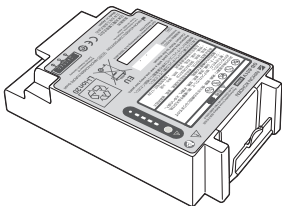
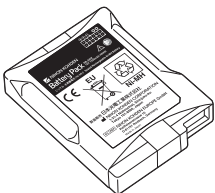

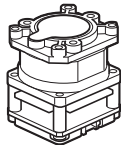
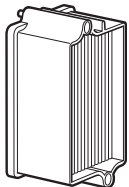
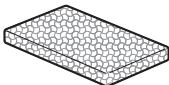
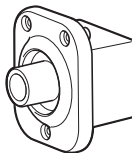

Peak inspiratory pressure (PIP), positive end expiratory pressure (PEEP), peak inspiratory flow (FI-PEAK), peak expiratory flow (FE-PEAK), total inspiratory minute volume (MVI), spontaneous inspiratory minute volume (MVI SPONT), total expiratory minute volume (MV), spontaneous expiratory minute volume (MVSPONT), inspiratory tidal volume (VTi), expiratory tidal volume (VT), expiratory tidal volume /kg (VT/kg), total respiratory rate (RRTOT), spontaneous respiratory rate (RRSPONT), inspiratory duty cycle (Ti/TTOT), I:E ratio (I:E), inspiratory time (Ti), expiratory time (TE), total leakage flow (LeakTOTAL), patient leakage flow (LeakPATIENT), leakage volume ratio (Leak%), spontaneous breathing ratio (Pt. Trig.), O<sub>2</sub> gas usage (O<sub>2</sub> Gas Usage), flow rate (Flow Rate), FiO<sub>2</sub>, SpO<sub>2</sub>, pulse rate (PR), pulse-amplitude index (PI), EtCO<sub>2</sub>, FiCO<sub>2</sub> and CO<sub>2</sub>, respiratory rate (CO<sub>2</sub>) (RR (CO<sub>2</sub>))

# System Configuration

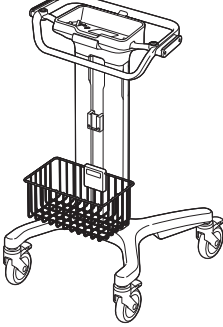
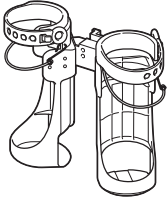
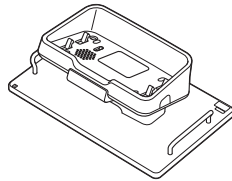
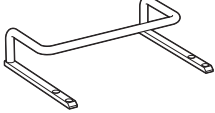
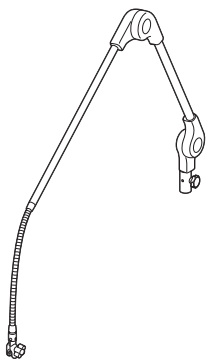
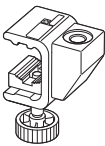
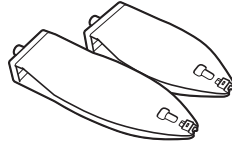
1

The ventilator has the following configuration.



| Standard Accessories  |   |   |   |
|---|---|---|---|
| <b>SB-831V</b> lithium ion battery  | <b>SB-330Z</b> battery pack   | <b>YS-119P4</b><br>galvanic oxygen sensor   | <b>YS-119P5</b><br>paramagnetic oxygen sensor   |
|   |   | Select one  |   |
|                               |   |    |   |
| <b>YS-119P7</b><br>air intake HEPA filter   | <b>YS-119P8</b><br>air intake dust filter   | <b>YS-119P6</b> internal filter   | <b>YS-119P9</b> fan filter  |
|                              |  |   |  |
| Options   |   |   |   |
| <ul style="list-style-type: none"> <li>• <b>QS-330Z</b> software kit</li> <li>• Grounding lead (DIN)</li> </ul> |   | <ul style="list-style-type: none"> <li>• YJ-332Z connection cable 2.5 m</li> <li>• YJ-333Z connection cable 5.0 m</li> <li>• YJ-334Z connection cable 10.0 m</li> </ul> |   |

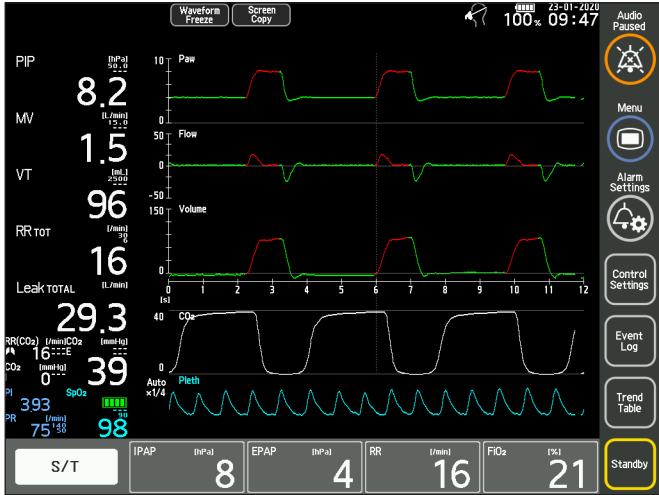
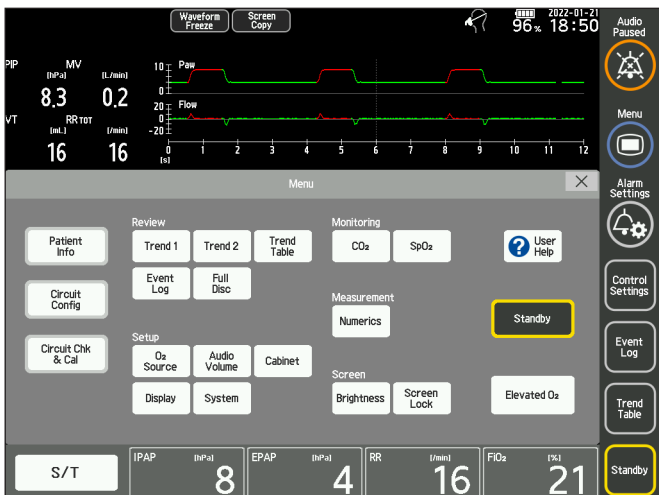
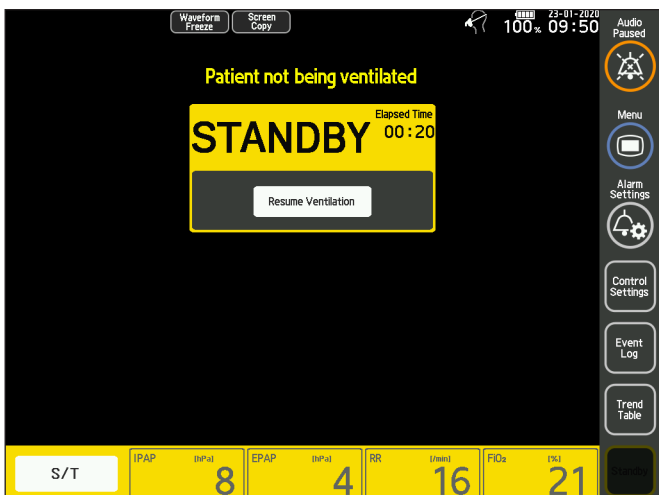


| Others  |  |   |   |
|---|--|---|---|
| KC-330Z cart M,<br>KC-331Z cart L   | YS-120P0<br>dual E-cylinder mount  | DH-330Z mount plate   | DH-331Z rail hook   |
|    |   |   |  |
| KH-330Z support arm <sup>1</sup>  | DH-332Z<br>support arm mount clamp   | YS-120P2 test lung 1L,<br>YS-120P3 test lung 0.5L   |   |
|   |  |    |   |
| <ul style="list-style-type: none"> <li>• YS-120P1 dual D-cylinder mount</li> <li>• SB-801V Battery charger</li> </ul>   |  | <ul style="list-style-type: none"> <li>• YS-123P9 support arm</li> <li>• YS-124P0 water bag pole</li> </ul>   |   |
| Adapters and Sensors  |  |   |   |
| <ul style="list-style-type: none"> <li>• JL-500P1 SpO<sub>2</sub> adapter</li> <li>• JL-500P2 SpO<sub>2</sub> adapter</li> </ul>  |  | <ul style="list-style-type: none"> <li>• TG-900P CO<sub>2</sub> sensor kit</li> <li>• TG-920P CO<sub>2</sub> sensor kit</li> <li>• TG-980P CO<sub>2</sub> sensor kit</li> </ul> |   |
| Breathing Circuits  |  |   |   |
| <ul style="list-style-type: none"> <li>• VB-310Z single limb breathing set HW-EXH</li> <li>• VB-311Z single limb breathing set WT-EXH</li> <li>• VB-312Z single limb breathing set EXH</li> <li>• VB-313Z single limb breathing set HW</li> <li>• VA-300Z exhalation port</li> <li>• VA-301Z breathing circuit filter</li> <li>• VA-302Z humidification chamber</li> <li>• TF-300Z flow sensor</li> </ul>   |  |   |   |
| Patient Interfaces  |  |   |   |
| <ul style="list-style-type: none"> <li>• VM-310Z NPPV full face mask set L</li> <li>• VM-311Z NPPV full face mask set M</li> <li>• VM-312Z NPPV full face mask set S</li> <li>• VM-313Z NPPV full face mask set XS</li> <li>• VM-321Z child/Infant NPPV full face mask XL</li> <li>• VM-322Z child/Infant NPPV full face mask L</li> <li>• VM-330Z NPPV cap-ONE mask set L</li> <li>• VM-331Z NPPV cap-ONE mask set M</li> <li>• VM-332Z NPPV cap-ONE mask set S</li> <li>• VM-333Z NPPV cap-ONE mask set XS</li> </ul> |  |   |   |

<sup>1</sup> With joint for cart

# Types of Screens and Windows

The ventilator has the following screens and windows.

|   |  |
|---|--|
| <p><b>Main screen</b><br/>(Refer to Section 6)</p>    |  <p>The main screen displays vital signs on the left and waveforms on the right. The vital signs include PIP (8.2), MV (1.5), VT (96), RR TOT (16), Leak TOTAL (29.3), RR(CO<sub>2</sub>) (16), CO<sub>2</sub> (39), SpO<sub>2</sub> (98), and PR (75). The waveforms show Paw, Flow, Volume, and CO<sub>2</sub>. The bottom status bar shows S/T, IPAP (8), EPAP (4), RR (16), and FIO<sub>2</sub> (21).</p>  |
| <p><b>Menu window</b><br/>(Refer to Section 1)</p>    |  <p>The menu window is overlaid on the main screen. It contains several sections: Review (Patient Info, Trend 1, Trend 2, Trend Table), Monitoring (CO<sub>2</sub>, SpO<sub>2</sub>, User Help), Circuit (Circuit Config, Circuit Chk &amp; Cal), Setup (O<sub>2</sub> Source, Audio Volume, Cabinet, Display, System), Measurement (Numerics, Standby), Screen (Brightness, Screen Lock, Elevated O<sub>2</sub>), and Control (Control Settings, Event Log, Trend Table). The bottom status bar remains visible.</p> |
| <p><b>STANDBY window</b><br/>(Refer to Section 7)</p> |  <p>The STANDBY window is displayed in the center of the screen. It features a large yellow 'STANDBY' text with 'Elapsed Time 00:20' next to it. Below this is a 'Resume Ventilation' button. The background shows the main screen's vital signs and waveforms dimmed. The bottom status bar is also visible.</p>  |



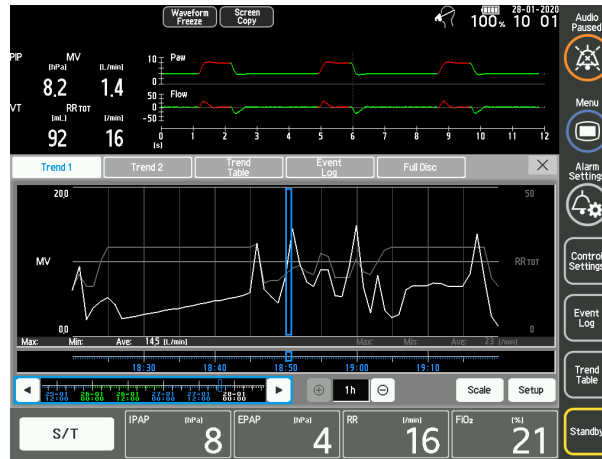
| <p><b>Patient Info window (Refer to Section 5 and 8)</b></p>               |   |                  |                                   |           |                  |        |           |               |   |                  |                                   |   |                  |                         |   |                  |                             |   |                  |
|--|---|------------------|-----------------------------------|-----------|------------------|--------|-----------|---------------|---|------------------|-----------------------------------|---|------------------|-------------------------|---|------------------|-----------------------------|---|------------------|
| <p><b>Circuit Configuration window (Refer to Section 5)</b></p>            |   |                  |                                   |           |                  |        |           |               |   |                  |                                   |   |                  |                         |   |                  |                             |   |                  |
| <p><b>Circuit Check &amp; Calibrations window (Refer to Section 5)</b></p> | <table border="1"> <thead> <tr> <th>Pre-Use Tests</th> <th>Result</th> <th>Date/Time</th> <th>Calibrations</th> <th>Result</th> <th>Date/Time</th> </tr> </thead> <tbody> <tr> <td>Circuit Check</td> <td>✓</td> <td>23-01-2020 13:08</td> <td>O<sub>2</sub> Sensor Calibration</td> <td>✓</td> <td>23-01-2020 13:23</td> </tr> <tr> <td>Flow Sensor Calibration</td> <td>✓</td> <td>23-01-2020 13:16</td> <td>CO<sub>2</sub> Sensor Zero</td> <td>✓</td> <td>23-01-2020 13:27</td> </tr> </tbody> </table> <p>Settings at the bottom show S/T, IPAP 8, EPAP 4, RR 16, and FiO2 21.</p> | Pre-Use Tests    | Result                            | Date/Time | Calibrations     | Result | Date/Time | Circuit Check | ✓ | 23-01-2020 13:08 | O <sub>2</sub> Sensor Calibration | ✓ | 23-01-2020 13:23 | Flow Sensor Calibration | ✓ | 23-01-2020 13:16 | CO <sub>2</sub> Sensor Zero | ✓ | 23-01-2020 13:27 |
| Pre-Use Tests  | Result  | Date/Time        | Calibrations                      | Result    | Date/Time        |        |           |               |   |                  |                                   |   |                  |                         |   |                  |                             |   |                  |
| Circuit Check  | ✓   | 23-01-2020 13:08 | O <sub>2</sub> Sensor Calibration | ✓         | 23-01-2020 13:23 |        |           |               |   |                  |                                   |   |                  |                         |   |                  |                             |   |                  |
| Flow Sensor Calibration  | ✓   | 23-01-2020 13:16 | CO <sub>2</sub> Sensor Zero       | ✓         | 23-01-2020 13:27 |        |           |               |   |                  |                                   |   |                  |                         |   |                  |                             |   |                  |
| <p><b>Control Settings window (Refer to Section 6-1)</b></p>               |   |                  |                                   |           |                  |        |           |               |   |                  |                                   |   |                  |                         |   |                  |                             |   |                  |

|   |  |
|---|--|
| <p><b>Alarm Settings window (Refer to Section 9)</b></p>      |  |
| <p align="center"><b>Monitoring (Refer to Section 10)</b></p> |  |
| <p><b>CO<sub>2</sub></b></p>                                  |  |
| <p><b>SpO<sub>2</sub></b></p>                                 |  |



Review Windows (Refer to Section 11)

Trend 1,  
Trend 2



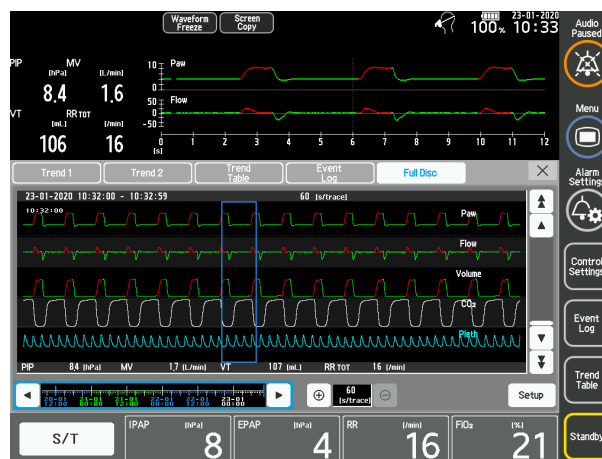
Trend Table

|                    | 10:09 | 10:10 | 10:11 | 10:12 | 10:13 | 10:14 | 10:15 | 10:16 | 10:17 | 10:18 | 10:19 | 10:20 |
|--------------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|
| PIP (kPa)          | 82    | 82    | 80    | 80    | 80    | 80    | 79    | 80    | 80    | 80    | 80    | 80    |
| PEEP (kPa)         | 39    | 39    | 39    | 39    | 39    | 39    | 39    | 39    | 39    | 39    | 39    | 39    |
| MV (l/min)         | 29    | 11    | 14    | 15    | 15    | 15    | 14    | 14    | 14    | 14    | 14    | 14    |
| MVSPONT (l/min)    | 00    | 00    | 00    | 00    | 00    | 00    | 00    | 00    | 00    | 00    | 00    | 00    |
| VT (ml)            | 0     | 89    | 84    | 85    | 85    | 83    | 82    | 83    | 84    | 84    | 83    | 83    |
| RR TOT (1/min)     | 5     | 11    | 15    | 16    | 16    | 16    | 16    | 16    | 16    | 16    | 16    | 16    |
| RR SPONT (1/min)   | 1     | 0     | 0     | 1     | 0     | 0     | 0     | 0     | 0     | 0     | 0     | 0     |
| Leak TOTAL (l/min) | 442   | 289   | 289   | 289   | 290   | 290   | 290   | 289   | 290   | 289   | 290   | 290   |
| FIO2 (%)           | 21    | 21    | 21    | 20    | 20    | 21    | 21    | 21    | 21    | 21    | 21    | 21    |

Event Log

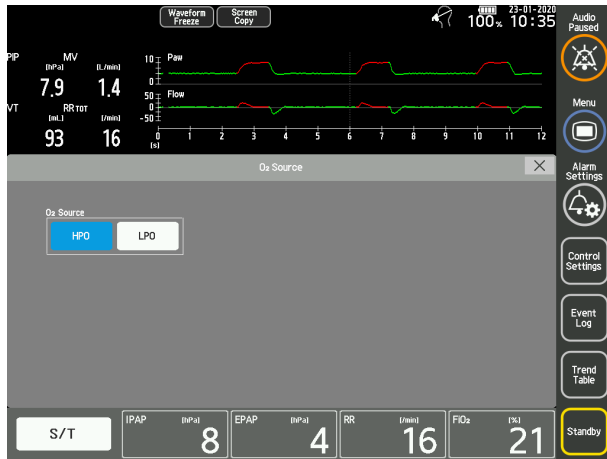
| Time                        | Event                | Value | Unit  |
|-----------------------------|----------------------|-------|-------|
| 23-01-2020 10:27:14 [00:03] | High PEEP            | > 50  | kPa   |
| 23-01-2020 10:27:02 [00:09] | SpO2 Check Probe     |       |       |
| 23-01-2020 10:26:54 [00:05] | SpO2 Detecting Pulse |       |       |
| 23-01-2020 10:26:01 [00:23] | Low MV               | ≤ 20  | l/min |
| 23-01-2020 10:25:42         | (S/T) Slope          | 3 → 2 |       |
| 23-01-2020 10:24:29 [00:11] | High RR TOT          | ≥ 30  | 1/min |
| 23-01-2020 10:24:17 [02:00] | Audio Paused         |       |       |
| 23-01-2020 10:23:39 [00:19] | High MV              | ≥ 150 | l/min |
| 23-01-2020 10:23:17 [00:05] | Audio Paused         |       |       |
| 23-01-2020 10:23:14 [00:58] | High RR TOT          | ≥ 30  | 1/min |

Full Disc



Setup Windows (Refer to Section 12)

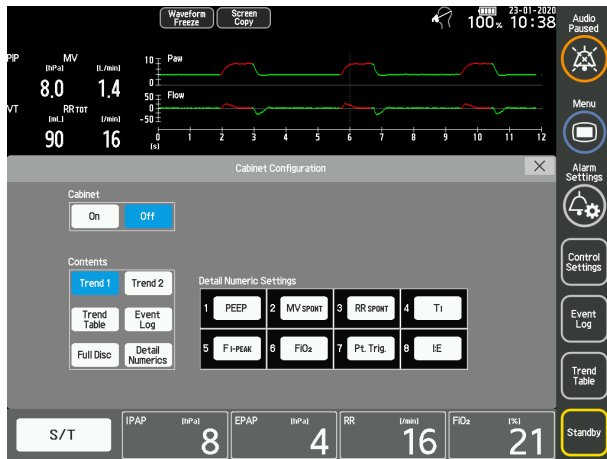
O<sub>2</sub> Source



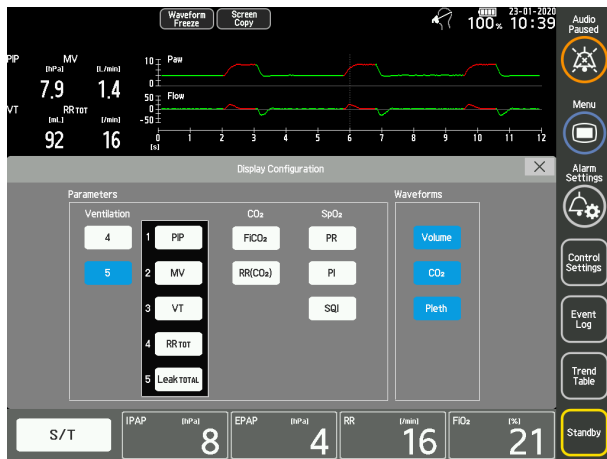
Audio Volume



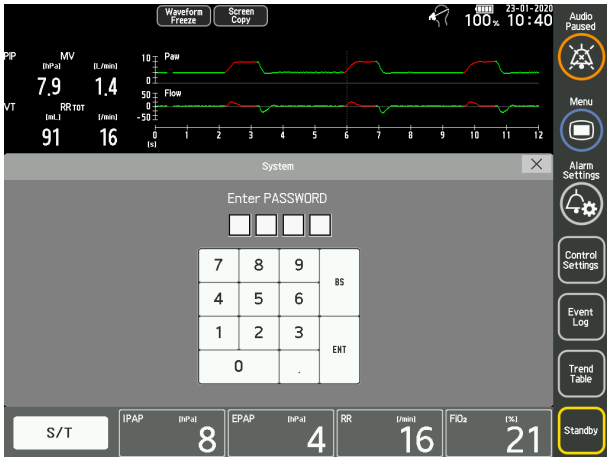
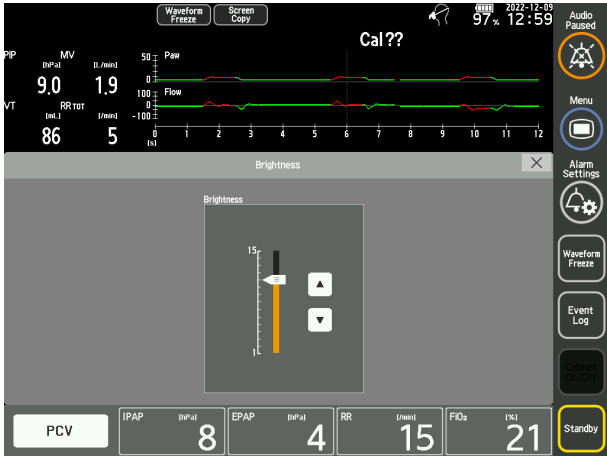
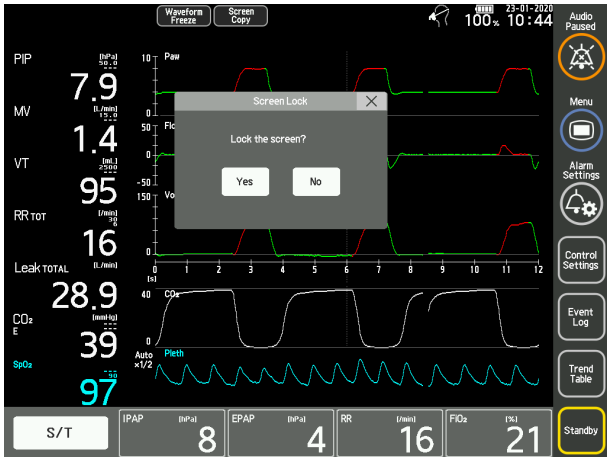
Cabinet Configuration



Display Configuration





|  |  |
|--|--|
| <p><b>System</b></p>                                   |    |
| <p><b>Others</b></p>                                   |  |
| <p><b>Brightness</b></p>                               |   |
| <p><b>Screen Lock<br/>(Refer to<br/>Section 1)</b></p> |  |

| Others   |  |
|--|--|
| <p><b>User Help</b><br/>(Refer to Section 1)</p> |    |
| <p><b>Numerics</b><br/>(Refer to Section 1)</p>  |   |
| <p><b>Date/Time Settings</b></p>                 |  |



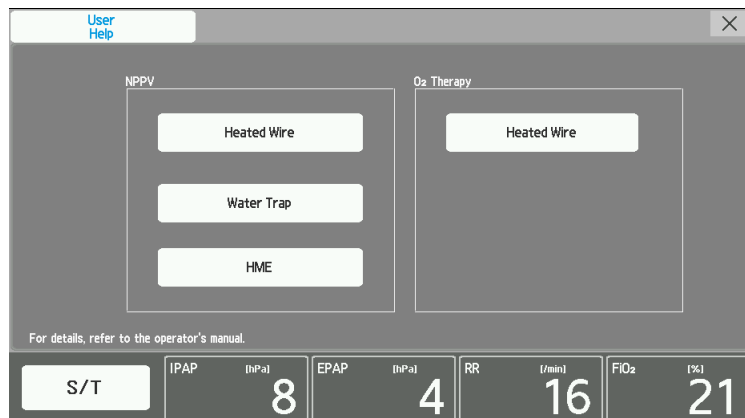
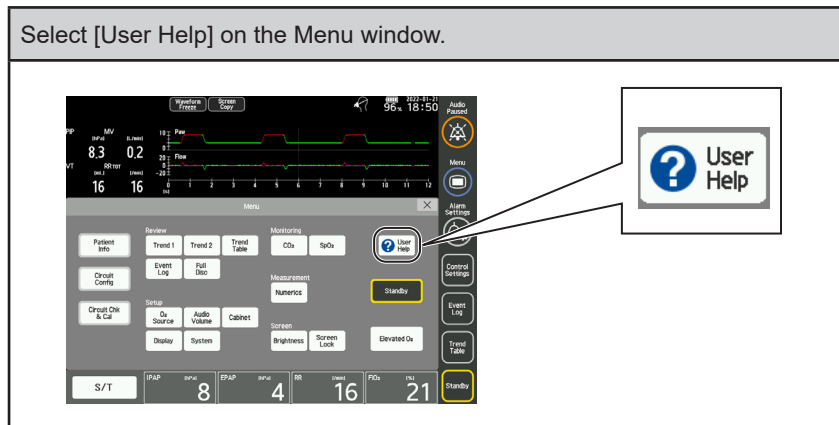
# User Help Window

The User Help window shows how to connect the breathing circuit with easy to understand illustrations and explanations. There are 2 ways to display the User Help window.

User Help window can also be displayed by selecting [User Help] from the function keys. (Only when it is assigned to a function key)



Refer to the following.  
 Administrator's Guide:  
 "Changing the Key Assignments" in Section 3



The "O<sub>2</sub> Therapy" setting on the right can only be set when "O<sub>2</sub> Therapy" is set to [On] in "Ventilation Mode" on the [Vent] window in System Configuration.

Refer to the following.  
 Administrator's Guide:  
 Section 2 "System Configuration Settings"

## Numerics Window

The Numeric window displays a table showing ventilation measurement parameters, such as airway pressure, respiratory volume, respiration rate, as well as the CO<sub>2</sub> and SpO<sub>2</sub> values. Only the currently measured parameters are displayed. Numerics are updated in one second increments.

You can display the Numerics window by any of the following method.

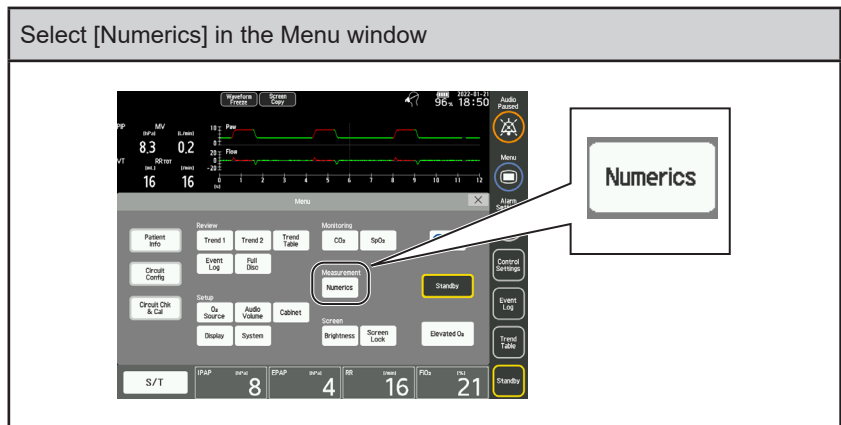
Selecting [Numerics] from the function keys also displays the Numeric window. (Only when the function is assigned to a function key)



Refer to the following.

Administrator's Guide:

“Changing the Key Assignments” in Section 3



| Numerics              |                         |                                  |                       |                          |                  |  |  |  |  |
|-----------------------|-------------------------|----------------------------------|-----------------------|--------------------------|------------------|--|--|--|--|
| PIP                   | PEEP                    | VT                               | VT/kg                 | F <sub>I</sub> -PEAK     | FE-PEAK          |  |  |  |  |
| 8.4                   | 4.0                     | 104                              | 1.5                   | 17.4                     | -26.6            |  |  |  |  |
| MV                    | MVSPONT                 | VT <sub>I</sub>                  | Pt. Trig.             | O <sub>2</sub> Gas Usage |                  |  |  |  |  |
| 1.6                   | 0.0                     | 92                               | 0                     | 0.0                      |                  |  |  |  |  |
| RR <sub>TOT</sub>     | RR <sub>SPONT</sub>     | MV <sub>I</sub>                  | MV <sub>I</sub> SPONT | EtCO <sub>2</sub>        | SpO <sub>2</sub> |  |  |  |  |
| 16                    | 0                       | 1.4                              | 0.0                   | 39                       | 98               |  |  |  |  |
| Leak <sub>TOTAL</sub> | Leak <sub>PATIENT</sub> | T <sub>I</sub>                   | T <sub>E</sub>        | FiCO <sub>2</sub>        | PR               |  |  |  |  |
| 17.3                  | 0.0                     | 1.00                             | 2.74                  | 0                        | 60               |  |  |  |  |
| FiO <sub>2</sub>      | Leak%                   | T <sub>I</sub> /T <sub>TOT</sub> | I:E                   | RR(CO <sub>2</sub> )     | PI               |  |  |  |  |
| 19                    | 0                       | 26                               | 2.7                   | 16                       | 3.03             |  |  |  |  |
| S/T                   | IPAP                    | EPAP                             | RR                    | FiO <sub>2</sub>         |                  |  |  |  |  |
|                       | 8                       | 4                                | 16                    | 21                       |                  |  |  |  |  |

When a upper and lower limit alarms occurs, the corresponding measurement value is highlighted. The colors in which measurement values are highlighted and alarm messages are displayed can be set in the System Setup window.



Refer to the following.

Administrator's Guide:

- “[Display] Page - Highlight Color” in Section 3
- “[Display/Sound] Page - Alarm Priority Color” in Section 3



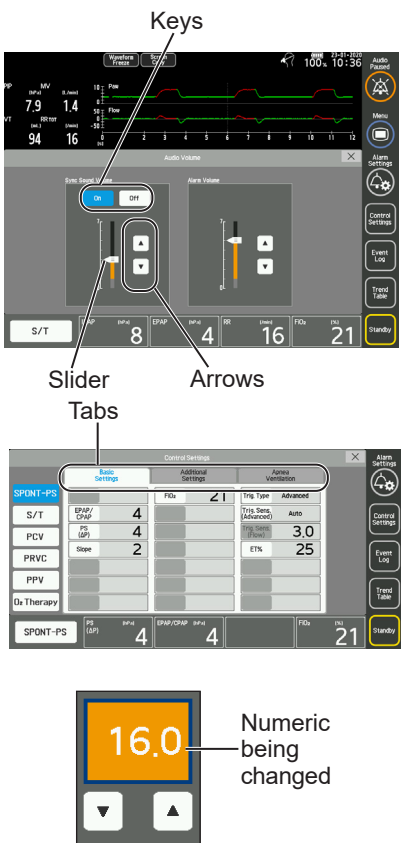
# Basic Operation

The ventilator is operated by the display touch screen and operation knob.

NOTE: Do not use sharp objects to operate the touch screen or other parts of the ventilator. This may damage the ventilator.

## Touch Screen Operation

The ventilator can be operated by using the display touch screen.



- **Keys**

Touch a key to display a window and select an item.

- **Tabs**

Touch a tab to change windows. The color of the displayed tab brightens and its letters appear in light blue.

- **Bars and arrows**

To move a scroll bar or slider, just touch and drag it. Touch an arrow (↑, ↓, ←, →, ↶ or ↷) to change data by steps according to the measurement unit or to move through the displayed page. Press and hold the arrow to sequentially change the data.

- **Selected items**

The color of the selected key changes. Selected items such as measurements displayed on the Main screen becomes enclosed.

- **Unselectable items**

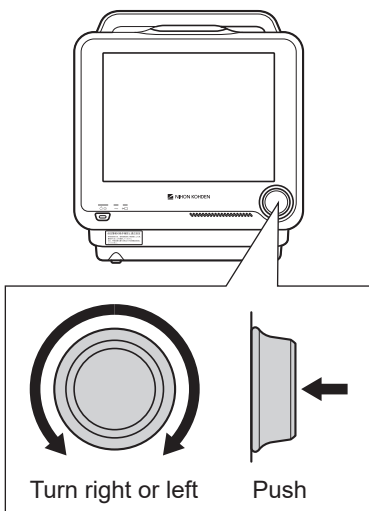
Items that cannot be selected appears with their name grayed out.

- **Confirming numeric changes**

When changing numeric values in the numeric settings window, the inside of frame for the numeric changes to orange. Confirm the content of the change by touching inside the orange frame once again.

## Using the Operation Knob

The ventilator's operation knob can be used to perform the same operations as the touch screen.



- **Selection operation**

Turn the operation knob to the right or left to select keys, tabs or items.

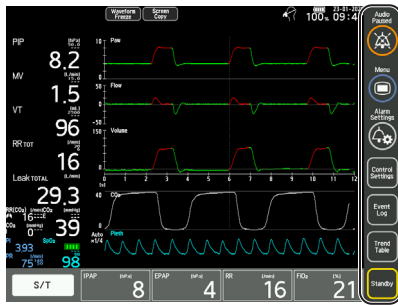
- **Change operation**

Turn the operation knob to the right or left to change selected items or numeric settings.

- **Confirming selections and changes**





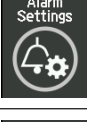






Confirm selections and changes by pushing in the operation knob.

## Operation Keys



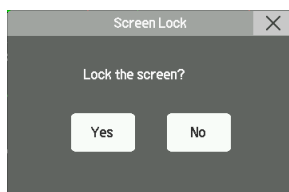
Operation keys

Various operation keys appears on the right side of the display.  
The ventilator's operation keys can perform the following operations.

| Operation Key  | Operation  |
|--|--|
| <br>[Audio Paused]  | Temporarily pauses any alarm sounds that are occurring.<br> Refer to Section 9 "Alarms".  |
| <br>[Menu]  | Shows the [Menu] window.<br> Refer to "Displaying the Main Screen" (p. 1-20).   |
| <br>[Alarm Settings]  | Shows the [Alarm Settings] window.<br> Refer to Section 9 "Alarms".   |
| <br><br><br><br>Function keys | The bottom 4 items show previously assigned operation keys.<br> Function key assignment<br>Refer to the following.<br>Administrator's Guide:<br>"Changing the Key Assignments" in Section 3 |

## Locking the Screen

Lock the screen when transporting a patient or cleaning the display so that the screen is not activated by accidentally touching the touch screen or operation knob.



- 1 Select [Menu] to display the [Menu] window.
- 2 Select [Screen Lock] to display the Screen Lock window.

Selecting [Screen Lock] from the function keys also displays the Screen Lock window. (Only when the function is assigned to a function key)



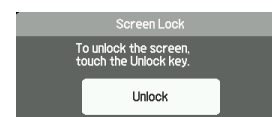
Refer to the following.  
Administrator's Guide:  
"Changing the Key Assignments" in Section 3

- 3 Select [Yes].

This turns off the touch screen and operation knob.



- Select [No] to cancel the screen lock and return to the Main screen.
- The following message appears when touching the touch screen or operation knob while the screen is locked.





## Unlocking the Screen

Operate the touch screen or operation knob to unlock the screen. When a confirmation message appears, touch [Unlock] on the message. The screen is unlocked.

---

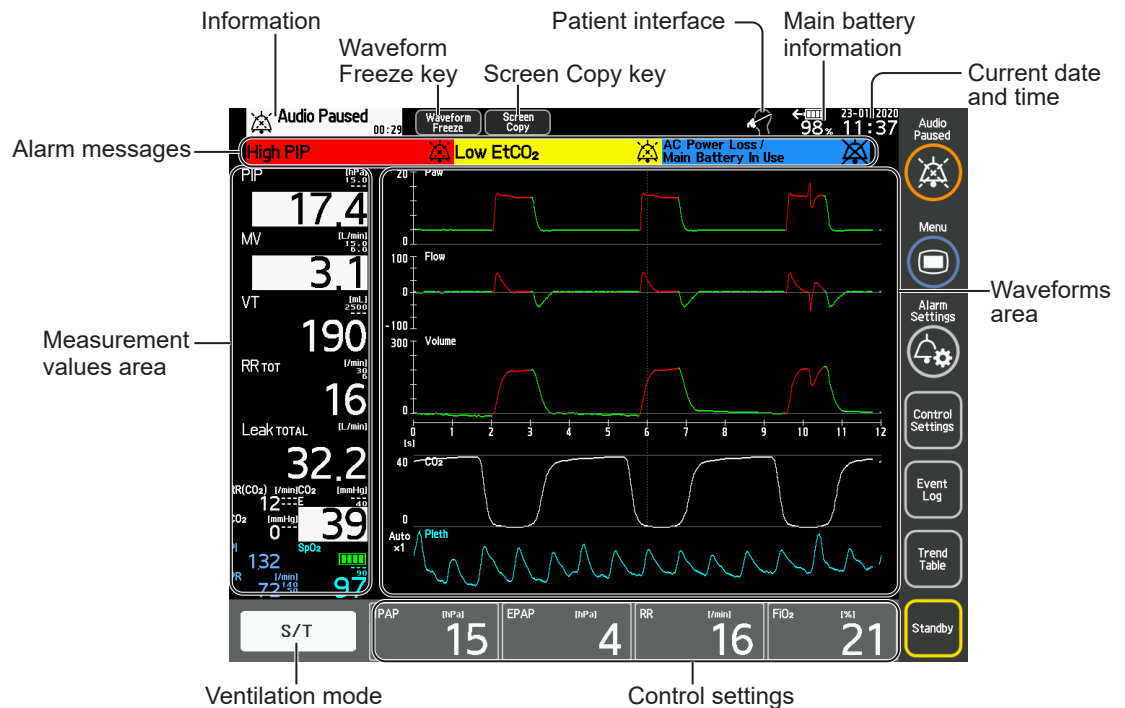
Pressing the **power switch** on the ventilator also unlocks the screen.

---

# Main Screen Descriptions

1

The Main screen is the home screen for the ventilator. It is used to display ventilation mode, control settings and patient monitoring information. Information displayed on the Main screen can be controlled by the touch screen and operation knob. For more details, refer to the relevant section in the table below.



Example: S/T Main Screen

| Information   | Description   | Section                   |
|---|---|---------------------------|
| Current date  | Shows the current date.   | Section 12                |
| Main battery information  | Shows the remaining capacity for the main battery.  | Section 4                 |
| Patient interface   | Shows the type of patient interface to use.   | Section 5                 |
| Waveform Freeze key   | All waveforms displayed on the screen are frozen.   | Section 6-2               |
| Screen Copy key   | Saves currently displayed screen to the SD card.  | Section 6-2               |
| Alarm messages  | Shows alarms which are not cleared yet.   | Section 9                 |
| Information   | Shows various types of information to indicate the measurement environment and current device status. | Section 13                |
| Waveform display (Paw waveform, Flow waveform, Volume waveform, CO <sub>2</sub> waveform and plethysmogram) | Shows the various waveforms being measured.   | Section 6-2               |
| Measurement display (Monitoring ventilation parameters, CO <sub>2</sub> and SpO <sub>2</sub> )              | Shows the parameter being measured.   | Section 6-2<br>Section 10 |
| Ventilation mode and control settings   | Shows the current ventilation mode and control settings.  | Section 6-1               |

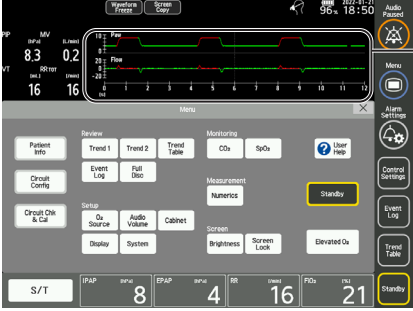


# Displaying the Main Screen

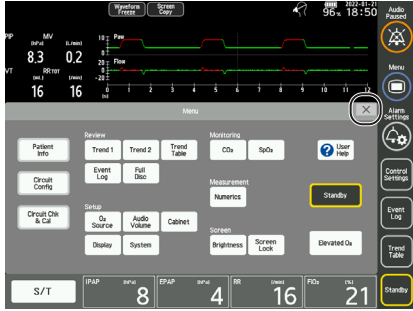
The following describes how to display the Main screen while viewing another window.

Either operation immediately changes the screen to the Main screen.

**Touch the ventilation waveform display area.**



**Select [x] on the other window.**



The ventilator automatically returns to the Main screen after 3 minutes of inactivity on another window such as the [Menu] window.

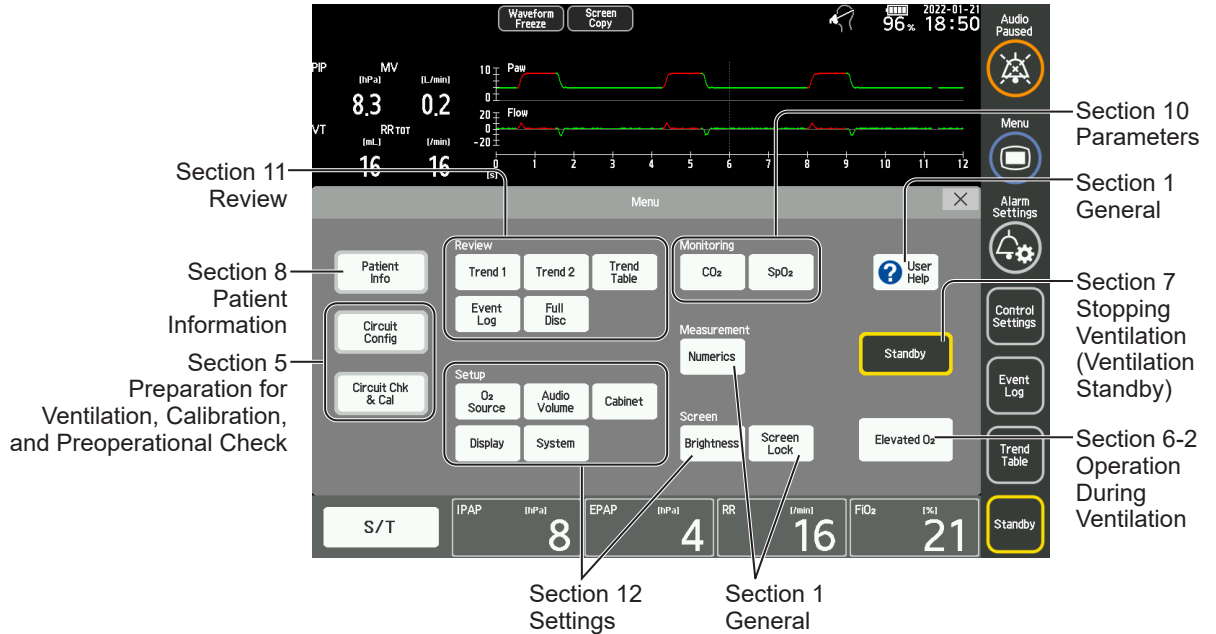
Main screen can also be displayed by selecting [Home] from the function keys. (Only when it is assigned to a function key)



Refer to the following.  
Administrator's Guide:  
"Changing the Key Assignments" in Section 3

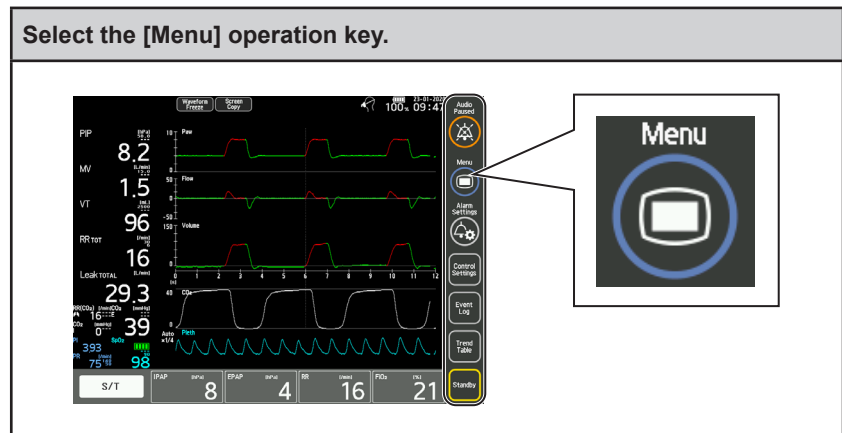
# Menu Window Descriptions

The [Menu] window displays the windows that can be opened with the ventilator. Windows can be checked easily since the buttons are laid out according to the content of each window. Select any key on the [Menu] window to change to that window.



[CO<sub>2</sub>] and [SpO<sub>2</sub>] in “Monitoring” are only displayed when a sensor or probe is connected to the ventilator.

## Displaying the Menu Window





# Symbols





The ventilator uses the following symbols. The names and meanings of the symbols are indicated in table below.




## Ventilator

| Symbol                     | Description                               |
|----------------------------|---|
|                            | Caution                                   |
| <br>Background color: Blue | Follow instructions for use               |
|                            | Alternating current                       |
|                            | Equipotentiality                          |
|                            | “On” for a part of equipment              |
|                            | “Off” for a part of equipment             |
|                            | Charging                                  |
|                            | Type BF applied part                      |
|                            | Defibrillation-proof type BF applied part |
|                            | Serial number                             |
|                            | Input/output                              |
|                            | Write and read data into and from store   |












| Symbol      | Description  |
|-------------|--|
|             | Computer network   |
|             | Gas output port  |
|             | SD card socket   |
| <b>IP22</b> | Protected against solid foreign objects of 12.5 mm ø and greater, Protected against vertically falling water drops when enclosure tilted up to 15°   |
|             | Date of manufacture  |
|             | Oxygen input rating label  |
|             | INMETRO mark   |
|             | The CE mark is a protected conformity mark of the European Union. The four digits after the CE mark indicate the identification number of the Notified Body involved in assessing the product's conformity as a medical device.      |
|             | Products marked with this symbol comply with the European WEEE directive 2012/19/EU and require separate waste collection. For Nihon Kohden products marked with this symbol, contact your Nihon Kohden representative for disposal. |












## Transport Packaging

| Symbol  | Description   |
|---|---|
|  | This way up   |
|  | Fragile   |
|  | Keep away from rain                                   |
|  | Stacking limit by number ("n" is the limiting number) |

| Symbol  | Description                 |
|---|-----------------------------|
|  | Temperature limits          |
|  | Humidity limits             |
|  | Atmospheric pressure limits |

## Screens and Windows

| Symbol  | Description  |
|---|--|
|    | Menu display   |
|    | Audio paused   |
|   | Audio off  |
|  | Alarm off  |
|  | Alarm settings   |
|  | Settings adjustment<br>Moves to the next or previous value |
|  | Move back and forth  |
|  | Change pages   |
|  | Zoom in or out   |
|  | Screen Copy  |
|  | Waveform Freeze  |

| Symbol   | Description              |
|--|--------------------------|
|    | Battery status           |
|    | Battery not connected    |
|   | Battery fault            |
|  | Mask                     |
|  | ETT/Trach                |
|  | O <sub>2</sub> Therapy   |
|  | Back up to SD card 1     |
|  | SD card 1 not inserted   |
|  | Back up to SD card 2     |
|  | SD card 2 not inserted   |
|  | Saving to USB flash disk |



# 2

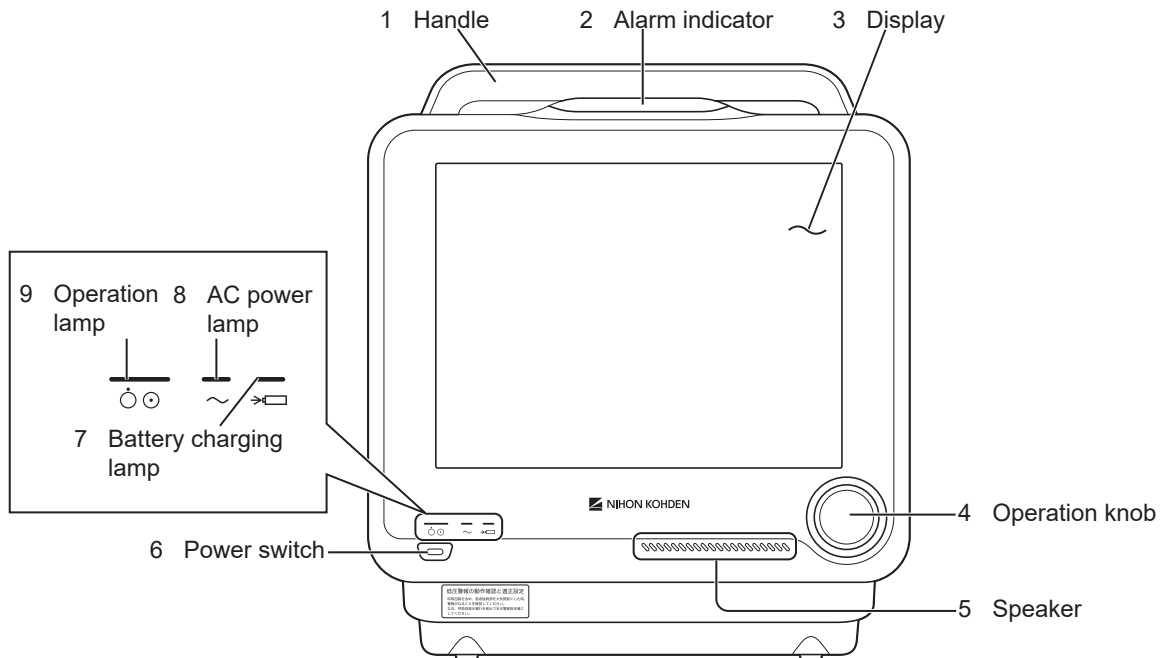
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# Ventilator

## Front Panel



### 1 Handle

Used when carrying the ventilator.

### 2 Alarm indicator

When an alarm occurs, this lights or blinks depending on the type of alarm. Furthermore, it blinks according to the pulse sync sound.

### 3 Display

Touch screen display that can be operated by directly touching the screen. It shows monitoring data.

### 4 Operation knob

Can be used to perform various screen operations just like the touch screen display.

### 5 Speaker

Outputs alarm sounds and sync sounds.

### 6 Power switch

Turns the ventilator's power on and off. It can also be used to unlock the screen.

### 7 Battery charging lamp

Shows the status (such as charging, abnormality) of the main battery (SB-831V) and backup battery (SB-330Z).

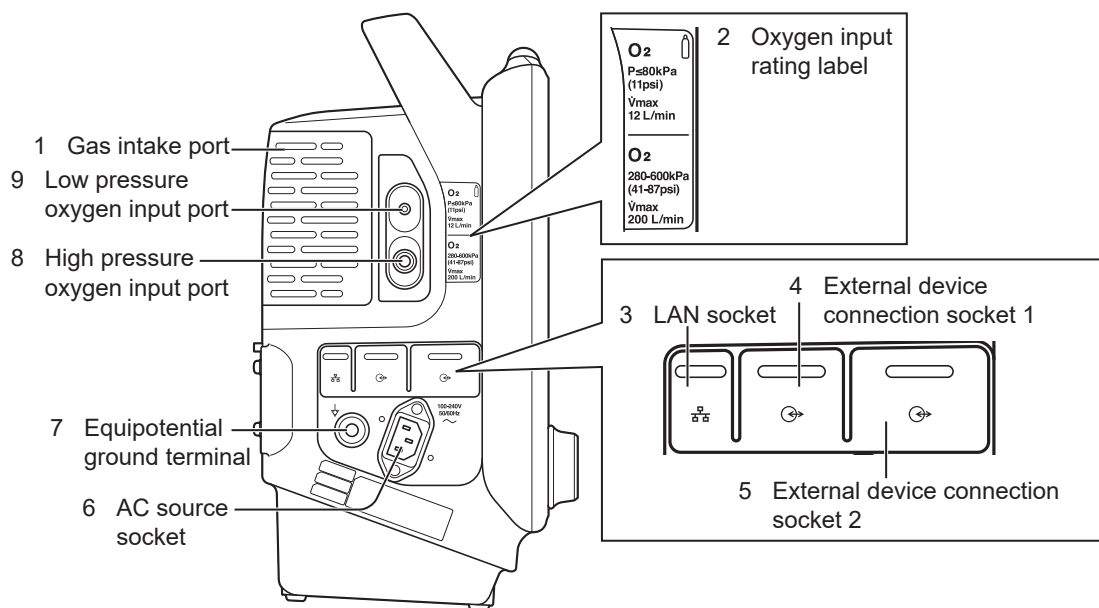
### 8 AC power lamp

Lights when AC power is supplied to the ventilator.

### 9 Operation lamp

Lights when the ventilator is turned on (when the ventilator is operated).

## Left Side Panel



### 1 Gas intake port

Takes in ambient air.

### 2 Oxygen input rating label

Indicates the rated pressure and rated flow rate to be supplied to the low-pressure oxygen input port and high-pressure oxygen input port.

### 3 LAN socket

Not used.

### 4 External device connection socket 1

Connects a nurse call connection cable.

### 5 External device connection socket 2

Connects an external device such as a bedside monitor.

### 6 AC source socket

Connects to a wall outlet using the AC power cord provided with the ventilator.

### 7 Equipotential ground terminal

For equipotential grounding with other devices by using the optional grounding lead.

### 8 High pressure oxygen input port

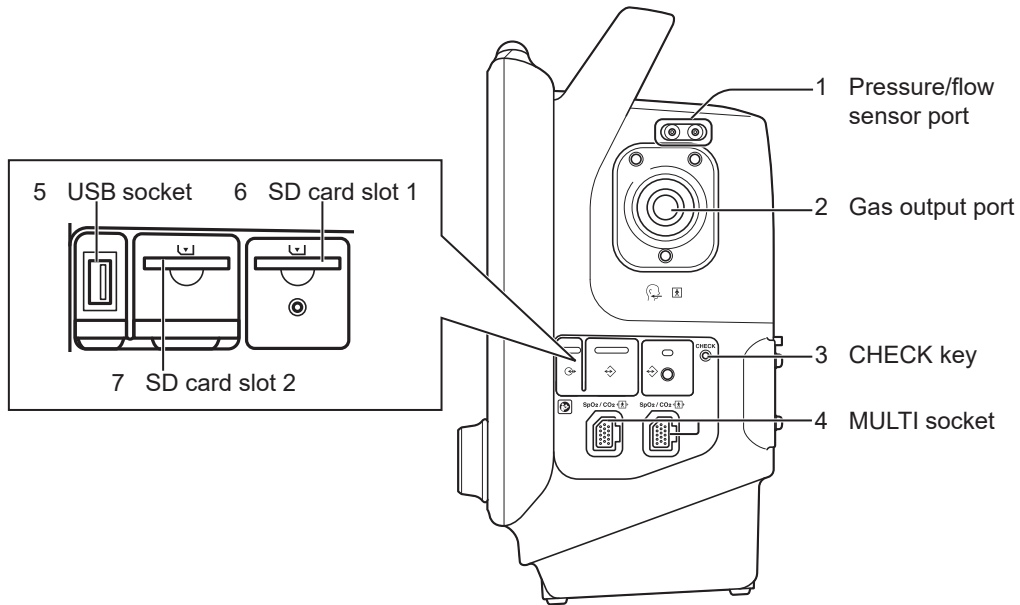
Connects the high-pressure oxygen hose.

### 9 Low pressure oxygen input port

Connects the low-pressure oxygen hose.



## Right Side Panel



**1 Pressure/flow sensor port**

Connects the pressure tube and flow sensor.

**2 Gas output port**

Connects the air inlet filter and breathing circuit.

**3 CHECK key**

For displaying the System Configuration window and Manual Check window.

**4 MULTI socket**

Connects the SpO<sub>2</sub> probe and CO<sub>2</sub> sensor.

**5 USB socket**

Connects a USB memory stick or USB mouse.

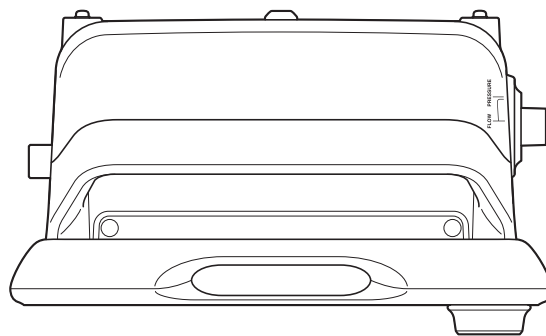
**6 SD card slot 1**

For saving monitoring data.

**7 SD card slot 2**

Use this for saving the currently displayed window, numeric data and event history, and for upgrading the software.

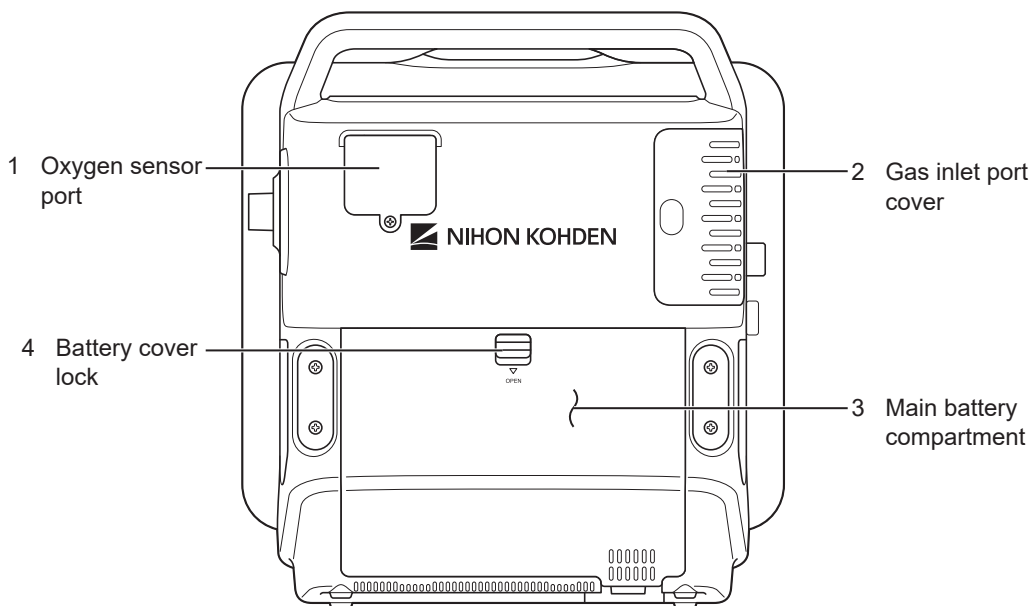
## Top View





## Rear Panel

2



### 1 Oxygen sensor port

Connects the oxygen sensor.

### 2 Gas inlet port cover

Used when changing the air intake HEPA filter and air intake dust filter.

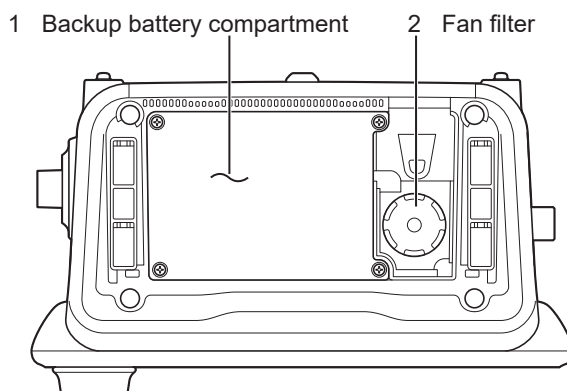
### 3 Main battery compartment

Installs the main battery (SB-831V).

### 4 Battery cover lock

Used when opening and closing the main battery compartment.

## Bottom Panel



### 1 Backup battery compartment

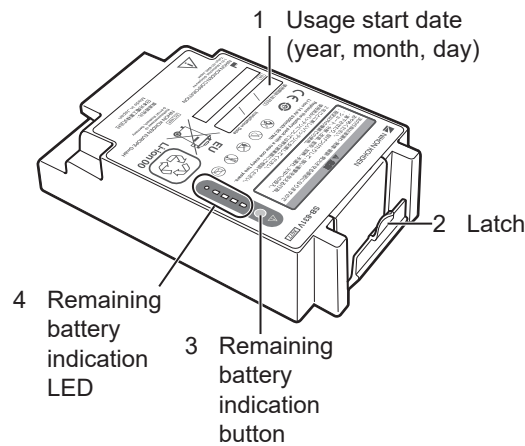
Installs the backup battery (SB-330Z).

### 2 Fan filter

Installs the fan filter.



## Main Battery (SB-831V)



**1 Usage start date (year, month, day)**

Write down the usage start date for the battery.

**2 Latch**

Press when removing the battery from the ventilator.

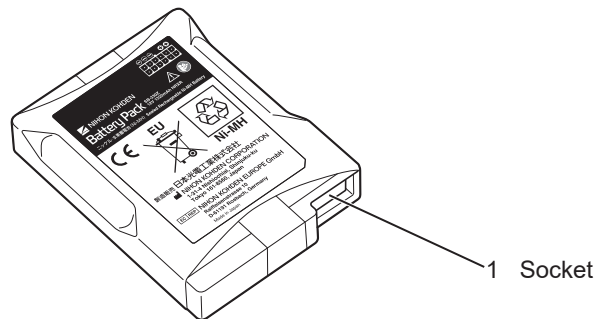
**3 Remaining battery indication button**

Press to check the remaining capacity of the battery.

**4 Remaining battery indication LED**

The LED lights when the remaining battery indication button is pressed.

## Backup Battery (SB-330Z)

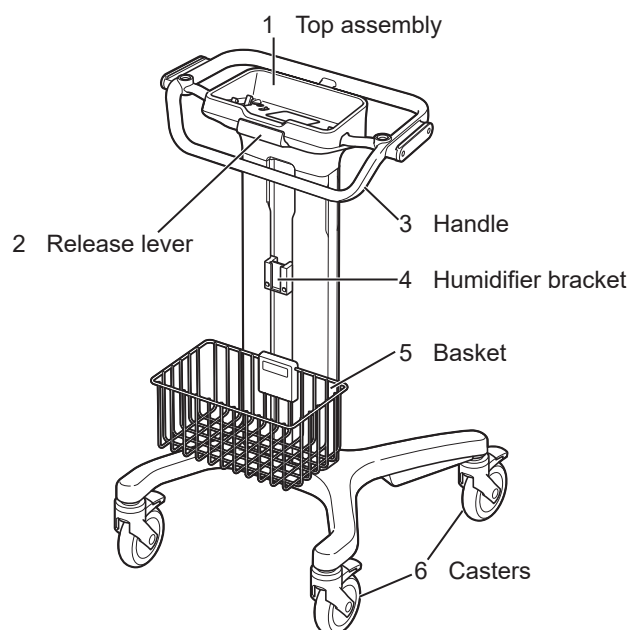


**1 Socket**

Connects to the connector of the backup battery compartment.

## KC-330Z Cart M and KC-331Z Cart L

2

**1 Top assembly**

Mounts the ventilator.

**2 Release lever**

Used to unmount the ventilator when it is mounted to the top assembly.

**3 Handle**

Used when moving the ventilator. It can also mount the KH-330Z support arm and water bag pole.

**4 Humidifier bracket**

Mounts the humidifier.

**5 Basket**

Stores the cords and breathing circuit hoses used with the ventilator.

**6 Casters**

These move the ventilator. The casters can also be locked to fix the cart.



# 3

## Safety Information

3

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# General Handling Precautions

In order to operate this device safely and correctly, read the following precautions thoroughly before operation.

These precautions are a list of general provisions for ensuring the safe operation of medical devices and the safety of patients and operators and may include some items that are not relevant to the operation of this device.

For precautions related to the operation of this device, refer to the other sections of this manual.

## 1. This device is for use by qualified medical personnel only.

### 2. When using, installing or storing the device, take the following precautions:

- (1) Place the device in a location where the specified environment conditions are satisfied.
- (2) Avoid moisture or contact with water, direct sunlight, dust, and saline or sulphuric air.
- (3) Place the device on an even, level floor. Avoid vibration and mechanical shock, even during transport.
- (4) Avoid placing the device in an area where chemicals are stored or where there is possibility of gas leakage.
- (5) Connect the device to a grounded 3-pin medical power supply that satisfies the requirements of the device specifications.

### 3. Before Operation

- (1) Check that the specified power cord is used.
- (2) Check that all cables and cords are connected properly. Make sure that sensors and electrodes are properly connected to the device and correctly attached to the patient.
- (3) When the device is used in combination with other devices, check that there is no interference between any of the devices and that all of the devices can be used safely together.

### 4. During Operation

- (1) Only use the device for the time period or number of times necessary for the current examination or other medical procedure.
- (2) Both the device and the patient must receive continual, careful attention.
- (3) Take all appropriate measures to assure the safety of the patient whenever any abnormality is detected in the operation of the device or in the patient condition.
- (4) Avoid direct contact between the device housing and the patient.

### 5. After Operation

- (1) Turn the power off by following the specified procedures.
- (2) Remove the cords gently. Do not use force to remove them or unplug them by pulling the cable.
- (3) Clean all accessories, cords and electrodes and store them appropriately.
- (4) Clean the device for its next use.

### 6. When trouble occurs

- (1) Remove all electrodes and sensors from the patient.
- (2) Turn the power off and remove the power cord from the AC power source.
- (3) Attach an "Out of Order" or "Do Not Use" warning label to the device and immediately contact your Nihon Kohden representative.

### 7. The device must not be altered or modified in any way.

### 8. Ensure that the device receives daily checks and periodic inspections and check that it can be used properly and safely.

### 9. Always have an alternative method of performing the device's function prepared in case of an accident or malfunction affecting the operation of the device.

### 10. Be careful of malfunctions that may occur when the device is exposed to strong electromagnetic fields.

Interference from a strong electromagnetic field may cause the device to malfunction or noise to appear in the waveforms. If an unexpected malfunction occurs during operation of the device, check the electromagnetic environment and take the necessary measures to rectify the situation.

The following items describe some common causes of interference and the recommended actions to take in response.

#### (1) Use of cellular phones

Electromagnetic interference can cause errors in the operation of the device. Turn off cellular phones and other wireless devices, remove them from the location where the device and/or system is installed, or exclude them from the facility altogether.

#### (2) Radio-frequency interference from other devices through the AC power supply of the device and/or system

- Identify the source of the interference and apply measures such as noise reduction circuits to reduce the interference.
- If the source of the interference is a device that can be turned off, stop using that device and turn its power off.
- Connect the device to different AC power supply.

#### (3) Effect of direct or indirect discharge of electrostatic energy to the device or the surrounding area

- Make sure all users and patients in contact with the device and/or system are free from electrostatic energy before using it.
- A humid room can help lessen this problem.

#### (4) Lightning

When lightning occurs near the location where the device and/or system is installed, it may induce an excessive voltage in the device and/or system. In such a case, take the following measures when using the device.

- Remove the power cord from the AC outlet and operate the device using the internal battery.
- Use an uninterruptible power supply.

#### (5) If the device and/or system interferes with any radio wave receiver such as a radio or television set, locate the device and/or system as far as possible from the radio wave receiver.

#### (6) Warning: Use adjacent to or stacked with other equipment

Malfunctions may occur during operation when the device and/or system is adjacent to or stacked with other equipment. Before use, check that the device and/or system operates normally with the other equipment.

#### (7) Warning: Use of unspecified devices and/or cables

When an unspecified device and/or cable is connected to this device and/or system, it may cause increased electromagnetic emissions or decreased electromagnetic immunity.

This device and/or system complies with all requirements of the relevant EMC standards when used with the specified accessories and cables. Only use this device and/or system with the specified accessories and cables.

#### (8) Measurement with excessive sensitivity

The device and/or system is designed to measure bioelectrical signals with a specified sensitivity. If the device and/or system is used with excessive sensitivity, artifact may appear as a result of electromagnetic interference and this may cause mis-diagnosis. When unexpected artifact appears, inspect the surrounding electromagnetic conditions and remove the source of the artifact.

#### (9) Use with radiation therapy devices

When the device and/or system is used in a radiotherapy room, it may cause failure or malfunction due to electromagnetic radiation or corpuscular radiation. When you bring the device and/or system into a radiotherapy room, constantly observe the operation of the device and/or system. Prepare countermeasures in case of failure or malfunction.

#### (10) Other

When the device and/or system is used in an unspecified system configuration different from the configuration used for EMC testing, it may cause increased electromagnetic emissions or decreased electromagnetic immunity.

## Warranty Policy

Nihon Kohden Corporation (NKC) shall warrant its products against all defects in materials and workmanship for one year from the date of delivery. However, consumable materials such as recording paper, ink, stylus and battery are excluded from the warranty.

NKC or its authorized agents will repair or replace any products which prove to be defective during the warranty period, provided these products are used as prescribed by the operating instructions given in the user's guide, operator's and service manuals.

No other party is authorized to make any warranty or assume liability for NKC's products. NKC will not recognize any other warranty, either implied or in writing. In addition, service, technical modification or any other product change performed by someone other than NKC or its authorized agents without prior consent of NKC may be cause for voiding this warranty.

Defective products or parts must be returned to NKC or its authorized agents, along with an explanation of the failure. Shipping costs must be pre-paid.

This warranty does not apply to products that have been modified, disassembled, reinstalled or repaired without Nihon Kohden approval or which have been subjected to neglect or accident, damage due to accident, fire, lightning, vandalism, water or other casualty, improper installation or application, or on which the original identification marks have been removed.

In the USA and Canada other warranty policies may apply.

### EMC Related Caution

This equipment and/or system complies with IEC 60601-1-2 International Standard for electromagnetic compatibility for medical electrical equipment and/or system. However, an electromagnetic environment that exceeds the limits or levels stipulated in IEC 60601-1-2, can cause harmful interference to the equipment and/or system or cause the equipment and/or system to fail to perform its intended function or degrade its intended performance. Therefore, during the operation of the equipment and/or system, if there is any undesired deviation from its intended operational performance, you must avoid, identify and resolve the adverse electromagnetic effect before continuing to use the equipment and/or system.

The following describes some common interference sources and remedial actions:

1. Strong electromagnetic interference from a nearby emitter source such as an authorized radio station or cellular phone

Install the equipment and/or system at another location. Keep the emitter source such as cellular phone away from the equipment and/or system, or turn off the cellular phone.

2. Radio-frequency interference from other equipment through the AC power supply of the equipment and/or system

Identify the cause of this interference and if possible remove this interference source. If this is not possible, use a different power supply.

3. Effect of direct or indirect electrostatic discharge

Make sure all users and patients in contact with the equipment and/or system are free from direct or indirect electrostatic energy before using it. A humid room can help lessen this problem.

4. Electromagnetic interference with any radio wave receiver such as radio or television

If the equipment and/or system interferes with any radio wave receiver, locate the equipment and/or system as far as possible from the radio wave receiver.

5. Interference of lightning

When lightning occurs near the location where the equipment and/or system is installed, it may induce an excessive voltage in the equipment and/or system. In such a case, disconnect the AC power cord from the equipment and/or system and operate the equipment and/or system by battery power, or use an uninterruptible power supply.

6. Warning: Use with other equipment

When the equipment and/or system is adjacent to or stacked with other equipment, the equipment and/or system may affect the other equipment. Before use, check that the equipment and/or system operates normally with the other equipment.



7. Warning: Use of unspecified accessory, transducer and/or cable

When an unspecified accessory, transducer and/or cable is connected to this equipment and/or system, it may cause increased electromagnetic emission or decreased electromagnetic immunity. The specified configuration of this equipment and/or system complies with the electromagnetic requirements with the specified configuration. Only use this equipment and/or system with the specified configuration.

8. Use of unspecified configuration

When the equipment and/or system is used with the unspecified system configuration different than the configuration of EMC testing, it may cause increased electromagnetic emission or decreased electromagnetic immunity. Only use this equipment and/or system with the specified configuration.

9. Measurement with excessive sensitivity

The equipment and/or system is designed to measure bioelectrical signals with a specified sensitivity. If the equipment and/or system is used with excessive sensitivity, artifact may appear by electromagnetic interference and this may cause mis-diagnosis. When unexpected artifact appears, inspect the surrounding electromagnetic conditions and remove this artifact source.

10. Use with radiation therapy equipment

When the equipment and/or system is used in a radiotherapy room, it may cause failure or malfunction due to electromagnetic radiation or corpuscular radiation. When you bring the equipment and/or system into a radiotherapy room, constantly observe the operation. Prepare countermeasures in case of failure or malfunction.

If the above suggested remedial actions do not solve the problem, consult your Nihon Kohden representative for additional suggestions.

# Dangers, Warnings and Cautions

## General

### WARNING

Never use the ventilator in the presence of any flammable anesthetic gas or high concentration oxygen atmosphere. Failure to follow this warning may cause explosion or fire.

### WARNING

Never use the ventilator in a hyperbaric oxygen chamber. Failure to follow this warning may cause explosion or fire.

### WARNING

Always prepare an alternative means of ventilation (such as a portable or manual control ventilator or a resuscitator) when using the ventilator to ensure responsive ventilation. If the ventilator fails to function correctly for any reason, disconnect the patient from it and immediately start ventilation with such a device, using PEEP and/or adjusting oxygen concentration. Remove the ventilator from clinical use, attach an "Unusable" or "Repair request" label to it and contact your Nihon Kohen representative.

### WARNING

Use the ventilator with the monitoring devices such as a pulse oximeter or capnometer with an alarm function during ventilation. The alarm and monitoring system functions of the ventilator are not substitute for a vital sign monitor. The patient condition should be regularly checked by trained and qualified medical personnel. Otherwise, sudden changes in the patient condition may be overlooked.

### WARNING

When an alarm is generated, check the patient condition and secure the patient safety. Depending on the generated alarm, perform appropriate treatment as described in the operator's manual and remove the cause of alarm. If there is a problem with the alarm setting, change it to an appropriate setting.

### WARNING

The ventilator is for use by qualified and trained personnel under the direction of a physician. When changing settings, follow the physician's judgement and instructions.

### WARNING

Only use the ventilator to augment the ventilation of a spontaneously breathing patient. It is not intended to provide the total ventilatory requirements of the patient.

### WARNING

The ventilator is intended for use with patients receiving noninvasive positive pressure ventilation. For applicable medical conditions, requirements and precautions, refer to the clinical guidelines for noninvasive positive pressure ventilation.

### WARNING

Do not use PRVC mode on patients who require rapid and frequent IPAP adjustments to maintain a consistent tidal volume. Because PRVC mode automatically changes the IPAP setting to achieve the target tidal volume, there may be a period of time before the set tidal volume is achieved.

### WARNING

Before defibrillation, all persons must keep clear of the bed and must not touch the patient or any equipment or cable connected to the patient. Failure to follow this warning may cause electrical shock or injury.

### WARNING

Do not use the ventilator near an ESU or a fire. High frequency energy from the ESU may cause the ventilator malfunction or failure. Use of the ventilator in a high concentration oxygen atmosphere may cause explosion or fire.

### WARNING

Do not bring the ventilator (including components and accessories) into an MRI room. It may cause stick, failure and damage to the MRI machine and skin burn on the patient. For details, follow the instruction in the manual for the MRI machine.

**⚠ WARNING**

Turn off the power of mobile phones, small wireless devices and other devices which produce strong electromagnetic interference in the facility using the ventilator (except for devices allowed by the hospital administrator). Radio waves may cause the ventilator to malfunction.

**⚠ WARNING**

Do not use nitric oxide, helium or helium gas mixtures in the ventilator. This may cause malfunction or failure.

**⚠ WARNING**

Do not use a heated humidifier with the HME filter. This causes the HME filter to crimp and prevents ventilation.

**⚠ WARNING**

When filling the heated humidifier with water, use the water supply port or a heated humidifier chamber which can continue watering. Do not use the gas port. Incorrect connection of tubes may cause skin burns or contamination of the internal circuits of the ventilator by bacteria admitted through the gas port.

**⚠ WARNING**

Do not use breathing circuit filters and HME filters when using a nebulizer. The exhalation impedance increases as a result of clogging of the filters, and this may obstruct the patient ventilation.

**⚠ WARNING**

Position the heated humidifier lower than both the ventilator and the patient. Otherwise, water may accumulate in the breathing circuit and the patient's lungs.

**⚠ WARNING**

In case of fire, immediately secure the patient's ventilatory needs, turn off the power of the ventilator, and disconnect it from its gas and power sources.

**⚠ WARNING**

Turn the power of the heated humidifier on after starting ventilation and turn the power off before stopping ventilation. Otherwise, it may cause skin burn on the patient, the breathing circuits may be deformed or a failure of the circuits may occur.

**⚠ WARNING**

Depending on the usage conditions of the device, it may be necessary to continuously monitor percutaneous oxygen saturation (SpO<sub>2</sub>) or end tidal CO<sub>2</sub> partial pressure (ETCO<sub>2</sub>) with a vital signs monitor with alarm function.

**⚠ CAUTION**

The ventilator is for use with a single patient only. Do not use the same ventilator for more than one patient at the same time.

**⚠ CAUTION**

When the oxygen monitoring function of the ventilator is turned off, use an external oxygen monitor.

**⚠ CAUTION**

Do not use with closed suction systems (CCS).

**Installation and Connection****⚠ WARNING**

When using the ventilator mounted on a cart or mount plate, do not block the vent holes on the rear panel of the mount. This reduces the effectiveness of cooling and may cause overheating and ventilator failure.

**⚠ WARNING**

Check that the base of the support arm is securely fixed before it is used for a patient. If the support arm comes loose, it may cause injury.

**⚠ WARNING**

Do not allow source of oxygen to come near the gas port of the ventilator. This may cause oxygen toxicity in the patient.

**⚠ CAUTION**

Use the ventilator mounted on a cart, mount plate or rail hook. After mounting the ventilator on a cart or mount plate, confirm that the ventilator is securely locked. If the ventilator is not locked, it may fall off.

**⚠ CAUTION**

Only use the specified carts, mount plate or rail hook for the ventilator. Otherwise, the ventilator may fall and injure the patient or operator.

**⚠ CAUTION**

Do not put heavy objects in the basket. The basket may be damaged or fall off and the cart may tip over.

**⚠ CAUTION**

- Release the caster locks when moving the cart. Do not move the cart with the casters locked. The cart may tip over.
- When moving the cart, hold the handle and ensure the support arm is folded.

**⚠ CAUTION**

- To prevent the cart from tipping over or the ventilator falling off the cart:
- Do not put or hook anything on the handle or column.
  - Do not ride on the cart.
  - Do not lean on the handle or column or, put your weight on the cart.
  - Make sure that the cart is on a flat surface which is not sloped.
  - Lock the casters so that the cart does not move accidentally.

**Transport within the Same Facility****⚠ WARNING**

When transporting the patient with the ventilator fixed to the cart, be careful that components such as the breathing circuit hose do not catch on or pull surrounding objects. This may cause the cart to tip over and the ventilator to fall off. Also, disconnection of the breathing circuit or kinks in the tubes may obstruct the patients respiration and prevent appropriate ventilation.

**⚠ CAUTION**

When moving a bed with the ventilator hooked to it on an uneven surface, ensure that the ventilator does not fall off because it may cause injury.

**⚠ CAUTION**

- Failure to follow the instructions below may cause the ventilator to fall off and cause injury.
- Do not block the fan outlet at the bottom panel of the ventilator.
  - Follow the installation instructions and confirm stability before use.
  - Do not hook onto a smooth or curved part.
  - Do not put weight on the rail hook and apply a load heavier than the ventilator.
  - Hook the ventilator onto a rail which can support the weight of the ventilator.

**⚠ CAUTION**

Check the O<sub>2</sub> Gas Usage and the current volume of oxygen in the gas cylinder before using the ventilator during patient transport. Make sure that the volume of oxygen in the cylinder is sufficient for the anticipated transport time. Also, make sure that the gas cylinder has a regulator valve correctly fitted.

**⚠ CAUTION**

Use an HME filter for humidification during patient transport.

**Turning Power On****⚠ CAUTION**

When the ventilator is turned on and periodically thereafter, check that the red, yellow, cyan and green alarm indicator lamps blink and there is a sound produced when an alarm occurs.

**Consumables and Accessories****⚠ DANGER**

Do not use antistatic or electrically conductive hoses (such as hoses for anesthesia) for the breathing circuit. This may cause fire or electrical shock to the patient.

**⚠ WARNING**

Do not reuse the single use options which are used with the ventilator. Use only for a single patient and single use. Failure to follow this warning may cause cross infection. Leakage or crimp may also occur as a result of deformation, damage or deterioration of the options when they are reused.

**⚠ WARNING**

Use a new breathing circuit that is not contaminated when connecting the ventilator to a new patient. Otherwise, it may cause infection of the patient.

**⚠ WARNING**

To prevent the influx of moisture into the flow sensor line and pressure sensor line, connect these in a vertical orientation. If water droplets are detected, immediately remove them. Otherwise, false alarms and inappropriate ventilation of the patient may occur.

**⚠ WARNING**

Check the connections of the flow sensor line and pressure sensor line to ensure that there are no disconnections or kinks. Otherwise, false alarms and inappropriate ventilation of the patient may occur.

**⚠ WARNING**

Check that the air intake HEPA filter and dust filter are attached to the gas port. Otherwise, the interior of the ventilator may be contaminated and particulates may be mixed into the gas.

**⚠ WARNING**

Only connect one breathing circuit at a time. Do not connect multiple circuits together. This may cause injury to the patient.

**⚠ WARNING**

Only connect Nihon Kohden specified breathing circuit filters to the gas port. Otherwise, infection of the patient and contamination of the ventilator may occur. If the ventilator is used on a patient without the breathing circuit filter attached, always inspect the ventilator and make sure all necessary repairs are performed.

**⚠ WARNING**

Do not attach parts to the breathing circuit that increase the impedance of the circuit. It may cause false alarms and inappropriate ventilation of the patient.

**⚠ WARNING**

Connect the ventilator to the exhalation port on the breathing circuit or use a patient interface with an exhalation port. If there is no exhalation port, the exhalation is obstructed, causing inappropriate ventilation of the patient.

**⚠ WARNING**

Only use parts and consumables specified by Nihon Kohden for the ventilator. Refer to the operator's manual of the parts and consumables to handle and use them. Otherwise, the performance and safety of the ventilator cannot be guaranteed.

**⚠ WARNING**

Only use the provided 3-pin power cord and connect it to a protectively grounded 3-pin power socket. Otherwise, the patient and operator may receive electrical shock or injury. Attach the AC power cord securely to the ventilator with the retainer.

**⚠ WARNING**

When it becomes necessary to connect an unspecified device to the ventilator, check that the Circuit Disconnect alarm occurs normally when all components of the breathing circuit are connected to the ventilator and disconnected, before connecting the ventilator to the patient.

**⚠ CAUTION**

Securely connect the breathing circuit. If there is a leak from any connection or a large leak from the patient interface, the alarm may malfunction and it may be impossible to provide appropriate ventilation to the patient.



**⚠ CAUTION**

Observe the patient condition when using an HME filter. A rise in the impedance of the breathing circuit may obstruct ventilation of the patient.

### O<sub>2</sub> Sensor

**⚠ WARNING**

Observe the following precautions when using a galvanic oxygen sensor.

- Keep the oxygen sensor away from fire. It may explode.
- Do not use oxygen sensors that have been disassembled, or damaged by dropping or impact. If the chemical contents of the oxygen cell come in contact with skin or clothing, immediately wash them with water.
- Do not place the galvanic oxygen sensor in reach of the patient.

**⚠ CAUTION**

Do not use the ventilator without attaching the oxygen sensor. Leaks occurring inside the ventilator might not be detected.

**⚠ CAUTION**

Replace deteriorated or non-functioning sensors with new ones. If they cannot be replaced, monitor the oxygen using external monitoring equipment. Otherwise, gas may be delivered to the patient without monitoring the appropriate oxygen concentration.

### Connecting Oxygen Tubes

**⚠ WARNING**

When using high-pressure oxygen, only use clean and dry medical-grade oxygen.

**⚠ WARNING**

Do not use high pressure gas hoses that are worn or contaminated with combustible materials such as grease or oil. Fire or leaks may occur.

**⚠ CAUTION**

Use an appropriate type of oxygen supply. Otherwise, it may be impossible to supply oxygen appropriately.

**⚠ CAUTION**

When using a low pressure oxygen source such as an oxygen cylinder, do not use a humidifier on the oxygen source. This may cause ventilator failure.

**⚠ CAUTION**

When using a low pressure oxygen source such as an oxygen cylinder, check that the oxygen concentration that can be delivered is appropriate for the patient. The oxygen concentration cannot be adjusted by the ventilator.

**⚠ CAUTION**

When using a low pressure oxygen source such as an oxygen cylinder, always have an alternate source of oxygen prepared, such as a gas cylinder.

### Connecting External Devices

**⚠ WARNING**

Connect only the specified device to the ventilator and follow the specified procedure. Failure to follow this warning may result in electrical shock or injury to the patient and operator, and cause device failure.

**⚠ WARNING**

Only use the USB interface on the ventilator for importing or exporting data. Otherwise, it may cause ventilator failure or malfunction.

**⚠ CAUTION**

When using the nurse call function, confirm that the nurse call function works normally beforehand.

**⚠ CAUTION**

Alarm or parameter information from the ventilator might not be transmitted by the nurse call function in the following situations.

- Communication failure due to deterioration of connection cables or contact failure
- Failure of nurse call system, telephone system, etc.
- Poor hospital equipment environment (power supply)
- Radio frequency interference from illegal radio frequency waves
- Incorrect setting of PHS notification at the nurse call system

**⚠ CAUTION**

When peripheral devices are connected to the ventilator, keep the cables out of the way. Otherwise people may trip over them, the ventilator or peripheral devices may fall and injure the patient and operator, and monitoring may be affected.

**Ventilation****⚠ WARNING**

Supplying high concentration oxygen to a patient continuously for an extended period of time can cause hyperoxemia. Always check the patient condition carefully when adjusting the oxygen concentration.

**⚠ WARNING**

The ultimate responsibility for judgement to wean patients off the ventilator should always be made by a physician.

**⚠ WARNING**

Always check the patient condition. In particular, check the patient condition when changing control settings or during patient circuit configuration. If there is a sudden change in the patient condition, provide appropriate ventilation.

**⚠ WARNING**

Follow the directions of a physician when changing the ventilator settings to the master setting. Otherwise, the patient may receive inappropriate ventilation.

**⚠ WARNING**

When providing mask ventilation, a discrepancy can occur between the VT settings and the tidal volume actually delivered as a result of leaks caused by incorrect attachment to the patient.

**⚠ WARNING**

When changing the ventilation to standby mode, turn the power of the heated humidifier off first. If the power remains on, the gas inside the heated humidifier may become overheated and cause burns to the patient when standby finishes and ventilation resumes.

**⚠ WARNING**

When ending the standby mode, manually restart ventilation and check that ventilation is resumed. Ventilation does not occur in standby mode so ventilation alarms do not occur.

**⚠ WARNING**

In O<sub>2</sub> Therapy mode, use the specified breathing circuit and patient interface and do not use any other combination that increases the dead space volume of the patient. Otherwise, malfunction or failure to provide correct ventilation to the patient may occur.

**⚠ WARNING**

The ventilator can provide a high flow volume of oxygen. Check that the flow rate of the ventilator does not exceed the specified limits of the connected oxygen tube system. This may affect the operation of other devices using the oxygen tube system.

**⚠ WARNING**

To reduce the risk of CO<sub>2</sub> rebreathing, check that there is no change in the respiratory status of the patient when changing control settings, circuit configuration settings or when the patient condition is changed.

**⚠ WARNING**

Be careful of contamination from patient expiration being exhausted into the room through the exhalation port.

**⚠ WARNING**

Take the following precautions to prevent asphyxiation and reduce the risk of rebreathing CO<sub>2</sub>.

- Use a Nihon Kohden specified patient interface in a size that fits the patient.
- Do not block the exhalation port or gas inlet port.
- Check before and during use that gas is being exhausted from the exhalation port.
- Remove the patient interface from the patient when not providing ventilation. If ventilation stops with the interface attached to the patient, exhaled gas cannot be exhausted from the exhalation port adequately.

When ventilation stops unintentionally, or the ventilator suddenly stops working, immediately remove the patient interface from the patient.



**⚠ CAUTION**

When changing the ventilation mode, always check that the control settings are appropriate.

**⚠ CAUTION**

When using auto-triggering, always ensure the patient safety before changing the trigger sensitivity. Also check the condition of the breathing circuit and the ventilator.

**⚠ CAUTION**

Regularly check breathing circuit and water traps for accumulated water and empty them as required. Otherwise, it may cause ventilator failure or malfunction. Also, the accumulated water may backflow and be swallowed by the patient.

**⚠ CAUTION**

When providing mask ventilation, use a specified mask that fits the patient and follow the instructions for attaching the mask to the patient in the operator's manuals for the mask. Regularly check the patient condition as well. The patient's skin may be damaged as a result of stimulation or pressure caused by ventilation.

**⚠ CAUTION**

An exhalation valve cannot be used for ventilation during O<sub>2</sub> therapy mode.

## Alarms

**⚠ WARNING**

Do not pause alarms when there are no medical personnel around the patient. This may cause critical changes in the patient condition to be overlooked.

**⚠ WARNING**

Check the control settings and alarm settings when starting ventilation of a new patient. Also check the settings during ventilation and whenever the patient condition changes and change the control settings and alarm settings if necessary.

**⚠ WARNING**

If the alarm sound volume is quieter than the surrounding sound, the alarm sound might not be heard and changes in the patient's condition or the operation of the ventilator may be overlooked. Set the appropriate alarm sound volume according to the environment where the ventilator is used, or frequently check the patient's condition and ventilator.

**⚠ WARNING**

When an alarm is generated, check the patient condition and secure the patient safety. Depending on the generated alarm, perform appropriate treatment as described in the operator's manual and remove the cause of alarm. If there is a problem with the alarm setting, change it to an appropriate setting.

**⚠ WARNING**

Do not use the alarm information transmitted by the nurse call function of the ventilator to diagnose a patient. There may be misjudging of the patient condition. Check the alarm information on the ventilator.

**⚠ WARNING**

While an Audio Paused message is displayed, there is no sound for all alarms. Be careful when you pause the alarm.

**⚠ CAUTION**

When the alarm limit is set to Off, there will be no alarm for that limit. Be careful when you set the alarm limit to Off.



## Battery

### Main Battery

#### **⚠ WARNING**

Do not do the following to the main battery. It may cause leakage, overheating, explosion and fire.

- Short-circuit the + and – terminals on the main battery.
- Put the main battery into fire or heat the main battery.
- Disassemble or modify the main battery.
- Give strong impact to or deform the main battery.
- Use the main battery on unspecified devices.
- Charge the main battery on unspecified instruments.
- Install the main battery with the wrong polarity.
- Leave the main battery in the reach of patients.
- Immerse the main battery in water.

#### **⚠ WARNING**

If the main battery is damaged and the substance inside the battery pack contacts the eyes, wash immediately and thoroughly with water and see a physician. Never rub your eyes, because you may lose your eyesight.

#### **⚠ WARNING**

The main battery has a lifetime. Replace the main battery at the end of the expected life span. Otherwise, liquid leakage, smoke, fire or explosion may occur.

#### **⚠ WARNING**

When the AC power supply is interrupted and the ventilator operates with the main battery, be careful for the remaining battery power. Replace it with a fully charged main battery as required. If the main battery and the backup battery are discharged, the ventilation operation stops.

#### **⚠ WARNING**

To prevent the main battery from becoming unavailable in case of a power failure, make sure to regularly calibrate the main battery. Otherwise, the remaining charge cannot be accurately calculated and the main battery may expire before the end of the expected operating time.

#### **⚠ WARNING**

Remove the main battery from the ventilator when it is not used for a long time. Otherwise the main battery may leak.

#### **⚠ WARNING**

- Calibrate the main battery every 6 months.
- When you start using a new main battery, write the date of first use on the labels on the main battery.
- Replace the main battery every 2 years.

#### **⚠ WARNING**

Do not expose the main battery to direct sunlight or leave it in a high temperature place. This may cause overheating, explosion and fire. Also, the lifetime of the main battery may be shortened.

#### **⚠ CAUTION**

Replace the battery pack immediately at the expiry of the expected life span. If the battery pack is deteriorated, the data in the device may be lost if there is a power failure.

#### **⚠ CAUTION**

Do not leave the main battery within reach of the patient.

#### **⚠ CAUTION**

Immediately stop using the main battery when abnormal smell, heat, deformation or discoloration is found. Otherwise overheating, smoke or explosion may occur.

### Backup Battery

#### **⚠ WARNING**

Do not do the following to the backup battery. It may cause leakage, overheating, explosion and fire.

- Short-circuit the + and – terminals on the backup battery.
- Put the backup battery into fire or heat the main battery.
- Disassemble or modify the backup battery.
- Give strong impact to or deform the backup battery.
- Use the backup battery on unspecified devices.
- Charge the backup battery on unspecified instruments.
- Install the backup battery with the wrong polarity.
- Leave the backup battery in the reach of patients.
- Immerse the backup battery in water.

**⚠ WARNING**

If the backup battery is damaged and the substance inside the battery pack contacts the eyes, wash immediately and thoroughly with water and see a physician. Never rub your eyes, because you may lose your eyesight.

**⚠ WARNING**

Do not use the backup battery installed in the ventilator as the primary power source. If the AC power supply is disconnected, operation of the ventilator stops in a short time.

**⚠ WARNING**

The backup battery has a lifetime. Replace the backup battery at the end of the expected life span. Otherwise, liquid leakage, smoke, fire or explosion may occur.

**⚠ WARNING**

To prevent the backup battery from becoming unavailable in case of a power failure, make sure to regularly calibrate the backup battery. Otherwise, the remaining charge cannot be accurately calculated and the backup battery may expire before the end of the expected operating time.

**⚠ WARNING**

If a backup battery is not installed in the ventilator, connect it to an uninterruptible power supply (IEC 60601-1 compliant) or the hospital emergency power supply.

**⚠ WARNING**

Remove the backup battery from the ventilator when it is not used for a long time. Otherwise the backup battery may leak.

**⚠ WARNING**

- Calibrate the backup battery every 6 months.
- When you start using a new backup battery, write the date of first use on the labels on the backup battery.
- Replace the backup battery every 2 years.

**⚠ CAUTION**

If the backup battery is damaged and the substance inside the backup battery contacts the skin or clothes, wash immediately with clear water. The skin may get irritated.

**⚠ CAUTION**

Replace the backup battery immediately at the expiry of the expected life span. If the backup battery is deteriorated, the data in the ventilator may be lost if there is a power failure.

**⚠ CAUTION**

To keep the backup battery fully charged, always keep the power cord connected to the AC outlet even when the ventilator is not used. Otherwise, the backup battery may discharge and become unusable.

**⚠ CAUTION**

Do not use or leave the backup battery in direct sunlight or high temperatures such as in a car in hot weather or in front of a stove. It may cause leakage of the backup battery and degrade the performance and lifetime of the backup battery.

**⚠ CAUTION**

Do not leave the backup battery within reach of the patient.

**⚠ CAUTION**

Immediately stop using the backup battery when abnormal smell, heat, deformation or discoloration is found. Otherwise overheating, smoke or explosion may occur.

**⚠ CAUTION**

Dispose of Nihon Kohden products according to your local laws and your facility's guidelines for waste disposal. Otherwise, it may affect the environment. If there is a possibility that the product may have been contaminated with infection, dispose of it as medical waste according to your local laws and your facility's guidelines for medical waste. Otherwise, it may cause infection.



## CO<sub>2</sub> Monitoring

### **⚠ WARNING**

When using the airway adapter or nasal adapter on a patient with low ventilatory volume, the CO<sub>2</sub> may mix in the inspiration due to the airway adapter's or nasal adapter's dead space, resulting in inaccurate measured values or difficulty in detecting no breath. Take the dead space into account when performing ventilation. If that dead space is too much for this patient, appropriate ventilation might be impossible.

### **⚠ WARNING**

Position the cable so that it cannot wind around the face or the neck of the patient.

### **⚠ CAUTION**

Select an airway adapter or nasal adapter that is appropriate for the patient weight and ventilation volume. If an inappropriate airway adapter or nasal adapter is used, the resistance in the respiratory circuit may increase and it may cause incorrect measurement value.

### **⚠ CAUTION**

The CO<sub>2</sub> data may be inaccurate when monitoring a patient with an extremely high respiration rate or irregular respiration. Read the measured values carefully.

### **⚠ CAUTION**

When the "Sensor Fault" or "Module Fault" message is displayed, check the CO<sub>2</sub> sensor kit and replace it if necessary. CO<sub>2</sub> cannot be monitored while the message is displayed.

### **⚠ CAUTION**

Follow the CAUTION label on the CO<sub>2</sub> gas cylinder.

## CO<sub>2</sub> Monitoring

### TG-900P CO<sub>2</sub> Sensor Kit

### **⚠ CAUTION**

Supply adequate oxygen when measuring CO<sub>2</sub> partial pressure of a patient connected to a Jackson Rees, Mapleson D or any other breathing circuit where CO<sub>2</sub> gas may be present during inspiration. The inspiration zero compensation method measures CO<sub>2</sub> partial pressure based on the assumption of no CO<sub>2</sub> gas in the inspired air; it assumes CO<sub>2</sub> partial pressure 0 mmHg (0 kPa) in the inspiration of every respiration. If the inspired air contains CO<sub>2</sub> gas, the displayed CO<sub>2</sub> value is lower than the actual value.

### **⚠ CAUTION**

The measured value may be incorrect when the operating temperature changes greatly.

## CO<sub>2</sub> Monitoring

### TG-980P C O<sub>2</sub> Sensor Kit

### **⚠ CAUTION**

The measured value may be incorrect when the operating temperature changes greatly.

## CO<sub>2</sub> Monitoring

### TG-920P CO<sub>2</sub> Sensor Kit

### **⚠ CAUTION**

Supply adequate oxygen when measuring CO<sub>2</sub> partial pressure of a patient connected to a Jackson Rees, Mapleson D or any other breathing circuit where CO<sub>2</sub> gas may be present during inspiration. The inspiration zero compensation method measures CO<sub>2</sub> partial pressure based on the assumption of no CO<sub>2</sub> gas in the inspired air; it assumes CO<sub>2</sub> partial pressure 0 mmHg (0 kPa) in the inspiration of every respiration. If the inspired air contains CO<sub>2</sub> gas, the displayed CO<sub>2</sub> value is lower than the actual value.

### **⚠ CAUTION**

When measuring CO<sub>2</sub> partial pressure of a patient with an oxygen mask, set the oxygen supply to 5 L/min or more. If CO<sub>2</sub> gas remains in the oxygen mask and mixes with the inspired air, the measured value may be lower than the actual value.

**⚠ CAUTION**

The measured value may be incorrect when the operating temperature changes greatly.

CO<sub>2</sub> Monitoring

## YG-122T Nasal Adapter

**⚠ WARNING**

The only oxygen cannula that can be used with YG-122T is #1103 manufactured by Hudson RCI. Do not use any other oxygen cannula. Other oxygen cannulas cannot be attached and oxygen cannot be delivered to the patient through the nostrils.

**⚠ WARNING**

- When you use YG-122T together with an oxygen cannula, check that the oxygen cannula is correctly attached on the patient by referring to other parameters and by observing the patient periodically.
- If arterial oxygen partial pressure does not increase, immediately stop using the oxygen cannula with the CO<sub>2</sub> sensor kit and select another way to supply oxygen.

**⚠ WARNING**

Check that the oxygen cannula tube is not bent, broken, or blocked by the nasal tube. If the ends of the oxygen cannula tube turn too far up or down, it causes insufficient O<sub>2</sub> supply or the CO<sub>2</sub> value may be incorrect.

**⚠ CAUTION**

When using the YG-121T or YG-122T nasal adapter on a patient, observe the patient condition all the time. The mouth guide touches the mouth and may cause pressure sores.

## YG-221T or YG-231T Nasal Adapter

**⚠ WARNING**

Before and during use, check that the oxygen cannula tube is firmly connected to the oxygen supply unit and that the oxygen tube is not bent, broken, or blocked. Failure to do so may cause insufficient oxygen delivery to the patient.

**⚠ WARNING**

If arterial oxygen partial pressure does not increase when using the YG-221T or YG-231T nasal adapter to deliver oxygen to the patient, immediately stop using the nasal adapter and select another way to deliver oxygen. Failure to do so may cause insufficient oxygen delivery to the patient.

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SpO<sub>2</sub> Monitoring**⚠ WARNING**

Only use the Nihon Kohden specified probes. If an unspecified probe is used, maximum performance from the ventilator cannot be satisfied.

**⚠ WARNING**

When not monitoring SpO<sub>2</sub>, disconnect the SpO<sub>2</sub> connection cord from the ventilator. Otherwise, noise from the probe sensor may cause interference and incorrect data may be displayed on the screen.

**⚠ WARNING**

After use, clean the reusable SpO<sub>2</sub> probe. Failure to follow this warning may cause cross infection.

**⚠ WARNING**

SpO<sub>2</sub> measurement may be incorrect in the following cases.

- When the patient's carboxyhemoglobin or methemoglobin increases abnormally.
- When dye is injected in the blood.
- During CPR.
- When measuring at a site with venous pulse.
- When there is body movement.
- When the plethysmogram is small (insufficient peripheral circulation).

**⚠ WARNING**

- When using the finger probe, do not fasten the probe and cable to the finger by wrapping with tape. This may cause burn, congestion or skin problems from poor blood circulation.
- When using probes other than the finger probe, to avoid poor circulation, do not wrap the tape too tight. Check the blood circulation condition by observing the skin color and congestion at the skin peripheral to the probe attachment site. Even for short-term monitoring, there may be burn or skin problems from poor blood circulation.



### **⚠ WARNING**

Check the circulation condition by observing the skin color at the measurement site and plethysmogram. Change the measurement site every 8 hours for disposable probes and every 4 hours for reusable probes. The skin temperature may increase at the attached site by 2 or 3°C (4 or 5°F) and cause a burn or skin problems. When using the probe on the following patients, take extreme care and change the measurement site more frequently according to symptoms and degree.

- Elderly patient
- Unconscious patient
- Patient with a fever
- Patient with insufficient peripheral circulation

### **⚠ WARNING**

When monitoring SpO<sub>2</sub> of a patient who is receiving photodynamic therapy, the light from the probe sensor may cause a burn where the probe is attached. Photodynamic therapy uses a photosensitizing agent that may cause photosensitive side effects.

The SpO<sub>2</sub> probe manufactured by Nihon Kohden have two wavelengths with peaks in the range of 650 and 950 nm. The maximum light intensity is 5.5 mW/s or less.

### **⚠ CAUTION**

While a patient is on medication which causes vasodilation, the plethysmogram may change and in rare cases the SpO<sub>2</sub> value might not be displayed.

### **⚠ CAUTION**

If the attachment site is dirty with blood or bodily fluids, clean the attachment site before attaching the probe. If there is nail polish on the attachment site, remove the polish. Otherwise, the amount of transmitted light decreases, and the measured value may be incorrect or measurement cannot be performed.

### **⚠ CAUTION**

When measuring SpO<sub>2</sub> under strong light such as surgical light or sunlight, cover the measuring site with a blanket to block the light. Otherwise measurement accuracy may be affected.

### **⚠ CAUTION**

When the probe is attached on an appropriate site with sufficient circulation and an error message about probe attachment repeatedly appears, the probe may be deteriorated. Replace it with a new one.

### **⚠ CAUTION**

When a message indicates a faulty probe or faulty SpO<sub>2</sub> connection cord, stop monitoring and replace the probe or SpO<sub>2</sub> connection cord with a new one.

### **⚠ CAUTION**

When monitoring the patient only with the ventilator, turn on both the upper and lower limit alarms for PR and SpO<sub>2</sub>. If the patient's pulse is not detected during asystole or other condition, a "Cannot Detect Pulse" or "Check Probe" alarm occurs instead of an SpO<sub>2</sub> limit alarm. Furthermore, if the patient has no pulse, noise from probe movement could be misjudged as a pulse and cause an incorrect PR or SpO<sub>2</sub> value to be displayed.

### **⚠ CAUTION**

If the patient requires respiration monitoring, monitor the respiration. Oxygen saturation (SpO<sub>2</sub>) is measured by pulse oximetry which cannot be used for respiration monitoring.

## Maintenance and Inspection

### **⚠ WARNING**

Always perform a preoperational check and confirm that the ventilator is functioning correctly before using it on a patient. If any abnormality is found, do not use the ventilator and immediately perform appropriate treatment.

### **⚠ WARNING**

Do not check the operation of the ventilator when it is connected to a patient.

### **⚠ WARNING**

When an emergency stop alarm occurs, immediately stop ventilation and secure the patient's breathing with an alternative mean of breath delivery.

**⚠ WARNING**

Replace all periodic replacement parts at the expiry of the expected life span and inspect the ventilator carefully after replacing the parts. Otherwise, the maximum performance from the ventilator cannot be guaranteed and failure of the ventilator may occur.

**⚠ WARNING**

If the cooling fan has a failure and high concentration oxygen accumulates inside the ventilator, it may cause fire. When a fan alarm occurs, stop using the ventilator and contact your Nihon Kohden representative. Oxygen accumulate inside the ventilator and may cause fire.

**⚠ WARNING**

Do not disassemble or modify the ventilator. It might cause overheat, fire, electrical shock or injury.

**⚠ WARNING**

Dispose of Nihon Kohden products according to your local laws and your facility's guidelines for waste disposal. Otherwise, it may affect the environment. If there is a possibility that the product may have been contaminated with infection, dispose of it as medical waste according to your local laws and your facility's guidelines for medical waste. Otherwise, it may cause infection.

**⚠ CAUTION**

The backup battery must be replaced by qualified service personnel.

**⚠ CAUTION**

If fluids are accidentally spilled into the ventilator, take the ventilator out of service and contact your Nihon Kohden representative. The ventilator must be disassembled, cleaned, dried and tested for safety, function and performance.

**⚠ CAUTION**

Before maintenance, cleaning or disinfection, turn the ventilator power off, disconnect the power cord from the AC socket and then remove the battery from the ventilator. Also remove the breathing circuit, sensors, probes and any other components connected to the ventilator from the patient. Failure to follow this instruction may result in electrical shock and ventilator malfunction.

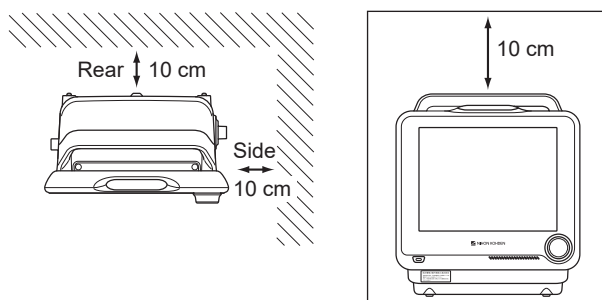


# Installation and Connection

## Installation Conditions

Note the following points for the installation of the ventilator.

- Place the ventilator so that the display can be clearly seen by the operator and so that light does not reflect off it.
- When installing the ventilator on a rack or shelf, make sure that the ventilator is placed and fastened so that it does not tip over. Be careful to avoid collisions or strong impacts when moving the ventilator on a cart. Do not mount the ventilator on a vehicle. It may cause the ventilator to malfunction.
- Do not block the air vents on the bottom panel of the ventilator. Blocking the air vents makes it more difficult to hear alarms and other sounds generated by the ventilator.
- The display screen is made of glass. Collisions or strong impacts may damage it.
- Avoid a location where the ventilator may be sprinkled with liquids. Avoid direct sprinkling, spray or moist air from a nebulizer or a humidifier. This may cause the ventilator to malfunction and shorten its lifetime.
- Avoid exposing the ventilator to direct sunlight. Temperature rises caused by direct sunlight may cause the ventilator to malfunction and shorten its lifetime.
- Ensure adequate airflow around the ventilator for cooling. Internal temperature rises may cause the ventilator to malfunction and shorten its lifetime.
- Make sure that there is more than 10 cm of space between the side and rear panels of the ventilator and the wall.
- When the ventilator is surrounded by walls or other objects, make sure that there is about 10 cm of space above the ventilator to ensure adequate airflow for cooling.



- Do not cover the ventilator with a blanket or cloth.
- Do not install the ventilator in a dusty area.

- Connect the AC power cord to an AC outlet which can supply sufficient power to the ventilator. The ventilator cannot function properly with insufficient power. Also, this might blow the breaker.
- Connect the power cord to an AC outlet that can supply enough AC current to the ventilator. The ventilator cannot function properly with low current. Also, this might blow the breaker.
- If an electronic blanket is used, the entire body of the patient is subjected to electromagnetic noise (pulsed noise is generated). This may affect SpO<sub>2</sub> measurement at close distances.
- When there are any problems with the ventilator after turning on the power, turn off the power immediately and disconnect the power cord from the AC outlet. Attach an “Unusable” or similar notice to the ventilator. Do not use the ventilator until it is inspected.
- If the earth cable or other connections seem to be faulty, disconnect the ventilator from the power and operate it using the battery pack.
- When using the ventilator in the presence of an electrosurgical unit (ESU), install the ventilator as far as possible from the ESU. If possible, locate them on opposite sides of the operating table.

## Equipotential Grounding

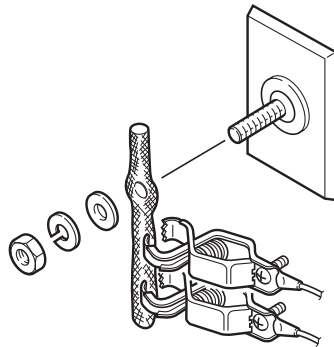
When equipotential grounding is required, connect the equipotential ground terminal on the ventilator (the terminal marked ⚡) to the equipotential ground terminal on the wall with the optional equipotential grounding lead.

### Necessity of Equipotential Grounding

When more than one electrical device is used, there may be electrical potential difference between the devices. The potential difference between the devices may cause current to flow to the patient connected to the devices, resulting in electrical shock. Always perform equipotential grounding when required. It is often required in the operating room, ICU room, CCU room, cardiac catheterization room and X-ray room. Consult with a biomedical engineer to determine if it is required.



When equipotential grounding is required, connect the equipotential ground terminal on the ventilator to the equipotential ground terminal on the wall (equipotential grounding system) with the equipotential grounding lead (potential equalization conductor).



## Cutting Off the Power Supply to the Ventilator

To cut off the power supply to the ventilator, disconnect the power cord of the ventilator from the wall AC outlet. When installing the ventilator, position the ventilator so that it is easy to disconnect the power cord from the wall AC outlet.

After disconnecting the AC power cord, fix the AC power cord holder to the AC power cord holder mount.

## Connecting Peripheral Devices to the Ventilator

### Warnings and Cautions

#### ⚠ WARNING

Connect only the specified device to the ventilator and follow the specified procedure. Failure to follow this warning may result in electrical shock or injury to the patient and operator, and cause device failure.

#### ⚠ WARNING

When several medical devices are used together, ground all devices to the same one-point ground. Any potential difference between devices may cause electrical shock to the patient and operator.

#### ⚠ CAUTION

Before connecting or disconnecting devices, make sure that each device is turned off and the power cord is disconnected from the AC socket. Otherwise, the patient or operator may receive electrical shock or injury, data may be lost or the device may malfunction.

NOTE: After changing the composition or arrangement of peripheral devices connected to the ventilator, check that all of the connected devices operate correctly.

### Safety Measures when Installing and Connecting Peripheral Devices

When more than one electrical device is used, there may be electrical potential difference between the devices.

Potential difference between devices may cause current to flow to the patient connected to the devices, resulting in electrical shock. Never use any medical equipment in patient treatment without proper grounding. Also never connect an additional power strip or extension cord to the medical electrical system.

Always perform equipotential grounding as specified in IEC 60601-1:2005+Amendment 1:2012 "General requirements for basic safety and essential performance" when required. It is often required in the operating room, ICU room, CCU room, cardiac catheterization room and X-ray room. Consult with a biomedical engineer to determine if grounding is required.

- NOTE
- For details on connecting a peripheral device to the ventilator, contact your Nihon Kohden representative.
  - Leakage current may increase when interconnecting many medical devices to the ventilator.



## Connecting the Ventilator to the Network

When connecting the ventilator to the network, the network connection method and installation method differ according to the installation location of the ventilator and the types and installation locations of other devices connected to the network.

### Warnings and Cautions

#### **WARNING**

Connect the ventilator to network as specified. Otherwise the patient and operator may receive electrical shock or injury. To connect to the network, contact your Nihon Kohden representative.

#### **WARNING**

Install all network devices, including printers and hubs, outside the patient environment. If they are installed inside the patient environment, the patient or operator may receive electrical shock or injury. For installation, contact your Nihon Kohden representative.

#### **WARNING**

In a network where this ventilator is connected, connect only the specified devices. Unspecified devices may cause electrical shock or injury to the patient and operator or cause device malfunction, device stop, or data loss.

#### **WARNING**

Check the software version number of the ventilator before connecting it to the network. Different software versions have different communication methods. More than one communication method in a network may cause communication failure. For details, refer to the Network and System Installation Guide.

#### **WARNING**

Do not use a damaged network cable. The patient or operator may receive electrical shock when the damaged part is touched.



Refer to “General Requirements for Connecting Medical Electrical Systems” (p. 3-25).

## About the SD Card

Use the SD card correctly in accordance with all operating instructions and safety precautions issued by the manufacturers of the connected device and any peripheral devices.

#### **WARNING**

Do not leave the SD card near the patient or in reach of children. This may lead to an accident such as the patient or child swallowing the SD card.

NOTE: Follow the precautions in this operator's manual when using the SD card.

## Precautions for Handling and Storage

- Do not disassemble or modify the SD card.
- Do not give impact to the SD card by dropping or bending it.
- Do not handle the SD card while smoking, eating or drinking. Do not get the SD card wet.
- Do not use the SD card with wet hands. It may cause malfunction of the SD card or electrical shock.
- Do not touch the terminal of the SD card with your hands or metal objects. Do not let the chemical solutions contact with the terminal.
- Do not peel off the label of the SD card or attach another label.
- Do not write on the SD card with a pencil, pen or marker. It may cause malfunction of the SD card or loss of data.
- Do not use the SD card in unspecified devices.
- Keep the SD card slot clean. If dust gets into the slot, the SD card may not function.
- Do not use the SD card in environments where static electricity or electrical noise is present. It may cause malfunction of the SD card or loss of data.
- Do not defragment the SD card.
- Clean the terminal of the SD card with dehydrated ethanol (concentration:  $\geq 99.5$  vol% at 15°C (59°F)). Using other substances to clean the SD card terminal may cause malfunction of the SD card.
- When cleaning other parts of the SD card than the terminal (for example, the label surface), wipe with a cloth or tissue paper soaked in a disinfecting ethanol (concentration: 76.9 to 81.4 vol% at 15°C (59°F)) and then wrung out.
- Observe the following precautions when storing the SD card.

- When the SD card is removed from the device, be careful not to lose the SD card. Choose a storage location where the patient cannot get the SD card. Do not let the patient swallow the SD card.
- Store the SD card in the provided case.
- Do not expose the SD card to direct sunlight or leave it in a high temperature place. It may cause deformation or malfunction of the SD card.
- Do not store the SD card where corrosive gas is generated.

## Precautions for Data Reading/ Writing

- Do not write data to the SD card in an unspecified device. The SD card might become unusable.
- Do not remove the SD card from the device or turn the power off while data is being written to or read from the card or initializing the card. Otherwise the SD card may be damaged.



# Cybersecurity

## About the Information Security User Agreement

The user agrees to implement the following measures with respect to the cybersecurity of this ventilator, including measures for the protection of confidentiality of patient information. Ensure that you have thoroughly read and complied with the contents of this user agreement before using the ventilator.

**⚠ CAUTION**

Store the ventilator in a securely managed environment.

**⚠ CAUTION**

Patient information stored on this ventilator is vulnerable to unauthorized access. Follow the provisions of the user agreement for this ventilator related to information security.

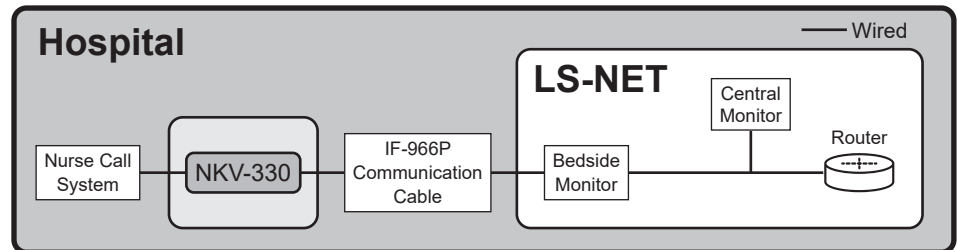
### **User Agreement with Relation to the Information Security of this Ventilator**

- NOTE
- The ventilator processes height and gender information that constitutes patient information. As well as being displayed on screen, this information is also stored in the memory of the ventilator. Implement effective cybersecurity measures to protect the ventilator before using it to process patient information.
  - Unauthorized use of the ventilator may cause operation of the system to become unstable or data to be lost. Establish appropriate cybersecurity management to prevent unauthorized users from accessing the ventilator.
  - In order to prevent unauthorized access to the ventilator, set appropriate passwords to authenticate users and store them securely.
  - Establish rules for accessing data and exercise caution to prevent unauthorized access to and use of information.
  - The ventilator (including data back-up devices) stores patient information inside it. Delete all patient information on the ventilator when selling, transferring or disposing of it. Obtain specialist advice on preventing unauthorized access to information and follow the recommendations contained in that advice.
  - Refer to the operator's manual for installation and connection of the ventilator and its components and connection to peripheral devices. Incorrect connection or use of the ventilator could interfere with other devices connected to the same network.

- Implementing effective cybersecurity measures to prevent infection by viruses when connecting external media to the ventilator is the responsibility of the user.
- When connecting to information networks, use the appropriate transmission protocols and other settings to allow communication between the systems. Incorrect settings and unintended changes could cause data inconsistencies that prevent interoperation between the systems.

## Network Environment

This ventilator is intended for use in a connected/networked environment.



In order to prevent infection with computer viruses, cyberattacks or unauthorized (arbitrary) software updates, use the ventilator in a network environment that is divided into network segments. To ensure the cybersecurity of the ventilator, it is recommended to implement the settings in the following caution on networking equipment used to connect the ventilator to external network. For further details on settings, contact your network administrator.

### CAUTION

To ensure the cybersecurity of the ventilator, implement the following network security measures under the supervision of the information security manager of the medical facility.

1. When a device in the network (LS-NET, HIS, LIS, etc.) is connected to an external network including the internet, access to sensitive information is protected by firewalls and ACL (access control lists).
2. When a device in an LS-NET network is connected to a network with a different protocol (HIS, LIS, etc.), access control is implemented on routers and switches to restrict communication to the designated source and destination devices only.

**NOTE:** Changing the network after installation creates new cybersecurity risks and requires a new risk analysis. The responsible organization should take action to isolate, analyze and manage these risks. "Changing the network" includes changing the network configuration, connecting additional devices to the network, removing devices from the network and updating or upgrading of connected devices, etc.



## Management of the Administrator Password for this Ventilator

### CAUTION

Some data and operations on this ventilator can be set, changed or managed only by a user with administrator privileges. Set a password for the administrator that is difficult to guess. Change the password at regular intervals and store it securely to prevent security breaches.



Refer to the following.  
Administrator's Guide:  
"Changing the Password" in Section 2

## When Cybersecurity Incidents Occur

The ventilator is designed to operate independently of any network communications devices connected to it. Even when a cybersecurity incident occurs that affects the ventilator (for example receiving a DoS<sup>1</sup> attack), oxygen administration and positive pressure ventilation and ventilatory assistance continue to operate unaffected.

<sup>1</sup> DoS attack (Denial of Service attack) is one method of cyberattack used by a malicious attacker. It involves sending a large volume of data to a network device with the aim of overloading the device and preventing it from functioning in accordance with its intended purpose.

When problems occur with the ventilator as a result of a cybersecurity incident that prevents it from communicating with external devices, the following message is displayed. When you see this message displayed on the ventilator, check the connection cables and network settings, and contact the information security manager at your facility.

"Check External Device"

When the ventilator is affected by a cybersecurity incident, it is possible to restore the ventilator to its factory default settings. Refer to the relevant section of the administrator's guide below. The administrator password is required to restoring the settings in the System Configuration window to their default values.



Refer to the following.  
Administrator's Guide:  
"Initializing All Settings" in Section 5

## Deleting Patient Information Saved on the Ventilator

When selling, transferring or disposing of the ventilator, initialize all settings on the ventilator and delete all patient information. For initializing settings, refer to the following section of the administrator's guide.



Refer to the following.  
Administrator's Guide:  
"Initializing All Settings" in Section 5

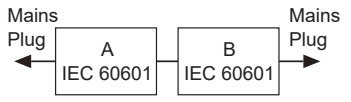
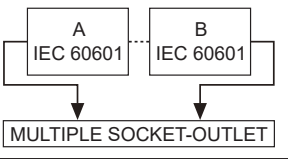
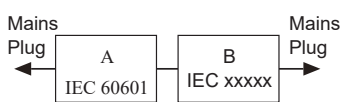
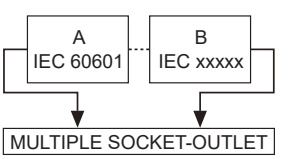
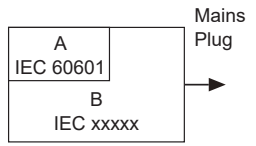
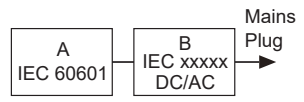
# General Requirements for Connecting Medical Electrical Systems

3

When more than one electrical equipment is used, there may be electrical potential difference between the equipment. Potential difference between equipment may cause current to flow to the patient connected to the equipment, resulting in electrical shock. Therefore, electrical equipment must be appropriately installed as specified in IEC 60601-1:2005+Amendment 1:2012.

The following is an extract from IEC 60601-1:2005+Amendment 1:2012 “Medical electrical equipment - Part 1: General requirements for basic safety and essential performance”. For details, refer to IEC 60601-1:2005+Amendment 1:2012 and consult a biomedical engineer.

## Examples of Combinations of MEDICAL ELECTRICAL EQUIPMENT and Non-medical Electrical Equipment

| Situation No.  | Medically used room   |                                 | Non-medically used room | Examples of possible causes for exceeding LEAKAGE CURRENT limits  | Practical means of compliance<br>Apply 16.5 in all situations                                  |
|--|---|---------------------------------|-------------------------|---|--|
|  | Inside the PATIENT ENVIRONMENT  | Outside the PATIENT ENVIRONMENT |                         |   |  |
| 1a Items A and B are ME EQUIPMENT  |   |                                 |                         | Multiplied APPLIED PARTS of the same type can cause the total PATIENT LEAKAGE CURRENT to exceed limits<br>See Note 1. | – Verify total PATIENT LEAKAGE CURRENT   |
| 1b Items A and B are ME EQUIPMENT powered via a MULTIPLE SOCKET-OUTLET                   |  |                                 |                         | Earth conductor of the MULTIPLE SOCKET-OUTLET is broken<br>See also 1a.   | – Additional PROTECTIVE EARTH CONNECTION<br>(for A or B) or,<br>– Separating transformer       |
| 1c Item A is ME EQUIPMENT and B is Non-ME EQUIPMENT                                      |  |                                 |                         | Due to high TOUCH CURRENT of B  | – Additional PROTECTIVE EARTH CONNECTION<br>(for B) or,<br>– Separating transformer<br>(for B) |
| 1d Item A is ME EQUIPMENT and B is non-ME EQUIPMENT powered via a MULTIPLE SOCKET-OUTLET |  |                                 |                         | The earth conductor of the MULTIPLE SOCKET-OUTLET is broken or,<br>Due to high TOUCH CURRENT of B                     | – Additional PROTECTIVE EARTH CONNECTION<br>(for A or B) or,<br>– Separating transformer       |
| 1e Item A is ME EQUIPMENT powered from specified power supply in item B                  |  |                                 |                         | Due to high TOUCH CURRENT of B  | – Additional PROTECTIVE EARTH CONNECTION<br>(for B) or,<br>– Separating transformer<br>(for B) |
| 1f Item A is ME EQUIPMENT powered from NON-ME EQUIPMENT power supply in B                |  |                                 |                         |   |  |



3. Safety Information

| Situation No. | Medically used room   |                                 | Non-medically used room | Examples of possible causes for exceeding LEAKAGE CURRENT limits  | Practical means of compliance Apply 16.5 in all situations   |
|---------------|---|---------------------------------|-------------------------|---|--|
|               | Inside the PATIENT ENVIRONMENT  | Outside the PATIENT ENVIRONMENT |                         |   |  |
| 2             | 2a Items A and B are ME EQUIPMENT   |                                 |                         | No causes of exceeding LEAKAGE CURRENT  | - No further measures are necessary  |
|               | 2b Items A and B are ME EQUIPMENT powered via a MULTIPLE SOCKET-OUTLET                        |                                 |                         | Earth conductor of the MULTIPLE SOCKET-OUTLET is broken   | - Additional PROTECTIVE EARTH CONNECTION (for A or B) or,<br>- Separating transformer  |
|               | 2c Item A is ME EQUIPMENT and item B is non-ME EQUIPMENT                                      |                                 |                         | Due to high TOUCH CURRENT of B<br>See rationale for 16.5.   | - Do not use metal connector housing or,<br>- SEPARATION DEVICE  |
|               | 2d Item A is ME EQUIPMENT and item B is non-ME EQUIPMENT powered via a MULTIPLE SOCKET-OUTLET |                                 |                         | The earth conductor of the MULTIPLE SOCKET-OUTLET is broken   | - Additional PROTECTIVE EARTH CONNECTION (for A or B) or,<br>- Separating transformer  |
| 3             | 3a Items A and B are ME EQUIPMENT   |                                 |                         | No causes of exceeding LEAKAGE CURRENT  | - No further measures are necessary  |
|               | 3b Item A is ME EQUIPMENT and item B is non-ME EQUIPMENT                                      |                                 |                         | Due to high TOUCH CURRENT of B<br>See rationale for 16.5.   | - Do not use metal connector housing for SIGNAL INPUT/OUTPUT PART or,<br>- SEPARATION DEVICE   |
|               | 3c Item A is ME EQUIPMENT and item B is ME EQUIPMENT or non-ME EQUIPMENT                      |                                 |                         | a) Potential difference between PROTECTIVE EARTH CONNECTIONs of A and B<br>b) Due to high TOUCH CURRENT of B<br>See rationale for 16.5. | - Additional PROTECTIVE EARTH CONNECTION for (A), or<br>- SEPARATION DEVICE, or<br>- Do not use metal connector housing in the PATIENT ENVIRONMENT |

NOTE 1 No causes of TOUCH CURRENT or EARTH LEAKAGE CURRENT exceeding limits.

NOTE 2 IEC 60601: MEDICAL ELECTRICAL EQUIPMENT in compliance with IEC 60601.

NOTE 3 IEC xxxxx: Non-medical equipment in compliance with relevant IEC safety standards.

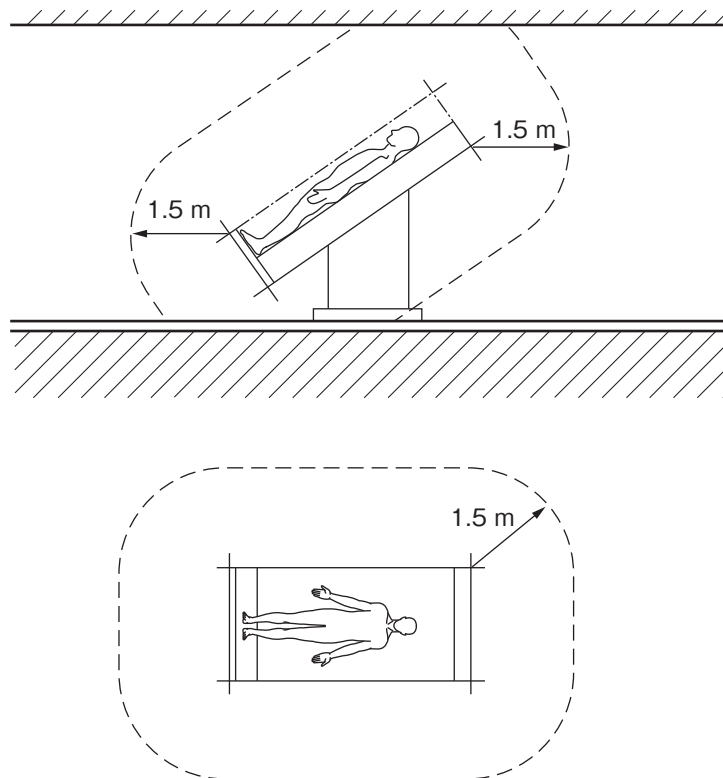
NOTE 4 Separating transformer: see 16.9.2.1.

NOTE 5 If equipment “B” is outside the PATIENT ENVIRONMENT and if equipment “A” is a CLASS II equipment and has accessible conductive parts connected to the PROTECTIVE EARTH CONNECTION of equipment “B” then additional safety measures could be necessary, for example: additional protective earth for “B” or separating transformer or SEPARATION DEVICE.

## Example of PATIENT ENVIRONMENT

The following is an extract from IEC 60601-1:2005+Amendment 1:2012 Clause 3 Subclause 3.79 Figure A.9.

It is difficult for this standard to define dimensions for the volume in which diagnosis, monitoring or treatment occurs. The dimensions for the PATIENT ENVIRONMENT given in Figure A.9 have been justified in practice.



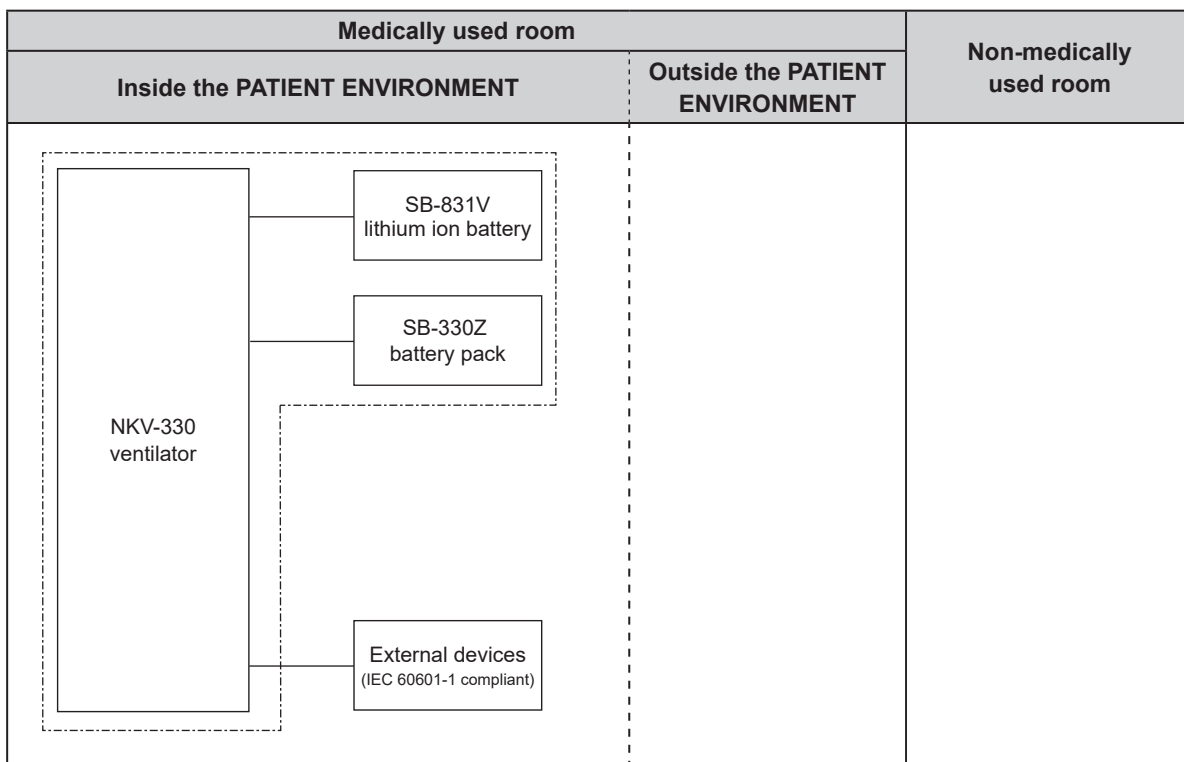
NOTE The dimensions in the figure show minimum extent of the PATIENT ENVIRONMENT in a free surrounding.

Figure A.9 - Example of PATIENT ENVIRONMENT



## Environment for Peripheral Devices

Use peripheral devices in the following environment.





# 4

## Preparation

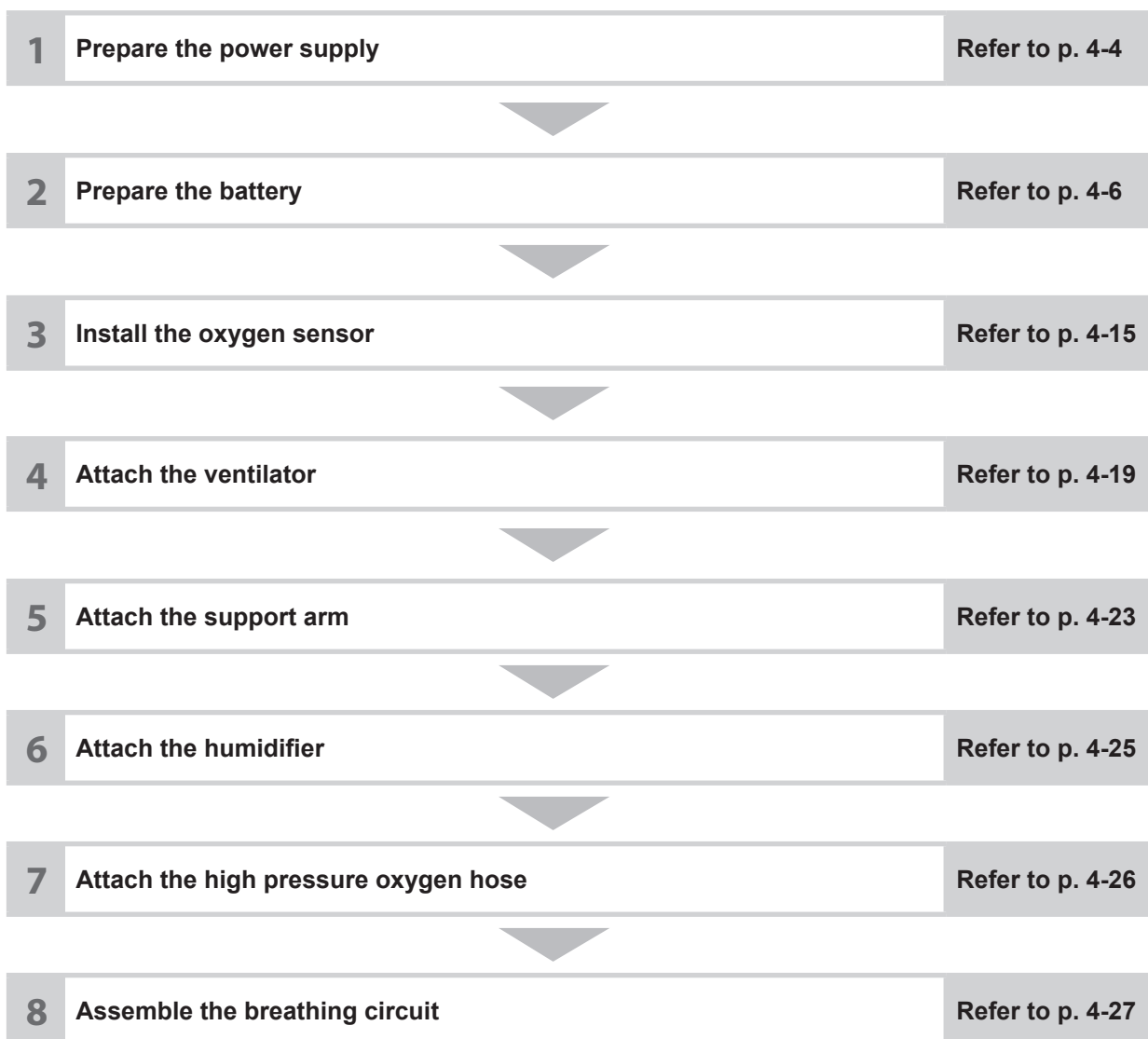
|  |      |   |      |
|--|------|---|------|
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| Checking the Battery Status on the Main<br>Screen.....                             | 4-13 | Transporting the Ventilator on a Cart.....                          | 4-36 |
| Checking the Main Battery LED Indication....                                       | 4-13 |   |      |
| Ventilator Operation Status and Lamp<br>Display.....                               | 4-14 |   |      |
| Installing the Oxygen Sensor.....  | 4-15 |   |      |
| Galvanic Oxygen Sensor.....  | 4-15 |   |      |
| Paramagnetic Oxygen Sensor .....   | 4-16 |   |      |



## Preparation Flow

Prepare the ventilator as follows.

NOTE: Check that there are enough accessories and optional items.



# Power

4

## Types of Power Supply

The ventilator can be operated by either AC power or battery.

Either can be selected depending on the location of use.

When operating on AC power, use the AC power cord and battery.

## AC Power

Connect the provided 3-pin power cord to the AC power outlet on the wall.

The ventilator is supplied with AC 100 V, and when the battery is inserted, charging of the battery starts automatically. The battery pack automatically starts charging when AC power is supplied if it is mounted to the ventilator.

If the AC power cord is connected to an AC power outlet while operating the ventilator with the battery, the power source automatically changes from the battery to AC power.

## Battery

The ventilator uses 2 types of batteries.

### Main Battery

The ventilator can be operated on battery power by connecting the optional SB-831V lithium ion battery (hereinafter referred to as “main battery”) to the main battery compartment on the rear panel of the ventilator.

- A new fully-charged main battery can achieve approximately 2 hours of continuous use at an ambient temperature of 25°C (77°F). However, this also depends on the operating environment. Use the AC power supply for situations requiring extended use.
- When using the AC power supply, the ventilator automatically changes from AC power to the battery in the event of a power failure or disconnection.



The main battery can be charged by connecting it to the ventilator or with the optional SB-801V battery charger.

### Backup Battery

The optional SB-330Z battery pack (hereinafter referred to as “backup battery”) can be used as the backup battery. By mounting it in advance to the backup battery compartment on the bottom panel of the ventilator, it can be used to replace the main battery when AC power is not available.

## Operation at Power Failure

Power will change to the backup battery immediately when the main battery runs out and AC power is not available.

The Crisis alarm is triggered when backup battery operation starts. In this case, immediately connect the ventilator to AC power or replace the main battery with a main battery which has remaining power.



## Using AC Power

### Connecting the Power Cord to the Ventilator

#### ⚠ WARNING

Only use the provided power cord and connect it to a 3-pin AC outlet which is properly grounded. Otherwise, it may result in electrical shock or injury to the patient and operator.

- 1 Connect the provided power cord connector to the AC source socket on the left side panel of the ventilator using the retainer.

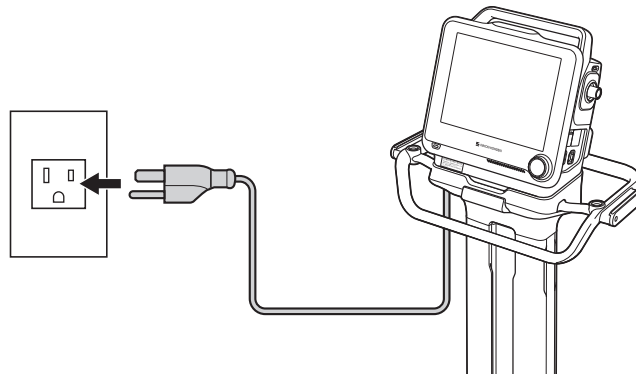


Refer to the following.  
Administrator's Guide:

“Connecting the Power Cord to the Ventilator” in Section 1

- 2 Connect the plug on the opposite side to the wall AC outlet.

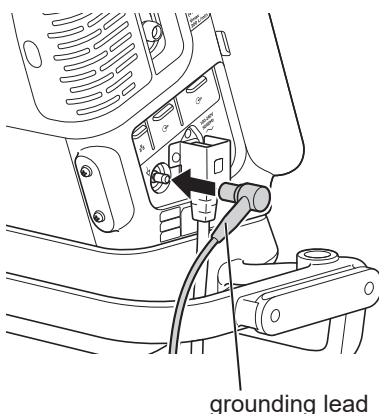
The AC power lamp (⎓) on the front panel of the ventilator lights when it is supplied with AC power.



Connecting the power cord to a grounded AC outlet automatically grounds the ventilator.

NOTE: Check the AC power cord connection if the AC power lamp does not light after connecting the cord.

### Connecting the Grounding Lead to the Ventilator (Equipotential Grounding)

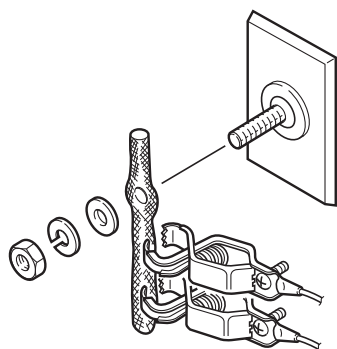


When using the ventilator in a location requiring equipotential grounding, connect the equipotential ground terminal (indicated by ⚡) on the left side panel of the ventilator with the wall ground terminal using the optional grounding lead.

#### ⚠ WARNING

When several medical devices are used together, ground all devices to the same one-point ground. Any potential difference between devices may cause electrical shock to the patient and operator.

## Equipotential Grounding



When more than one electrical device is used, there may be electrical potential difference between the devices. The potential difference between the devices may cause current to flow to the patient connected to the devices, resulting in electrical shock. Always perform equipotential grounding when required. It is often required in the operating room, ICU room, CCU room, cardiac catheterization room and X-ray room. Consult with a biomedical engineer to determine if it is required.

When equipotential grounding is required, connect the equipotential ground terminal on the ventilator to the equipotential ground terminal on the wall (equipotential grounding system) with the equipotential grounding lead (potential equalization conductor).



## Using the Battery

The ventilator can be battery operated when the main battery and backup battery are installed.

The ventilator automatically uses the battery when AC power is not available.

- NOTE
- Use the SB-831V lithium ion battery as the main battery.
  - Use the SB-330Z battery pack as the backup battery.
  - New main batteries and backup batteries are not charged. Always charge them before and after use.
  - Replace the main battery and backup battery every 2 years, and inspect them regularly to ensure that they can be used any time in the event of an emergency.
  - Calibrate the main battery and backup battery once every 6 months.

---

## Approximate Battery Operation Time

### Main Battery

A new fully-charged main battery can achieve approximately 2 hours of use when all of the following conditions are met.

- Ventilation mode: S/T
- IPAP: 8 hPa
- EPAP: 4 hPa
- Ti: 1.0 s
- RR: 15/min
- FiO<sub>2</sub>: 21%

---

## Battery Precautions

### Use

- Always calibrate the battery before using new main batteries and backup batteries.
- When using the battery for the first time, write the usage start date on the battery label (MM/DD/YY). Furthermore, when using batteries to power the ventilator, check the dates on which the installed main battery and backup battery were first used and replace them every 2 years.
- The warranty period for the main battery and backup battery is 1 year.
- The ventilator may be unusable if a degraded or unusable main battery remains connected to the main battery connection. Immediately replace degraded main batteries with new ones.
- Do not keep discharged batteries installed in the ventilator when AC power is not connected. They may become unusable due to overdischarge. Therefore, store them with AC power connected.

---

## Charging

- Always charge batteries at an ambient temperature between 5 and 40°C (41 to 104°F). Charging may fail at temperatures outside of this range. Moreover, batteries may deteriorate more quickly when charged at temperatures above 40°C (104°F).
- The battery charging lamp blinks quickly if the batteries heat up due to extended charging. Immediately stop the charging and only begin it again after moving the ventilator to a cool location. Charging starts once the batteries cool down.
- Charge the main battery with the ventilator or the SB-801V battery charger. Using an unspecified device may cause malfunction or failure.
- Charge the backup battery with the ventilator. Charging the backup battery using a power source other than the ventilator may cause malfunction or failure.

---

## Inspection

- Replace the main battery and backup battery every 2 years.
- Inspect and calibrate the main battery and backup battery every 6 months to prevent battery trouble. Replace the main battery and backup battery with new ones if any damage such as cracks or deformations are seen on them. Moreover, make sure to clean them if they become dirty.

---

## Storage

- When storing the battery pack mounted on the ventilator, always supply the AC power to the ventilator.
- When not using the ventilator for an extended period of time (approximately 6 months or longer), remove the batteries from the ventilator and store them in a dry location at a temperature between -20 and +35°C (-4 and +95°F) to prevent rust.
- If the battery has been stored for 1 month or more, charge it before use. Even if the battery was only used for a short time before storage and the battery was fully charged before storage, the main battery and the backup battery undergo self-discharge which reduces the usable operation time of the battery after storage.
- Replace the main battery and backup battery every 2 years from the usage start date to ensure full functionality for the ventilator.
- Charge the batteries once every 6 months when not using them for an extended period of time.

---

## Disposal

Contact a Nihon Kohden representative before disposing of the main battery and backup battery. Do not dispose of the main battery and back up battery together with other waste, since disposal procedures differ depending on the region. The batteries should be recycled to help preserve the environment.

When disposing of the ventilator, make sure that the main battery and backup battery are not mounted to it.



## Inserting the Main Battery

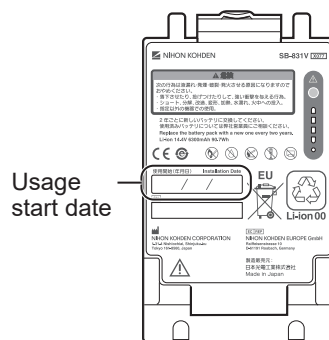
Install the main battery by inserting it at the main battery compartment located on the back of the ventilator.

Write the usage start date on the label of the new main battery before mounting it. Furthermore, make sure to charge it after mounting.

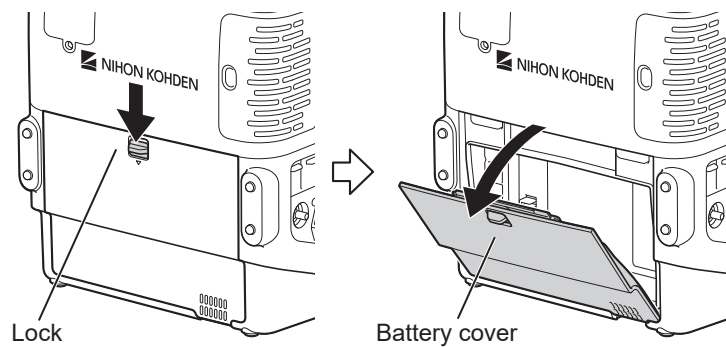
**NOTE** • Use the SB-831V lithium ion battery as the main battery.

- Replace the main battery every 2 years, and inspect it regularly to ensure that it can be used any time in the event of an emergency.
- The main battery cannot be inserted when the ventilator is mounted to the cart.

- 1 Check the usage start date for the main battery to ensure that 2 years has not elapsed since the date on which the battery was first used.

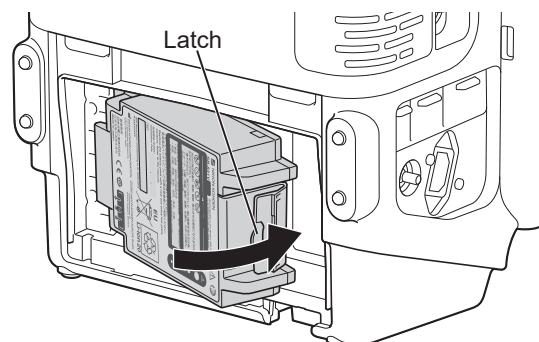


- 2 Release the lock on the rear panel of the ventilator and remove the battery cover.

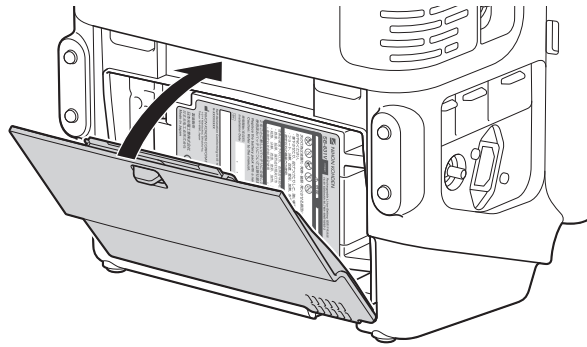


- 3 Install the main battery by inserting it at the **main battery compartment** as shown in the figure.

Insert the main battery all the way into the compartment until it clicks into place.



- 4 Close the battery cover on the rear panel of the ventilator.

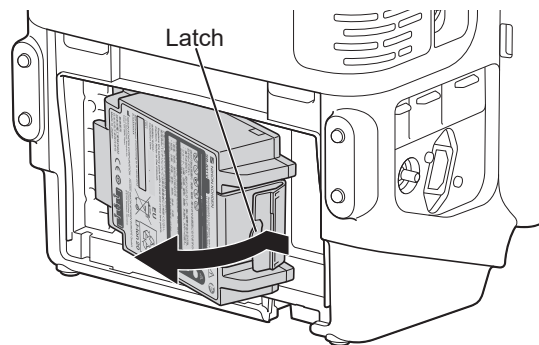


4

## Removing the Main Battery

- 1 Release the lock on the rear panel of the ventilator and remove the battery cover.
- 2 Push in the latch and slowly pull out the main battery as shown in the figure.

NOTE: When removing the main battery, slowly remove it while pushing inward with your hand to ensure that it does not fall out.





## Charging the Battery

The ventilator can be used to charge the main battery and backup battery.

The main battery can also be charged using the optional SB-801V battery charger. This manual explains how to charge the battery using the ventilator.

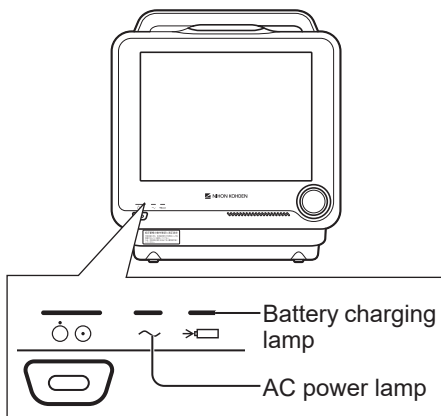
Refer to the manual for the SB-801V battery charger for details on how to charge the battery using the SB-801V battery charger.



Refer to the SB-801V Battery Charger Operator's Manual.

- NOTE**
- Newly purchased main batteries and backup batteries are not charged. Always charge them before use.
  - Charge the main battery with the ventilator or the SB-801V battery charger. Using an unspecified device may cause malfunction or failure.
  - Charge the backup battery with the ventilator. Charging the backup battery using a power source other than the ventilator may cause malfunction or failure.

## Charging Procedure



Connect the provided 3-pin power cord to the AC power outlet on the wall to operate the ventilator using AC power.

The AC power lamp on the front panel of the ventilator lights and the battery charging lamp starts blinking slowly to indicate that the battery is charging.

When charging is complete, the battery charging lamp will light up.

- NOTE**
- Always charge the main battery and backup battery at an ambient temperature between 5 and 40°C (41 to 104°F). Charging may fail at temperatures outside of this range. Moreover, the main battery and backup battery may deteriorate more quickly when charged at temperatures above 40°C (104°F).
  - Do not disconnect the power cord until charging is complete.
  - When the main battery and backup battery are charged for an extended period of time, the battery charging lamp starts blinking rapidly to indicate that the batteries are overheating. Immediately stop charging and only start it again after moving the ventilator to a cool location. Charging starts once the main battery and backup battery cool down.
  - When charging the main battery and backup battery, make sure that the AC power lamp is on and that the battery charging lamp is blinking slowly.

## Approximate Charging Time

### When charging with the ventilator:

- Main battery: Up to 7 hours
- Backup battery: Up to 3 hours

### When charging with the battery charger:

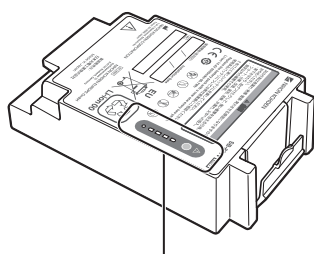
Refer to the manual for the battery charger for details on the charging time for the main battery using the SB-801V battery charger.



Refer to the SB-801V Battery Charger Operator's Manual.

4

## Main Battery LED Indicator



LED blinks according to remaining battery power.

When charging with the SB-801V battery charger, the LED blinks according to the remaining battery power.

The number of blinking LEDs increases as charging continues. When charging is complete, all the LEDs turn off.

When replacing a main battery with a battery charged with the SB-801V battery charger, refer to the table below to check the charge of the replacement main battery.

| Remaining battery power <sup>1</sup> |          |          |          |          | Charging complete |
|--------------------------------------|----------|----------|----------|----------|-------------------|
| 1 - 20%                              | 21 - 40% | 41 - 60% | 61 - 80% | 81 - 99% |                   |
|                                      |          |          |          |          |                   |

<sup>1</sup> Remaining battery power indicates the amount of charge left in the battery.




## Auxiliary Charging of Main Battery (Trickle Charging)

Always store the ventilator with the AC power connected even after fully charging the main battery (battery charging lamp is off), regardless of whether the ventilator will be used. Auxiliary charging (trickle charging) ensures that the main battery remains fully charged.

### CAUTION

To keep the battery fully charged, always keep the power cord connected to the AC outlet even when the ventilator is not used. Otherwise, the battery may discharge and become unusable.

- NOTE
- If the battery charge icon falls to “” soon after a fully charged main battery is used, deterioration of the main battery is suspected.
  - Calibrate the battery once every 6 months.



#### Auxiliary Charging (Trickle Charging)

Auxiliary charging (trickle charging) refers to applying a small current to a charged battery to prevent it losing charge by self-discharging.

---

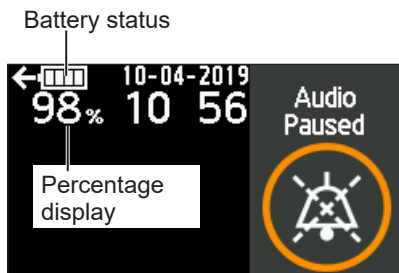
## Remaining Main Battery Power Indication

You can check the remaining power of the main battery with the battery status indicator on the upper right screen or with the LED indicator on the battery.

NOTE: If the battery is repeatedly charged to a level below fully charged, the correct remaining power might not be displayed.



## Checking the Battery Status on the Main Screen

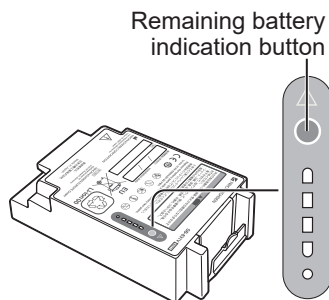


Check the remaining battery power on the battery status and percentage display at the upper right of the screen. A message is displayed depending on the battery level.

| Battery Status | Display Color | Remaining Battery Power and Operating Condition  | Message                           |
|----------------|---------------|--|-----------------------------------|
|                | White         | 91% to 100%                                      | AC Power Loss/Main Battery In Use |
|                |               | 61% to 90%                                       |                                   |
|                |               | 31% to 60%                                       |                                   |
|                | Yellow        | 11% to 30%                                       | Main Battery Low                  |
|                | Red           | 0% to 10%  | Main Battery Empty                |
|                |               | Battery not connected                            | Main Battery Disconnect           |
|                | Yellow        | Battery fault                                    | Main Battery Fault                |
|                | —             | Battery charging                                 | —                                 |
|                |               | Operating on battery power (battery discharging) |                                   |

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## Checking the Main Battery LED Indication



Press the remaining battery indication button on the main battery to check the remaining battery power.

NOTE: The numeric values in the table below assume that the “Battery Precautions” are being followed. These values are provided for reference purposes only. Actual battery life may vary according to battery usage and storage conditions.

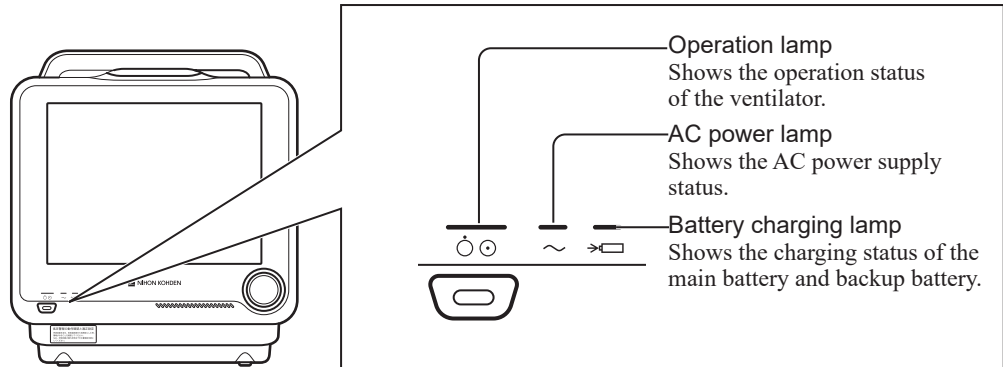
| Remaining battery power <sup>1</sup> |          |          |          |          |         |    |
|--------------------------------------|----------|----------|----------|----------|---------|----|
| 100 - 81%                            | 80 - 61% | 60 - 41% | 40 - 21% | 20 - 11% | 10 - 1% | 0% |
|                                      |          |          |          |          |         |    |





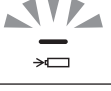
<sup>1</sup> Remaining battery power indicates the amount of charge left in the battery.



# Ventilator Operation Status and Lamp Display

The operating status of the ventilator and the display status of each lamp are as follows.



| Lamp                  | Lamp Display   | Ventilator and Battery Operation Status  |
|-----------------------|--|--|
| Operation lamp        | Lit<br>                                       | The ventilator is operating.   |
|                       | Not lit  | The ventilator is not operating.   |
| AC power lamp         | Lit<br>                                     | AC power is supplied.  |
|                       | Not lit  | AC power is not connected.   |
| Battery charging lamp | Lit<br>                                     | The main battery and backup battery are fully charged.   |
|                       | Slow blinking<br>(once every 2 seconds)<br> | The main battery and backup battery are installed, and one or both batteries are charging.   |
|                       | Fast blinking<br>(5 times per second)<br>   | <ul style="list-style-type: none"> <li>The main battery or backup battery are not inserted.</li> <li>The main battery or backup battery are not operating normally.</li> </ul> |
|                       | Not lit  | Operating on main battery or backup battery.   |

# Installing the Oxygen Sensor

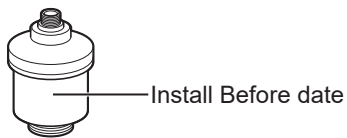
Install the oxygen sensor inside the **oxygen sensor port** on the rear panel of the ventilator.

The following oxygen sensors can be used with the ventilator.

- YS-119P4 galvanic oxygen sensor
- YS-119P5 paramagnetic oxygen sensor

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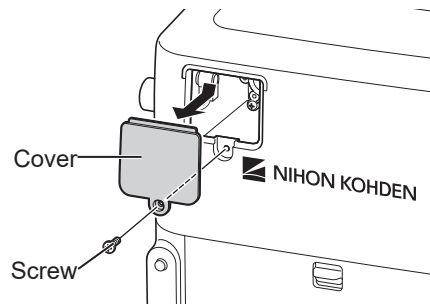
## Galvanic Oxygen Sensor



Install the YS-119P4 galvanic oxygen sensor to the ventilator.

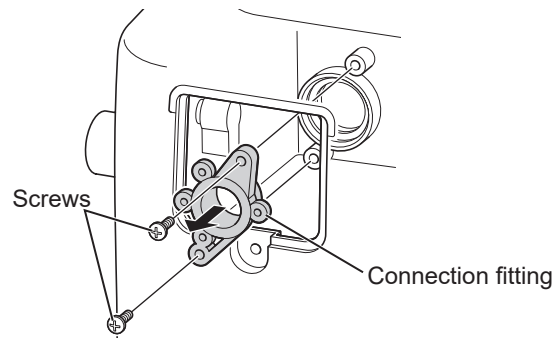
- 1 Check the Install Before date for the galvanic oxygen sensor.
- 2 Remove the **oxygen sensor port** screw on the rear panel of the ventilator, and then remove the cover.

The removed screw will be used again.



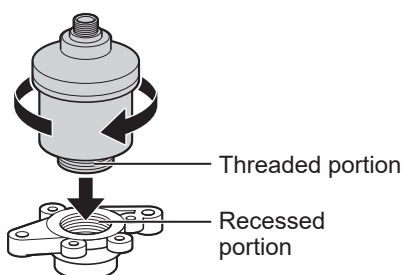
- 3 Remove the 2 screws inside the **oxygen sensor port**, and then remove the connection fitting.

The removed screws will be used again.



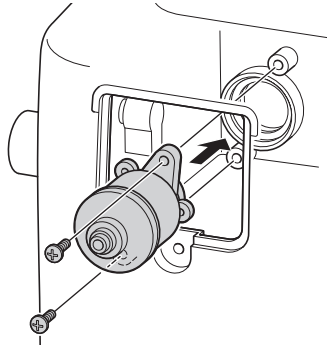
- 4 Insert the threaded portion of the galvanic oxygen sensor into the recessed portion of the connection fitting and turn it clockwise. Tighten it securely until it cannot be turned anymore.

**NOTE:** Gas leakage may occur if the oxygen sensor is not connected securely.

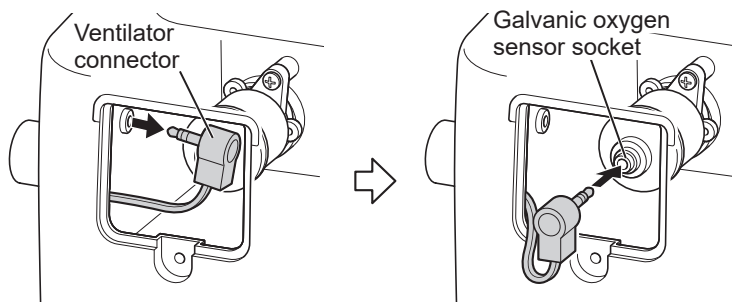




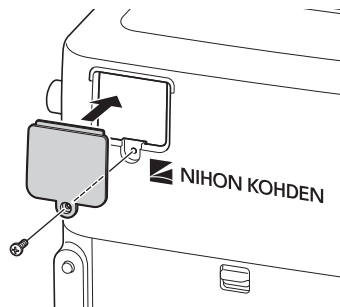
- 5** Use the 2 screws that was removed in Step 3 to attach the connection fitting and galvanic oxygen sensor to the **oxygen sensor port**.



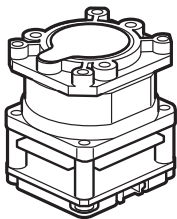
- 6** Remove the black connector located on the left of the **oxygen sensor port** from the ventilator, and connect the black connector to the galvanic oxygen sensor socket.



- 7** Use the screw that was removed in Step 2 to attach the **oxygen sensor port cover**.



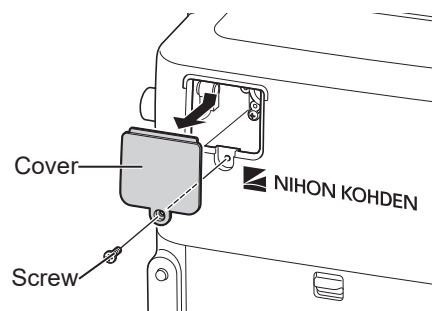
## Paramagnetic Oxygen Sensor



Install the YS-119P5 paramagnetic oxygen sensor to the ventilator.

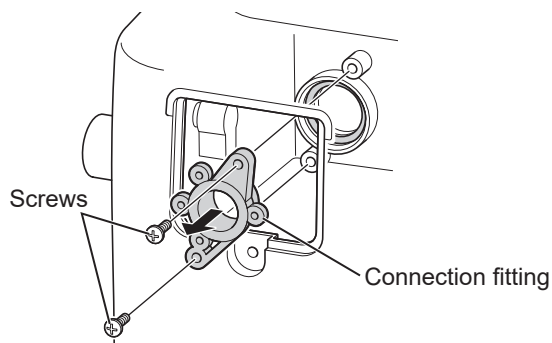
- 1** Remove the **oxygen sensor port** screw on the rear panel of the ventilator, and then remove the cover.

The removed screw will be used again.



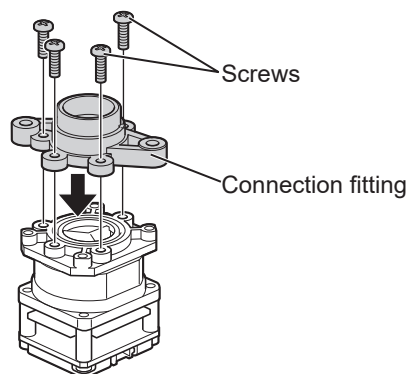
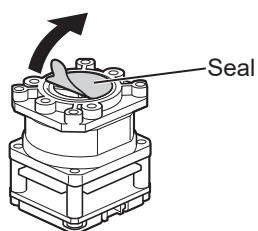
- 2** Remove the 2 screws inside the **oxygen sensor port**, and then remove the connection fitting.

The removed screws will be used again.

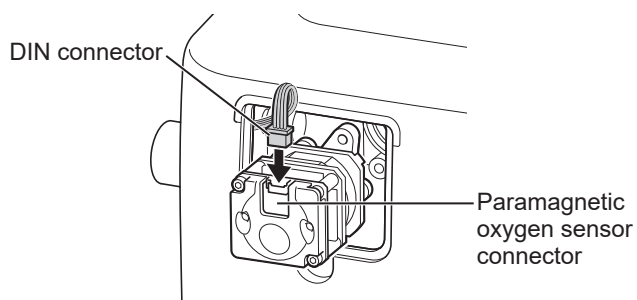


- 3** Attach the connection fitting to the paramagnetic oxygen sensor.

- 1) Remove the seal on the paramagnetic oxygen sensor.
- 2) Use the 4 screws provided with the paramagnetic oxygen sensor to attach the connection fitting that was removed in Step 2.



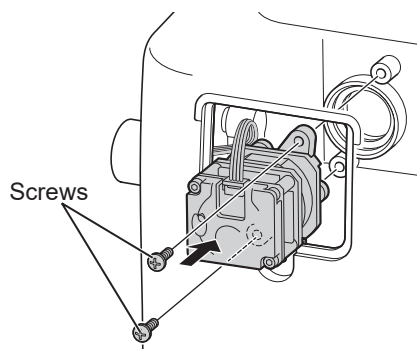
- 4** Connect the white DIN connector in the **oxygen sensor port** to the paramagnetic oxygen sensor connector.



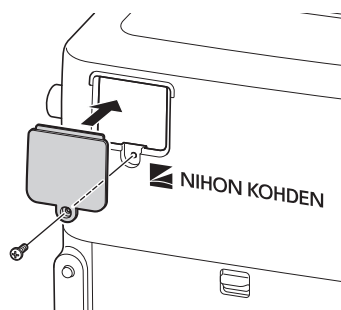


- 5** Use the screws that were removed in Step 2 to attach the paramagnetic oxygen sensor to the **oxygen sensor port**.

NOTE: Gas leakage may occur if the oxygen sensor is not connected securely.



- 6** Use the screw that was removed in Step 1 to mount the **oxygen sensor port** cover.



# Mounting the Ventilator

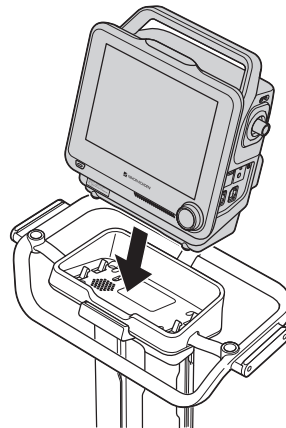
To use the ventilator, mount it to the optional KC-330Z or KC-331Z cart, or to the DH-330Z mount plate. It can also be mounted to a bed rail with the DH-331Z rail hook.

4

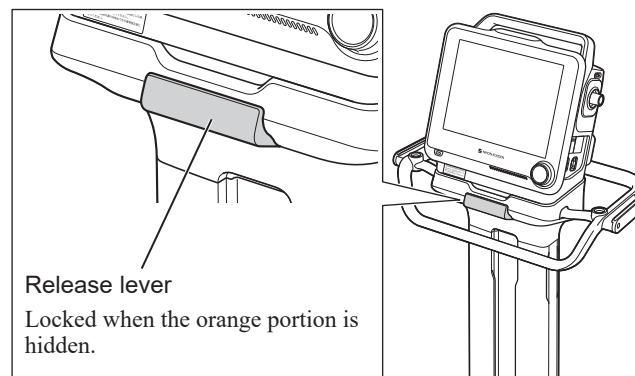
## Mounting the Ventilator on the Cart

NOTE: Before mounting the ventilator on the cart, lock the casters so that the cart does not move.

- 1 Place the ventilator on the top assembly of the cart.



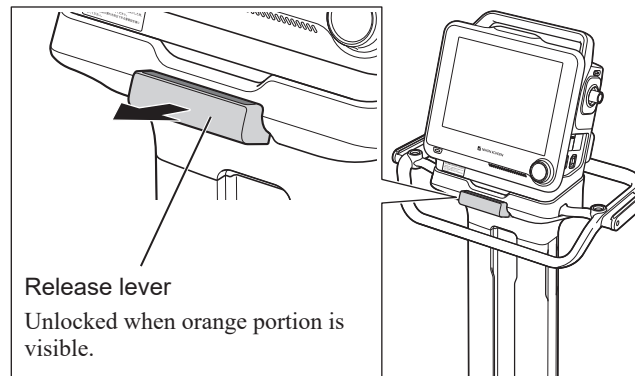
- 2 Check that the release lever is securely locked. A click sound indicates that the lever is locked.



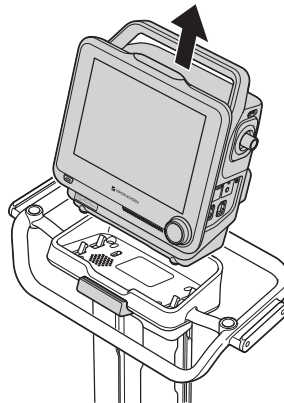


## Removing the Ventilator from the Cart

- 1 Pull the release lever toward you to unlock it.



- 2 Remove the ventilator from the cart.

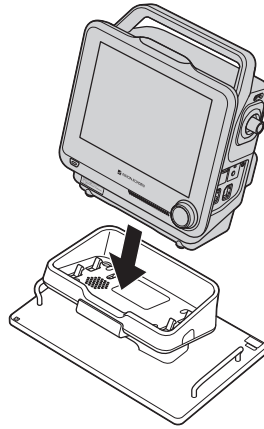




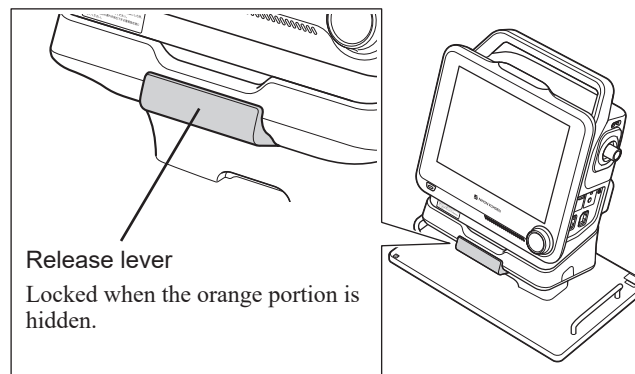
## Mounting the Ventilator on the Mount Plate

Install the optional DH-330Z mount plate to a desk or table, and then mount the ventilator to it.

- 1 Place the ventilator on the top assembly of the mount plate.



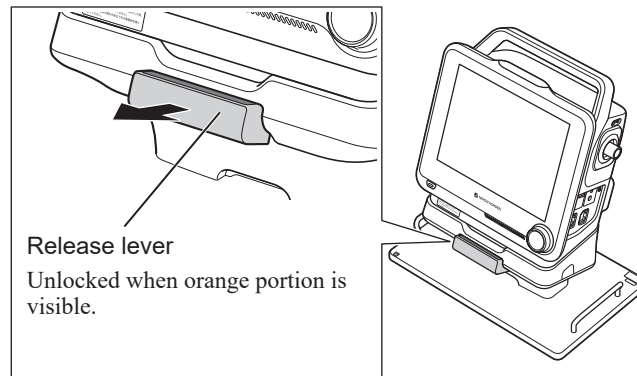
- 2 Check that the release lever is securely locked. A click sound indicates that the lever is locked.



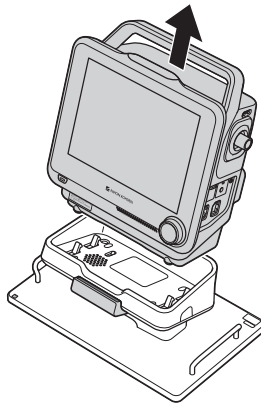


## Removing the Ventilator from the Mount Plate

- 1 Pull the release lever toward you to unlock it.



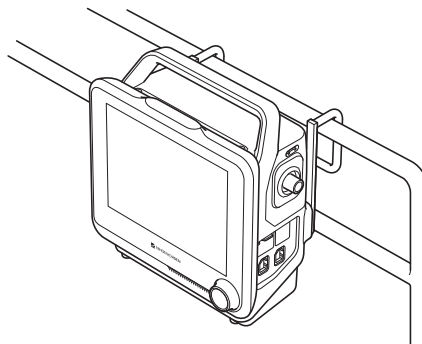
- 2 Remove the ventilator from the mount plate.



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## Attaching the Ventilator to a Bed Rail

If the optional DH-331Z rail hook is attached to the rear panel of the ventilator, the ventilator can be hung on the bed rail during patient transport.

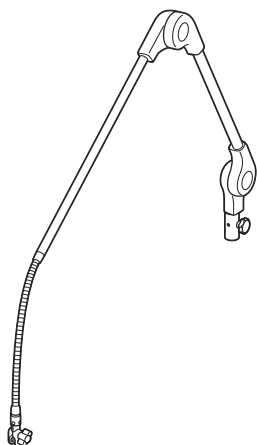


**NOTE:** When mounting the ventilator on a bed rail, lock the screen to prevent accidental operation of the touch panel or control knob.



Refer to “Locking the Screen” (p. 1-17).

## Attaching the Support Arm on the Cart

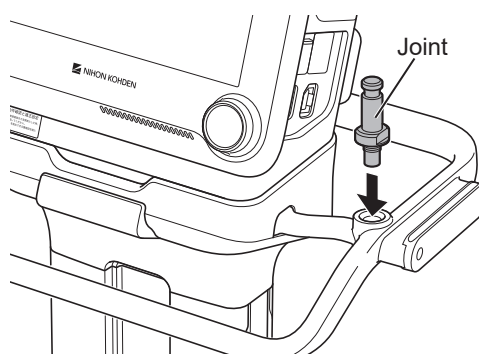


Attach the KH-330Z support arm to one of the holes located on either side of the handle.

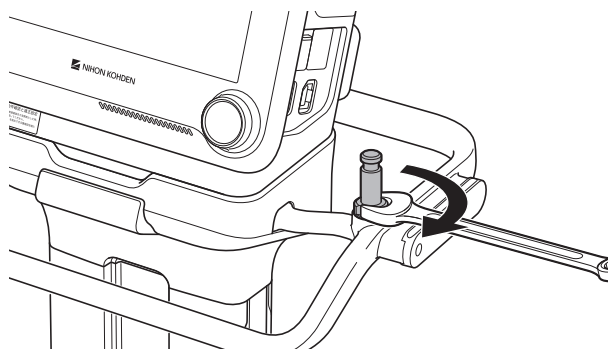
A single limb or dual limb type hose hanger can be attached to the end of the arm.

- NOTE**
- Before mounting the arm to the ventilator, lock the casters on the cart to prevent the cart from moving.
  - When a water bag pole for a heated humidifier is used at the same time, attach the support arm to the position opposite the water bag pole.

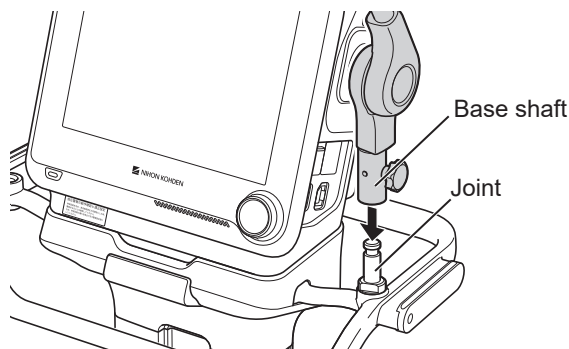
- 1** Insert the joint provided with the support arm into the left or right hole on the cart handle.



- 2** Tighten the joint bolt to fix the joint.

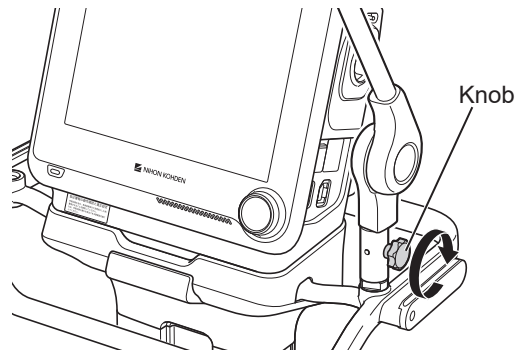


- 3** Insert the support arm base shaft onto the joint.

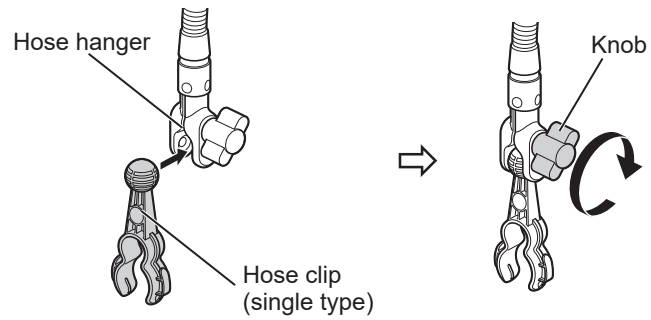




- 4** Tighten the base shaft knob to fix the support arm.



- 5** Attach the hose clip to the hose hanger at the bottom of the support arm.



## Attaching the Heated Humidifier to the Cart

Attach the heated humidifier to the humidifier bracket located on the front of the cart.

Refer to the manual for the heated humidifier for details on preparing the heated humidifier.



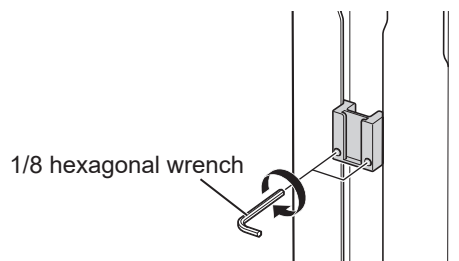
Heated Humidifier Operator's Manual

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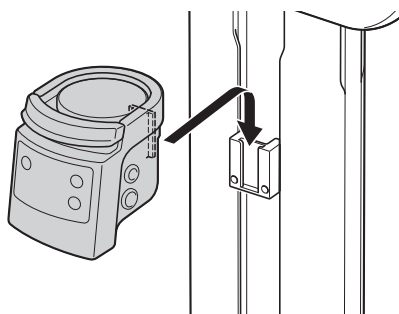
**NOTE:** Before attaching the heated humidifier to the cart, lock the casters on the cart to prevent the cart from moving.

- 1 Loosen the 2 screws on the bottom of the humidifier bracket on the front of the cart, adjust the position of the humidifier bracket, then tighten the 2 screws to fix the position.

**NOTE:** If the position of the bracket is low, it might not be possible to connect the breathing circuit. If the position of the bracket is high, there might be collision with the handle of the cart.



- 2 Attach the heated humidifier to the humidifier bracket.



- 3 Connect the AC power cord for the heated humidifier to a wall AC outlet.



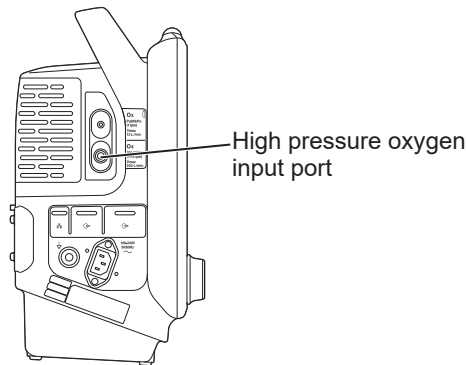
## Connecting the High Pressure Oxygen Hose to the Ventilator

Attach the O<sub>2</sub> hose for connecting to the high pressure oxygen supply to the ventilator.

### ⚠ WARNING

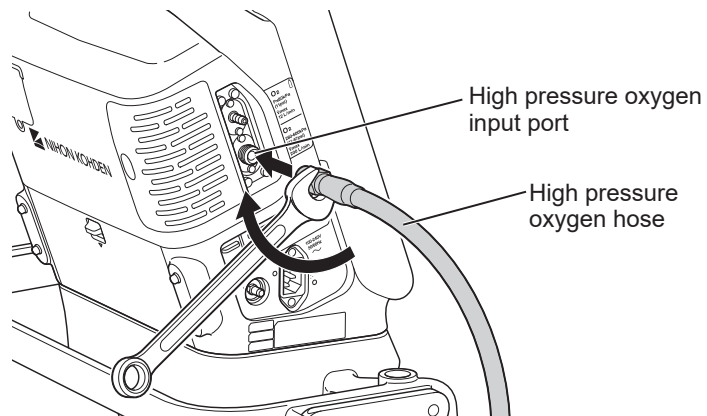
The ventilator can provide a high flow volume of oxygen. Check that the flow rate of the ventilator does not exceed the specified limits of the connected oxygen tube system. This may affect the operation of other devices using the oxygen tube system.

- 1 Connect the O<sub>2</sub> hose to the **high pressure oxygen input port** located on the left side panel of the ventilator.



- 2 Tighten the screw for connecting the O<sub>2</sub> hose and **high pressure oxygen input port**.

**NOTE:** Securely tighten the screw for the O<sub>2</sub> hose. Gas leakage may occur if the O<sub>2</sub> hose connection is loose.



- 3 Connect the O<sub>2</sub> hose to the high pressure oxygen supply.

## Procedures after Turning On the Ventilator

**NOTE:** After turning on the ventilator, set the O<sub>2</sub> Source to [HPO] on the O<sub>2</sub> Source window in “Setup” on the Menu window.



Refer to the “O<sub>2</sub> Source Settings” in Section 12.

# Connecting the Breathing Circuit to the Ventilator

## Selecting the Breathing Circuit

The following breathing circuits can be used with this ventilator.

- VB-310Z single limb breathing set HW-EXH
- VB-311Z single limb breathing set WT-EXH
- VB-312Z single limb breathing set EXH
- VB-313Z single limb breathing set HW
- VA-300Z exhalation port
- VA-301Z breathing circuit filter
- VA-302Z humidification chamber
- TF-300Z flow sensor

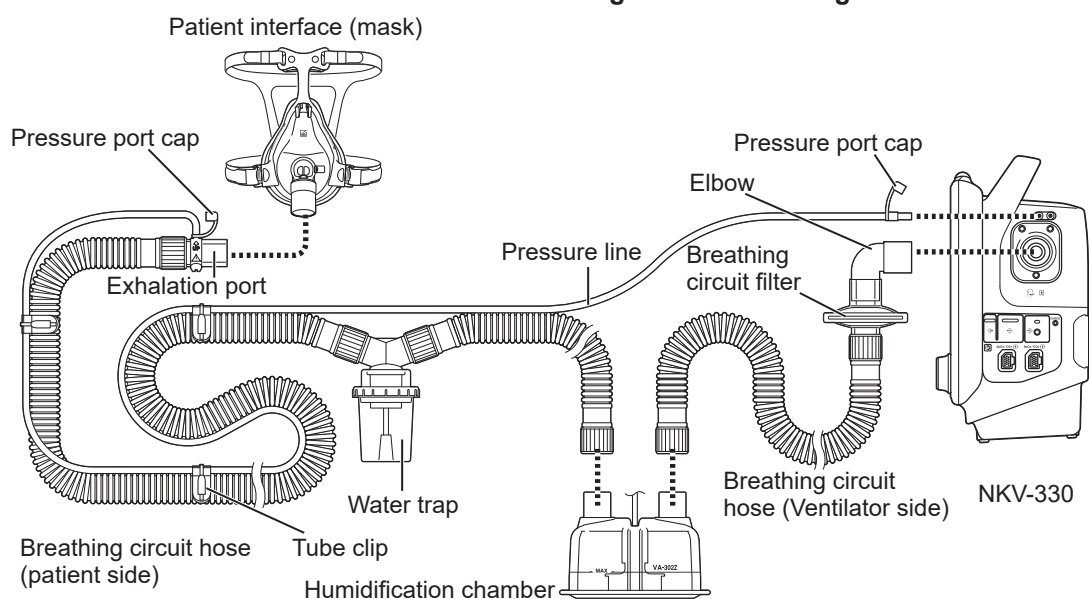
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## Breathing Circuit Connection Example

The following diagram shows an example of circuit connection.

### Ventilation mode (with heated humidifier)

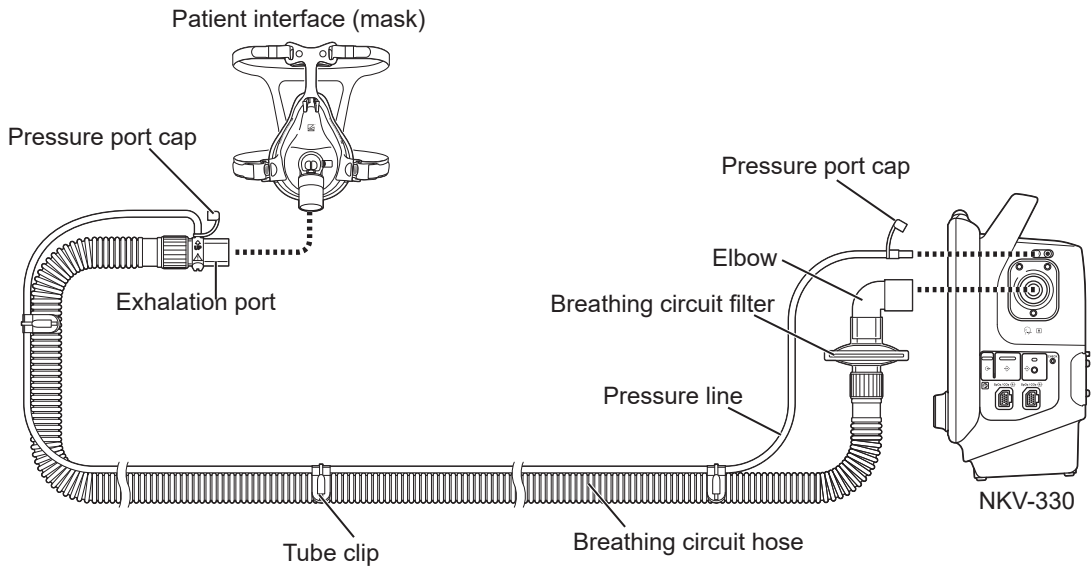
#### VB-311Z WT-EXH Single Limb Breathing Set





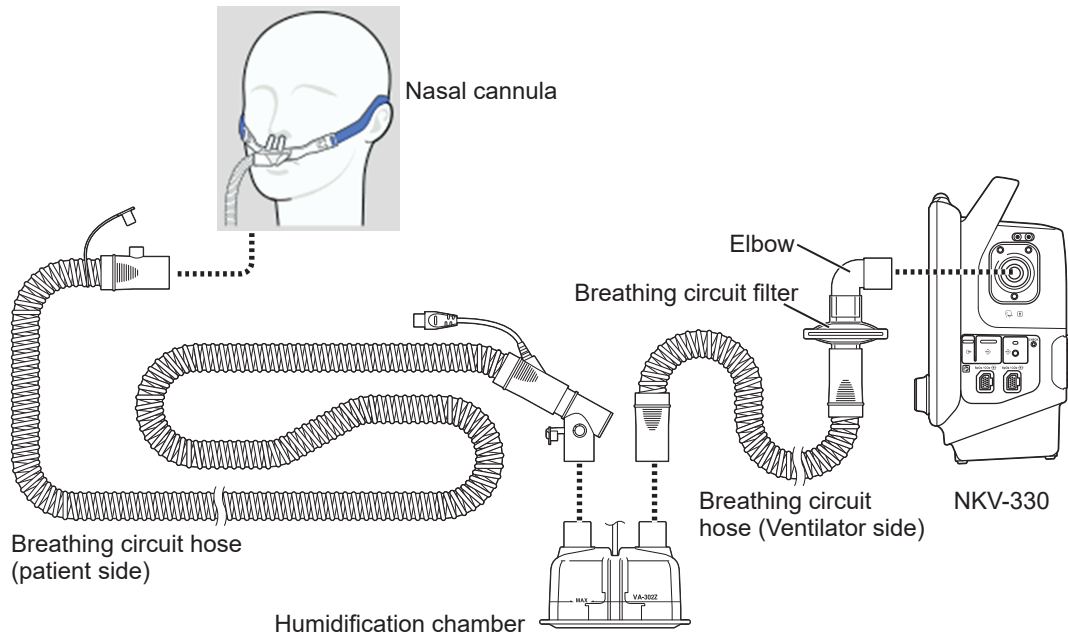
### Ventilation mode (without heated humidifier)

#### VB-312Z single limb breathing set EXH



### O<sub>2</sub> therapy mode

#### VB-313Z single limb breathing set HW

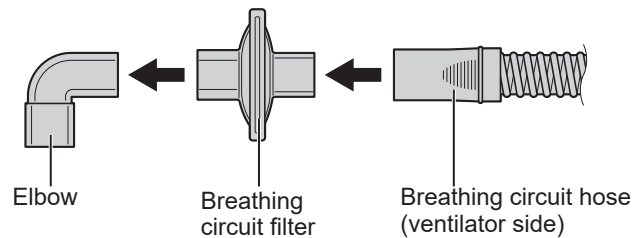


## Assembling the Breathing Circuit

NOTE: Securely connect the hose and connector. Gas leakage may occur if the connection is loose.

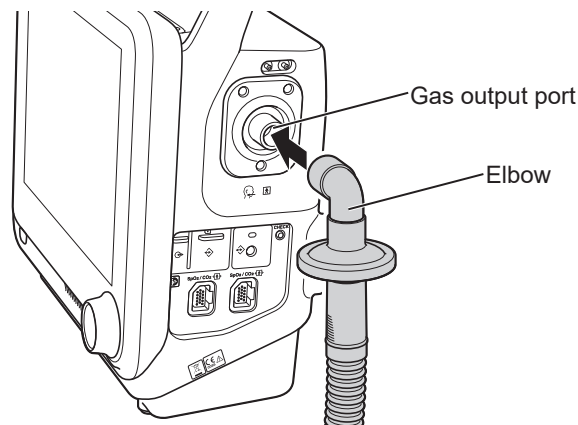
### Connecting the Breathing Circuit Filter

- 1 Connect the breathing circuit filter to the L-shaped elbow connector on the breathing circuit.
- 2 Connect the ventilator side hose for the breathing circuit to the breathing circuit filter.



- 3 Connect the elbow of the breathing circuit to the **gas output port** on the right side panel of the ventilator.

NOTE: Insert the elbow into the port as far as it will go. Gas leakage may occur if the connection is loose.



### Connecting the Humidifier Chamber

- 1 Mount the humidifier chamber to the heated humidifier.



Refer to the Heated Humidifier Operator's Manual.

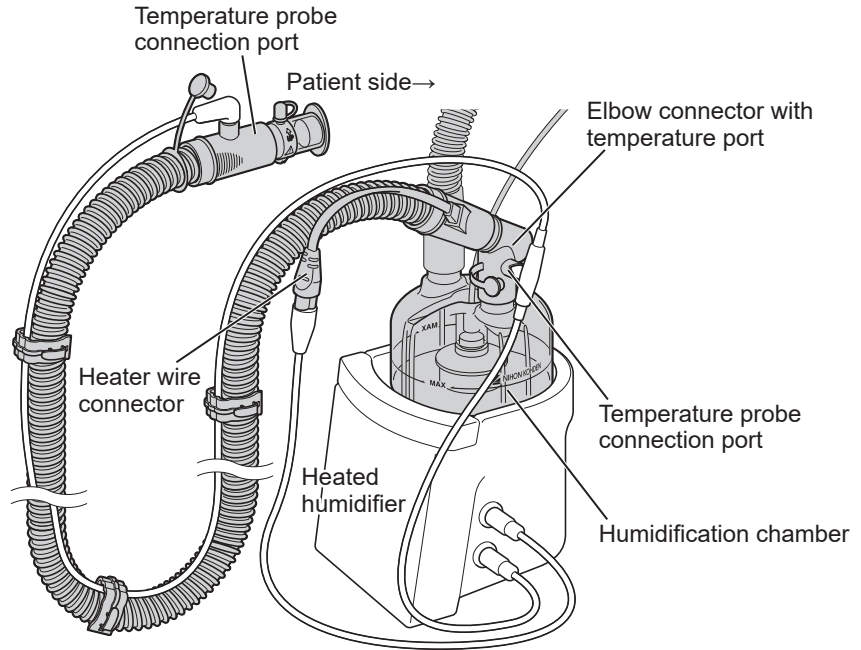
- 2 Connect the ventilator side hose for the breathing circuit to the humidifier chamber.
- 3 Connect the patient side hose for the breathing circuit to the humidifier chamber.

When using a water trap, connect the short end of the patient side hose to the humidifier chamber.

- 4 Fasten the end of the patient side hose to the hose clip on the support arm.



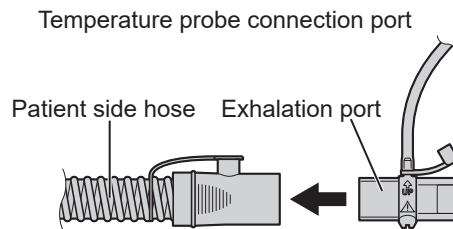
- When the breathing circuit is a heater wire type, connect the humifier's temperature probe and the heater wire connector to the breathing circuit.



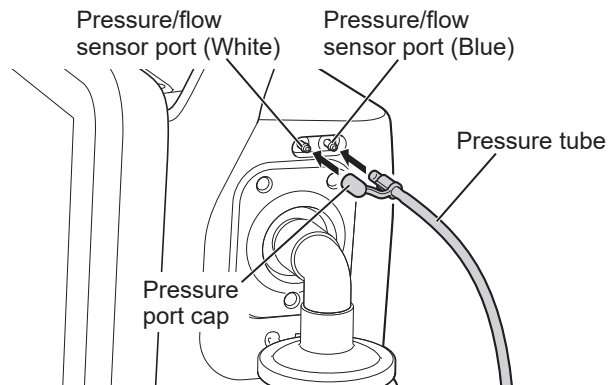
## Connecting the Exhalation Port

- Connect the exhalation port to the end of the patient side hose of the breathing circuit.

NOTE: Connect the temperature probe connection port so that it faces up.



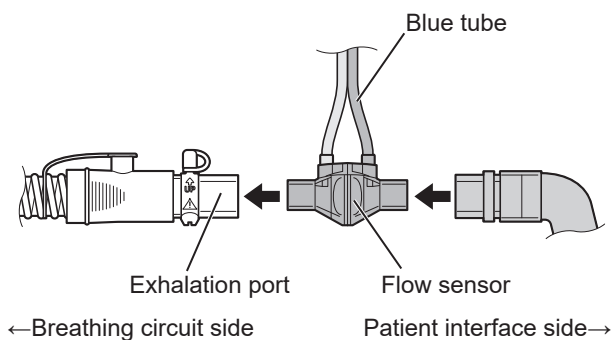
- On the right side panel of the ventilator, connect the end of the pressure tube to the blue port on the **pressure/flow sensor port** and connect the pressure port cap to the white port.



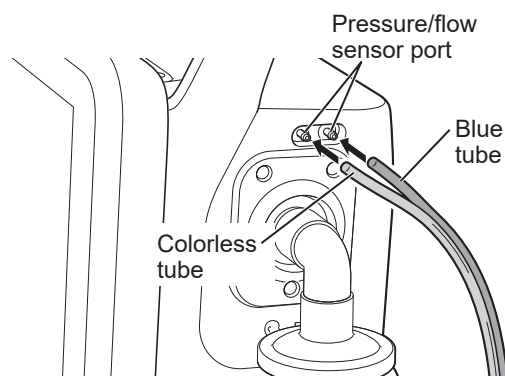
## Connecting the Flow Sensor (Option)

Follow the steps below to connect the flow sensor when using an optional single-use flow sensor.

- 1 Connect the flow sensor to the end of the patient side hose (exhalation port) so that the blue tube of the flow sensor is on the patient interface side.



- 2 Connect the flow sensor tubes by matching their colors to the **pressure/flow sensor port** on the right side panel of the ventilator.





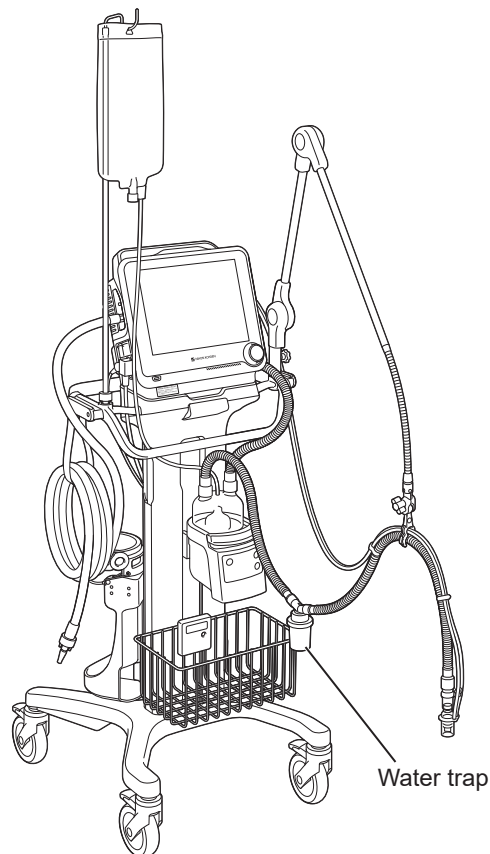
## Arranging the Breathing Circuit

Arrange the breathing circuit after assembling it.

Arrange the breathing circuit hose and flow sensor tubes carefully so that they are not pushed, pulled, or bent due to patient movement, posture change or for any other reason.

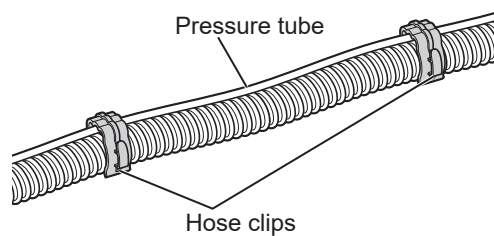
### Water Trap Position

Adjust the position of the water trap so it is at the lowest point in the breathing circuit.



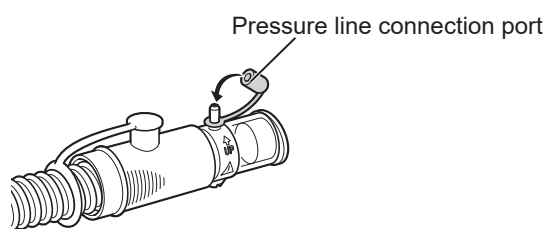
### Fixing the Tube

Fix the pressure tube to the breathing circuit hose using the hose clips that are provided with the breathing circuit set.



### Unused Connection Port

Plug the unused pressure line connection port with the supplied pressure port cap.





## Preparing for Patient Transport

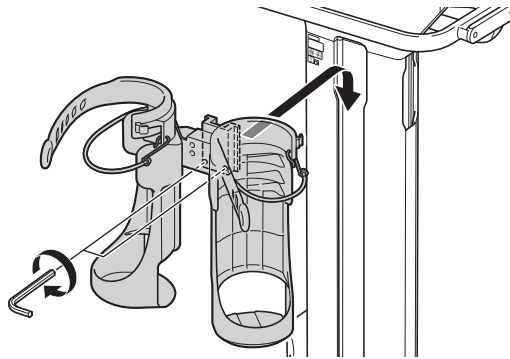
When transporting a patient, the oxygen supply can be changed from high pressure oxygen supply to low pressure oxygen supply (oxygen cylinder).

### Mounting the Oxygen Cylinders on the Cart

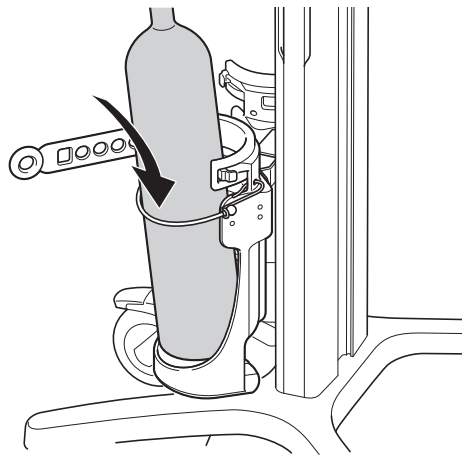
Mount the oxygen cylinder to the cylinder mount that was installed on the back of the cart.

NOTE: Before mounting the oxygen cylinder to the cart, lock the casters to ensure the cart does not move.

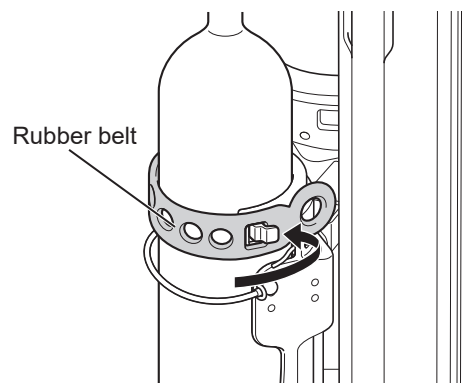
- 1 Insert the cylinder mount into the cart and tighten the 2 screws firmly.



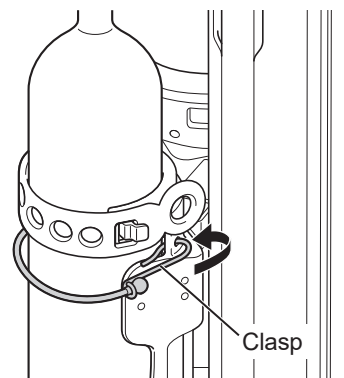
- 2 Place the oxygen cylinder on the cylinder mount.



- 3 Secure the oxygen cylinder with the rubber belt. Adjust the position of the rubber belt to prevent the cylinder falling out.

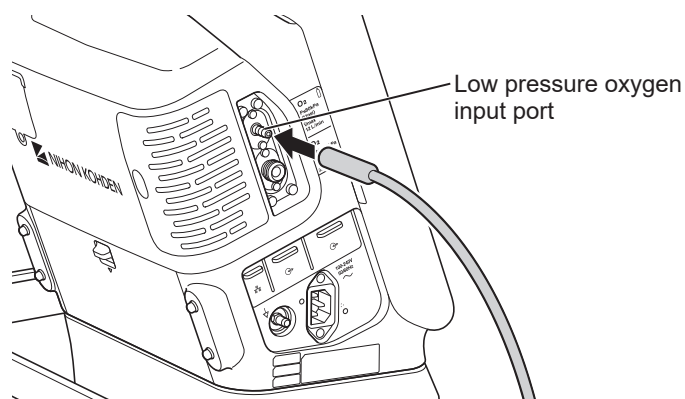


- 4** If the clasp with the black strap is not attached, hook the clasp into the hole in the cylinder mount.



- 5** Connect the oxygen cylinder and the **low pressure oxygen input port** on the left side of the ventilator using the oxygen tube.

**NOTE:** Insert the oxygen tube as far into the low pressure oxygen input port as possible. Gas leakage may occur if the connection is loose.



- 6** Adjust the flow of oxygen using the flow regulator on the oxygen cylinder.

**NOTE:** The maximum low pressure oxygen supply flow is 12 L/min. Do not connect a low pressure oxygen supply that exceeds 12 L/min.

## Procedures after Turning On the Ventilator

**NOTE:** After turning on the ventilator, set the O<sub>2</sub> Source to [LPO] on the O<sub>2</sub> Source window in "Setup" on the Menu window.



Refer to "O<sub>2</sub> Source Settings" in Section 12.

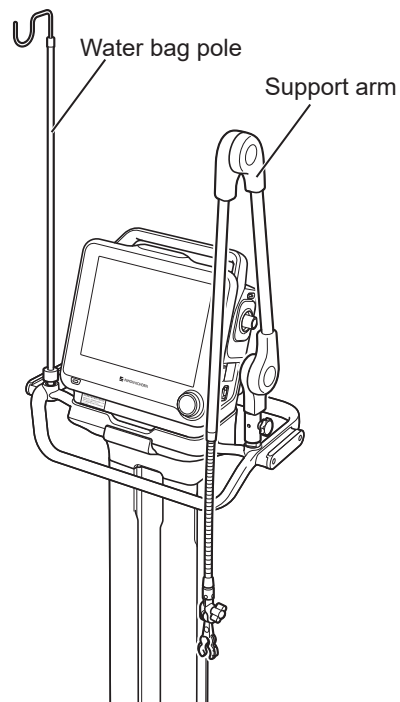


## Transporting the Ventilator on a Cart

- NOTE
- When transporting the ventilator on a cart, fold the support arm as shown below. Do not attach the water bag pole for the heated humidifier on the same side of the cart as the support arm. It may cause the cart to tip over.
  - When transporting the ventilator on a cart, lock the screen to prevent accidental operation of the touch panel or control knob.



Refer to “Locking the Screen” (p. 1-17).





# 5

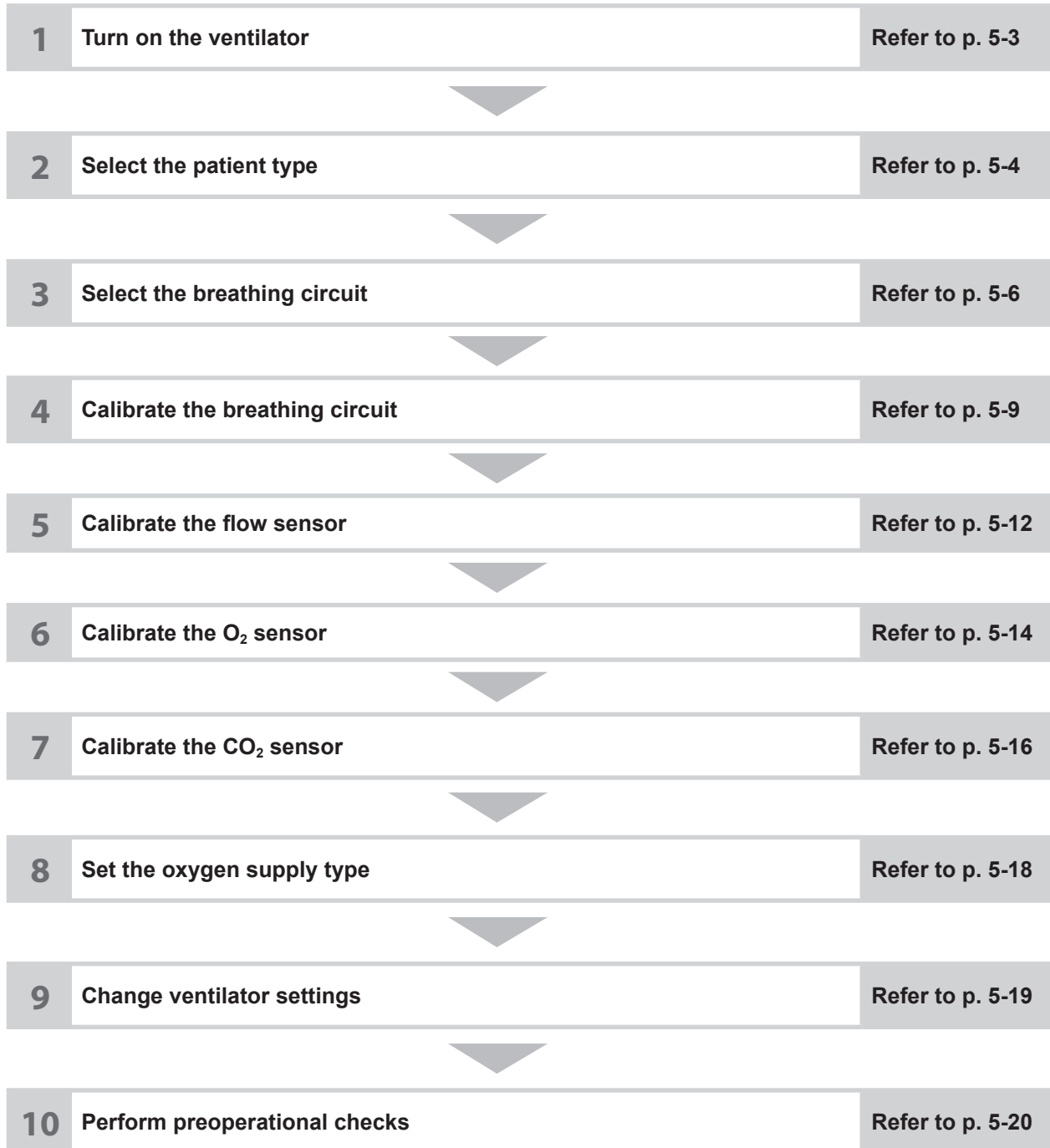
## Preparation for Ventilation, Calibration and Preoperational Check

|  |      |
|--|------|
| Flow of Preparation for Ventilation, Calibration and Preoperational Check..... | 5-2  |
| Turning On the Ventilator.....   | 5-3  |
| Selecting the Patient Type.....  | 5-4  |
| Selecting the Breathing Circuit.....   | 5-6  |
| Displaying the Circuit Check & Calibrations Window.....                        | 5-8  |
| Calibrating the Breathing Circuit.....   | 5-9  |
| Calibrating the Flow Sensor.....   | 5-12 |
| Calibrating the O <sub>2</sub> Sensor.....                                     | 5-14 |
| Calibrating the CO <sub>2</sub> Sensor (Zero Calibration).....                 | 5-16 |
| Setting the Oxygen Supply Type.....  | 5-18 |
| Changing Ventilator Settings.....  | 5-19 |
| Performing Preoperational Checks.....  | 5-20 |
| Preoperational Checks.....   | 5-20 |



# Flow of Preparation for Ventilation, Calibration and Preoperational Check

Perform the preparation for ventilation, calibration and preoperational check as follows.



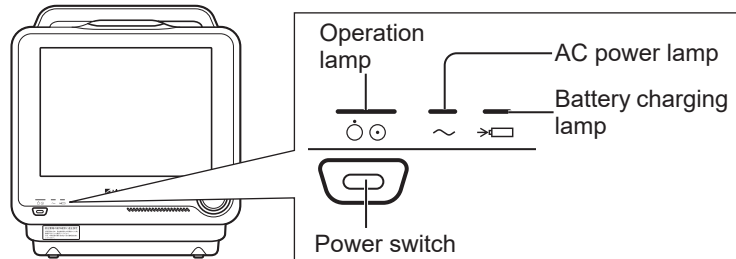
# Turning On the Ventilator

NOTE: Check the following when the ventilator starts.

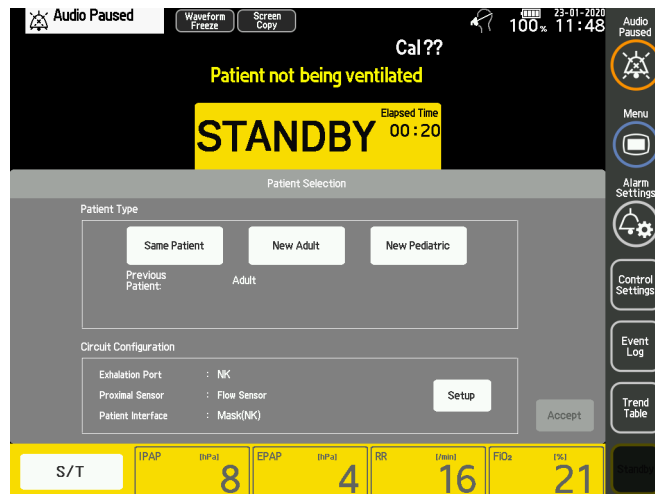
- There is no fire, smoke or unusual odor.
- The red, yellow, blue and green alarm indicators light.
- There are no error messages on the screen.

- 1 Press the **power switch** on the front panel of the ventilator to turn it on. There is a buzzing sound and the operation lamp lights.

The AC power lamp also turns on when connected to AC power.



- 2 After the start-up screen appears, confirm that the following Patient Selection window appears.



- 3 Select the patient type.



Refer to “Selecting the Patient Type” (p. 5-4).

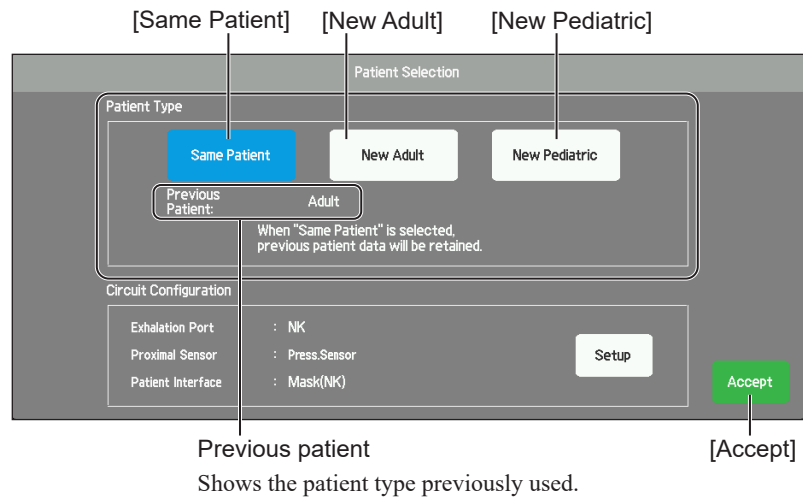


## Selecting the Patient Type

Select the patient type (adult or pediatric) for ventilation with this ventilator. The control and alarm and other settings all have initial values for each patient type. When you change the patient type, the settings change to the initial values for the selected patient type.

Or, you can continue to use your previous settings.

- 1 Select [Same Patient], [New Adult] or [New Pediatric] on the Patient Selection window.



### When selecting [New Adult] or [New Pediatric]:

A “When ‘xxx’ is selected, previous patient data will be deleted.” message is displayed.

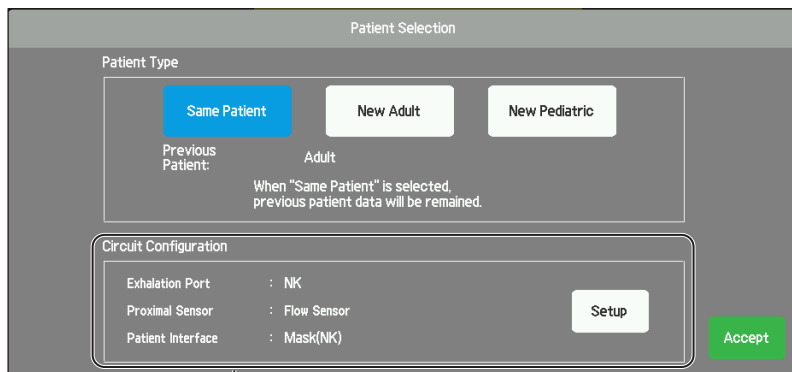
The data of the previous patient that is saved in the ventilator is deleted and each setting of the ventilator is initialized. The following data and settings are deleted or initialized.

- Review data (trend, trend table, event log, full disclosure waveform)
- Ventilation mode (initialized to the master values)
- Control settings (initialized to the master values)
- Alarm settings (initialized to the master values)
- Display settings (initialized to the master values)
- Height
- Gender

### When [Same Patient] is selected:

A “When ‘Same Patient’ is selected, previous patient data will be retained.” message is displayed.

- 2 Make sure that the exhalation port, proximal sensor, and patient interface used for “Circuit Configuration” are displayed.



Circuit configuration settings

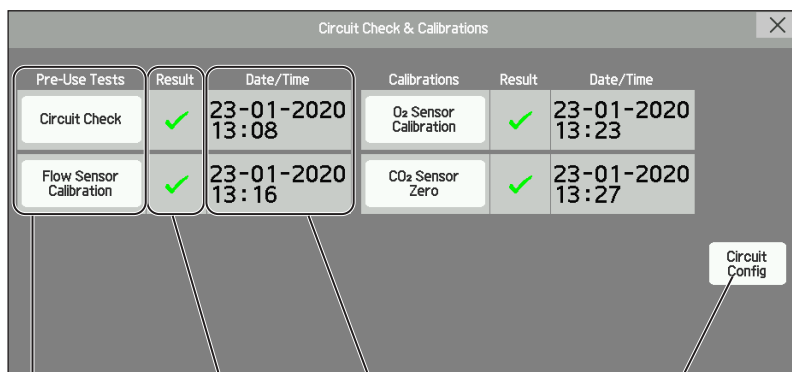
Select [Setup] to change the patient circuit settings. Refer to “Selecting the Breathing Circuit” for setting the patient circuit.



Refer to “Selecting the Breathing Circuit” (p. 5-6).

- 3 Select [Accept].

The last calibration result and calibration date are displayed on the Circuit Check & Calibrations window.



|                             |                               |   |   |
|-----------------------------|-------------------------------|---|---|
| Pre-Use Tests               | Result                        | Date/Time                                   | [Circuit Config]                        |
| Shows the calibration type. | Shows the calibration result. | Shows the date and time of the calibration. | Shows the Circuit Configuration window. |

### Meaning of result icons

- : Calibration was successful.
- : Calibration failed, or calibration was not performed.



# Selecting the Breathing Circuit

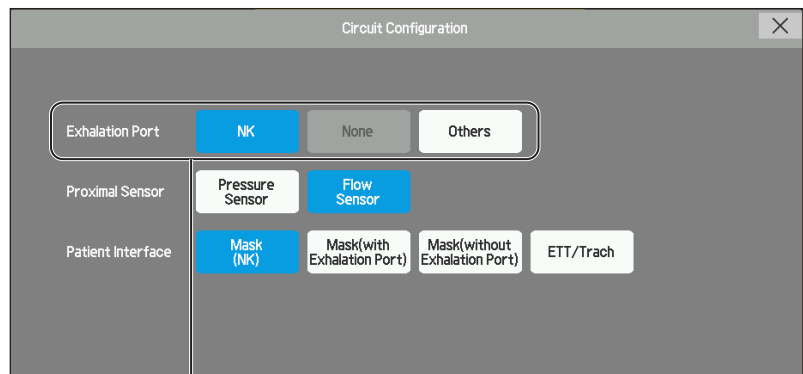
Set the breathing circuit to use.

- 1 Select [Setup] on the Patient Selection window to display the Circuit Configuration window.

You can also display the patient circuit settings screen by the following methods.

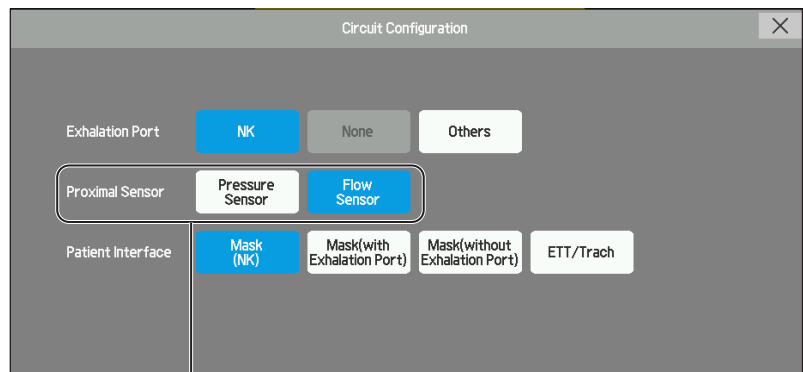
- Select [Circuit Config] on the Menu window.
- Select [Circuit Config] on the Circuit Check & Calibrations window.

- 2 Set the exhalation port to use.



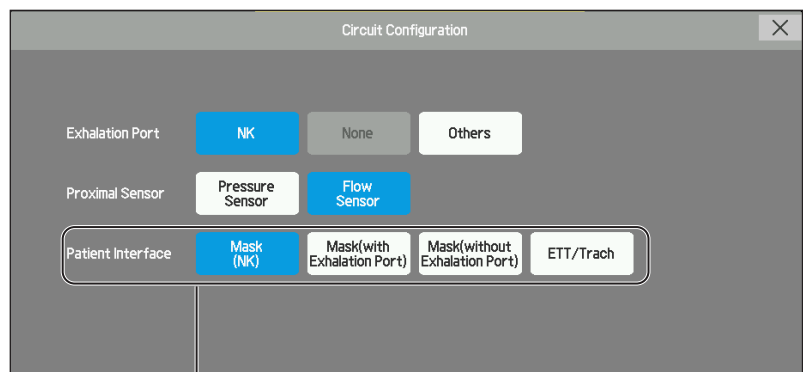
The selected item is displayed in light blue.

- 3 Set the proximal sensor to use.



The selected item is displayed in light blue.

- 4 Set the patient interface to use.



The selected item is displayed in light blue.



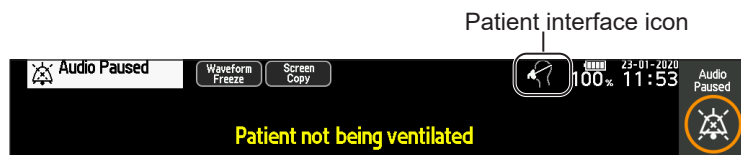
[ETT/Trach] is only displayed when [ETT/Trach] is set to [On] on the [Vent] window in the System Configuration window.

Refer to the following.

Administrator's Guide:

Section 2 "System Configuration Settings"

The patient interface icon at the upper right of the main screen changes according to the patient interface setting.



| Patient Interface              | Icon | Remarks  |
|--------------------------------|------|--|
| Mask (NK)                      |      | —  |
| Mask (without Exhalation Port) |      |  |
| Mask (with Exhalation Port)    |      |  |
| ETT/Trach <sup>1</sup>         |      |  |
|                                |      | Displayed only when the ventilation mode is "O <sub>2</sub> Therapy". <sup>2</sup> |

<sup>1</sup> The "ETT/Trach" icon is only displayed when "ETT/Trach" is set to [On] on the [Vent] window in the System Configuration window.

<sup>2</sup> The "O<sub>2</sub> Therapy" icon is only displayed when "O<sub>2</sub> Therapy" is set to [On] in the Ventilation Mode settings on the System Configuration ► [Vent] window.

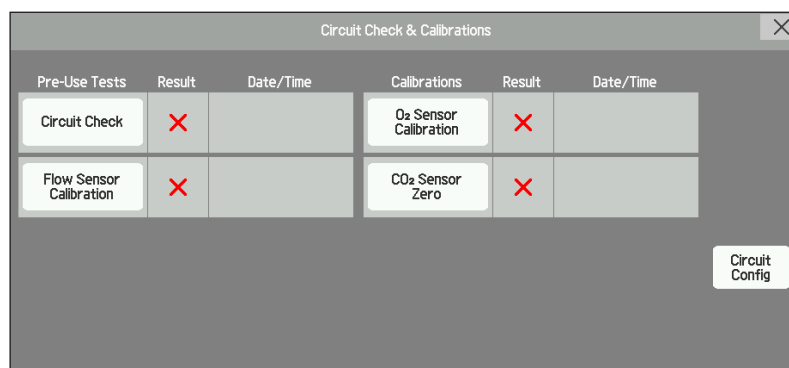


Refer to the following.

Administrator's Guide:

Section 2 "System Configuration Settings"

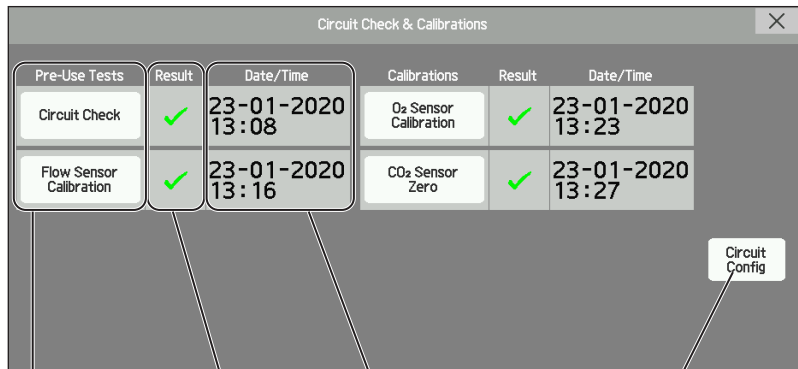
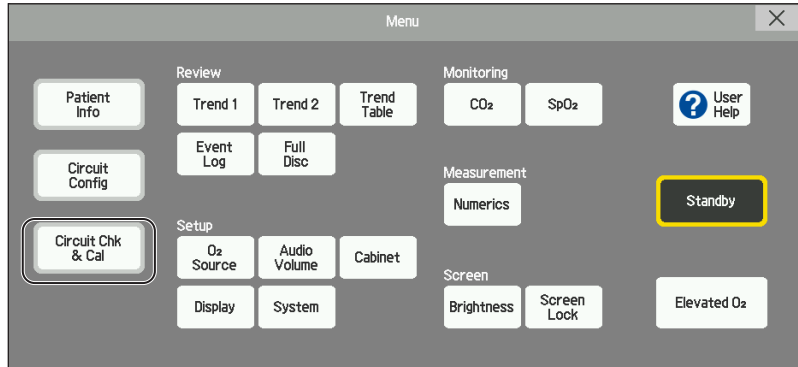
- 5 Select [×] to display the Circuit Check & Calibrations window. When the patient circuit settings are changed, it may be necessary to do the circuit check and recalibrate the flow sensor.





# Displaying the Circuit Check & Calibrations Window

- 1 Select the [Menu] operation key to display the [Menu] window.
- 2 Select [Circuit Chk & Cal] to display the Circuit Check & Calibrations window.



**Pre-Use Tests**  
Shows the calibration type.

**Result**  
Shows the calibration result.

**Date/Time**  
Shows the date and time for the calibration.

**[Circuit Config]**  
Shows the Circuit Configuration window.

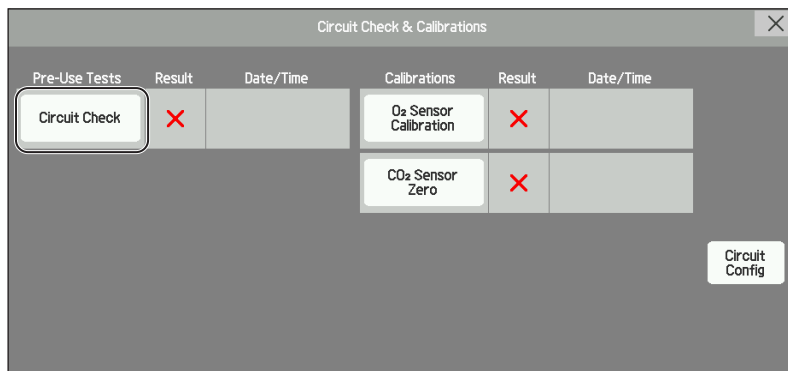


# Calibrating the Breathing Circuit

Calibrate the breathing circuit resistance and the amount of leak from the exhalation port.

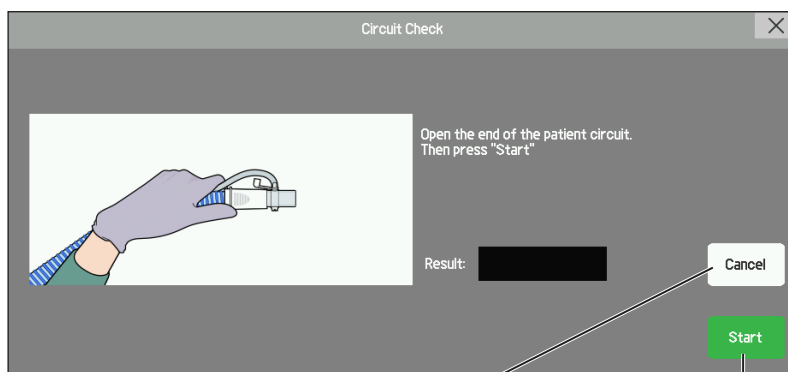
NOTE: When calibrating the breathing circuit, set the ventilator to ventilation standby mode. If calibration is performed while ventilation is in progress, an error message appears.

- 1 Select [Circuit Check] on the Circuit Check & Calibrations window.



5

- 2 Open the patient side of the breathing circuit and select [Start] on the Circuit Check window.



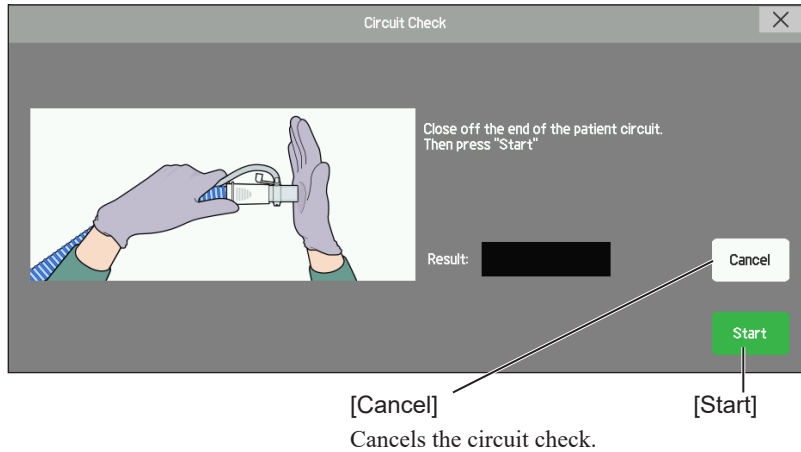
[Cancel]  
 Cancels the circuit check.

[Start]

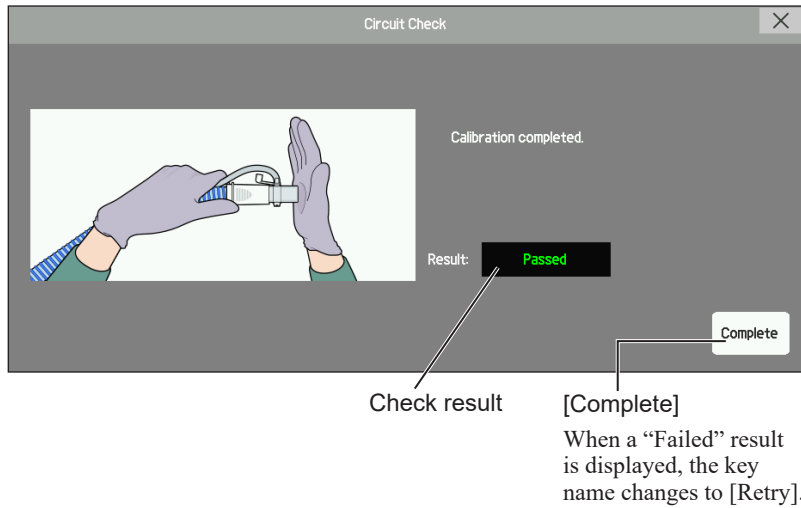


**3** Use the hose cap or the palm of your hand to block the patient side of the breathing circuit then select [Start].

 Nihon Kohden recommends that wearing sterilized gloves.




The circuit check is completed and the result is displayed.



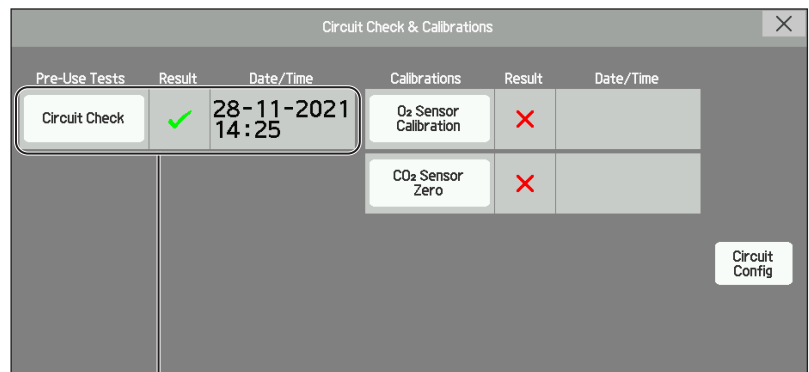
If no error: "Passed" is displayed on the window. Proceed to Step 4.

If error: If there is a blockage or large leak in the circuit, a "Failed" error message is displayed on the window.

 Refer to "Breathing circuit calibration failure" in Section 13 "Troubleshooting" (p. 13-25).



#### 4 Select [Complete] to close the Circuit Check window.

The result and the calibration date and time are displayed beside [Circuit Check] on the Circuit Check & Calibrations window.



Result and date and time of circuit check

#### Check result

- : Calibration was successful.
- : Calibration failed. Check the connection of the breathing circuit and do the circuit check again.

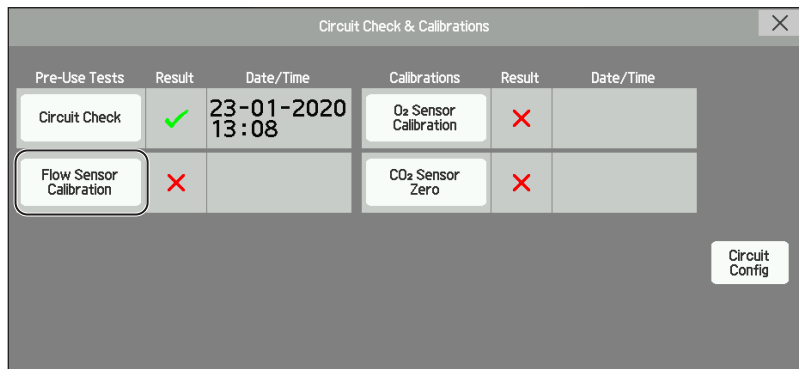


# Calibrating the Flow Sensor

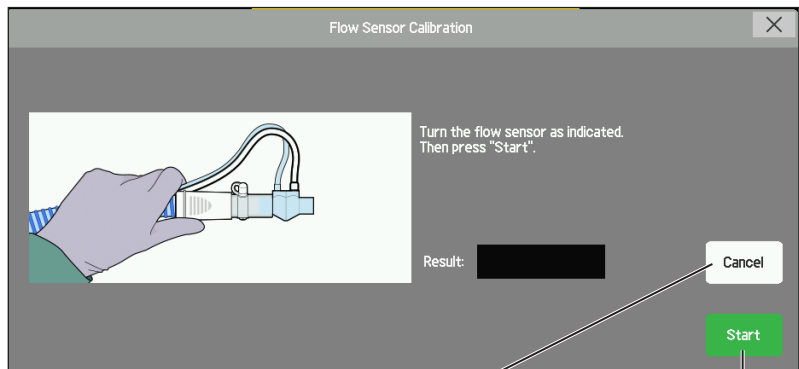
Calibrate the flow sensor if it is being used.

- NOTE
- Put the ventilator in standby mode before calibrating the flow sensor. If the calibration is done during ventilation operation, an error message appears.
  - Before calibrating the flow sensor, be sure to do the circuit check. If circuit check is not done, an error message appears when the flow sensor is calibrated.

1 Select [Flow Sensor Calibration] on the Circuit Check & Calibrations window.



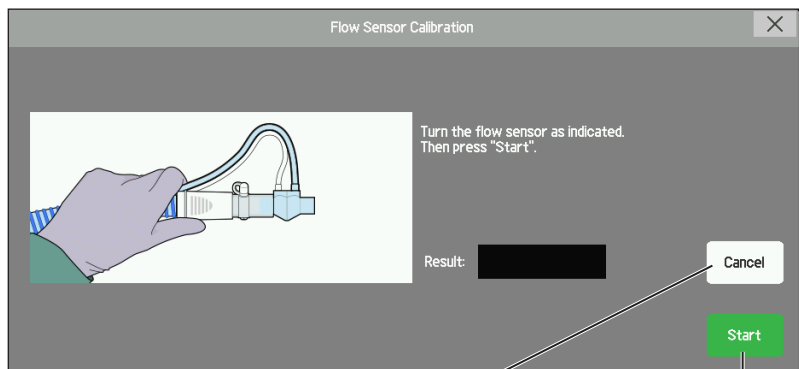
2 Orient the flow sensor as shown in the figure below and select [Start] on the Flow Sensor Calibration window.



[Cancel]  
Cancels the calibration.

[Start]

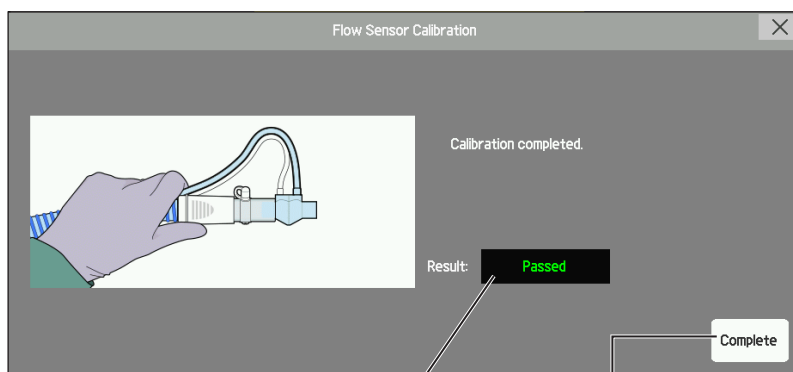
3 Orient the flow sensor as shown in the figure below and select [Start] on the Flow Sensor Calibration window.



[Cancel]  
Cancels the calibration.

[Start]

When flow sensor calibration is complete, the results are displayed.




Check result

[Complete]

When a “Failed” result is displayed, the key name changes to [Retry].

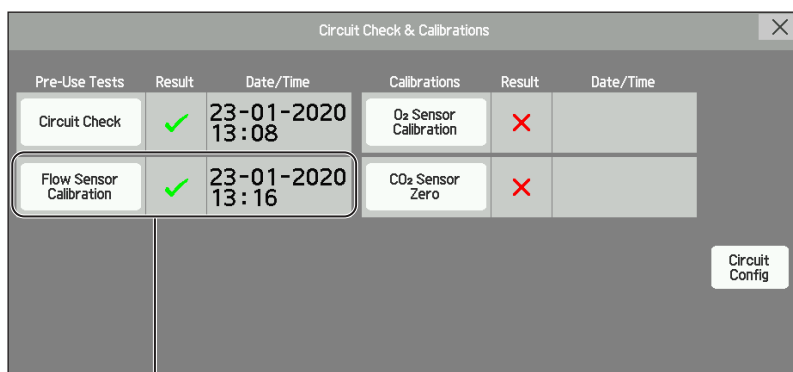
When calibration succeeds: “Passed” appears on the screen. Proceed to Step 4.

When calibration fails: The error message “Failed” appears on the window.

 Refer to “Flow sensor calibration failure” in Section 13 “Troubleshooting” (p. 13-25).



#### 4 Select [Complete] to close the Flow Sensor Calibration window.

The result and the calibration date and time are displayed beside [Flow Sensor Calibration] on the Circuit Check & Calibrations window.



Result and date and time of flow sensor calibration

#### Check result

- : Calibration was successful.
- : Calibration failed. Check the flow sensor connection and check again.



# Calibrating the O<sub>2</sub> Sensor

Calibrate the oxygen sensor.

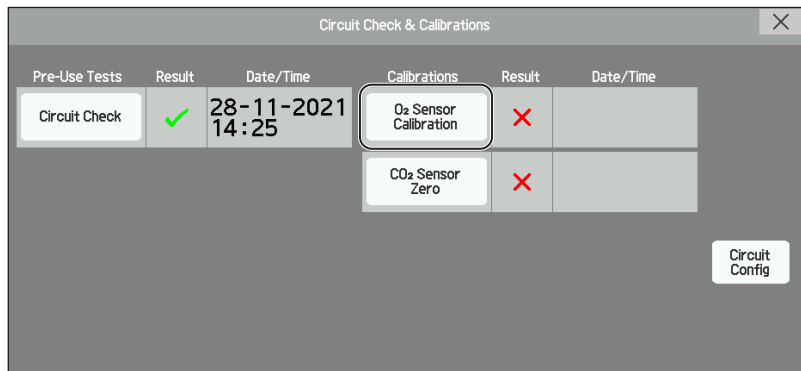
**NOTE** • The O<sub>2</sub> sensor can only be calibrated when [Setup] ► [O<sub>2</sub> Source] on the Menu window is set to [HPO] and the ventilator is connected to a high pressure oxygen supply.

 Refer to “Setting the Oxygen Supply Type” (p. 5-18).

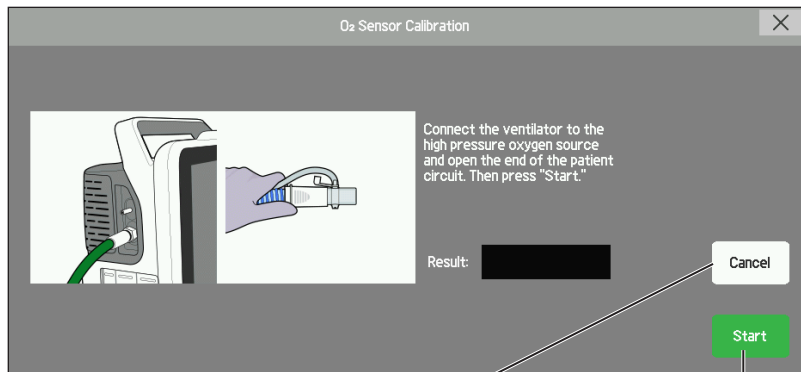
- To perform O<sub>2</sub> calibration, set the ventilator to ventilation standby. If calibration is performed during ventilation operation, an error message appears.

 Refer to “Ventilation Standby” in Section 7.

**1** Select [O<sub>2</sub> Sensor Calibration] on the Circuit Check & Calibrations window.



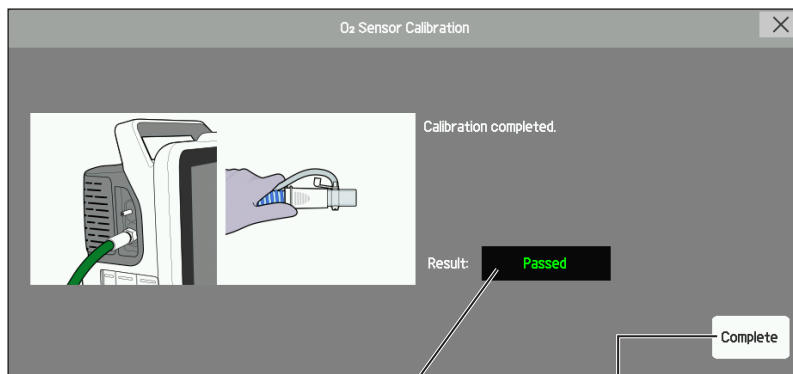
**2** Select [Start] on the O<sub>2</sub> Sensor Calibration window.



[Cancel]  
Cancels the calibration.

[Start]

When calibration is complete, the results are displayed.



Check result

[Complete]

When a "Failed" result is displayed, the key name changes to [Retry].

5

When calibration succeeds: "Passed" appears on the screen. Proceed to Step 3.

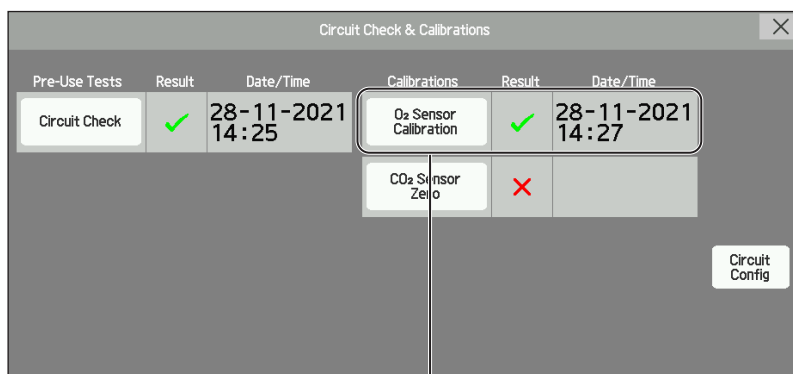
When calibration fails: The error message "Failed" appears on the window.



Refer to "O<sub>2</sub> sensor calibration failure" in Section 13 "Troubleshooting" (p. 13-25).

### 3 Select [Complete] to close the O<sub>2</sub> Sensor Calibration window.

The result and the calibration date and time are displayed beside [O<sub>2</sub> Sensor Calibration] on the Circuit Check & Calibrations window.



Result and date and time of O<sub>2</sub> sensor calibration

#### Check result

- : Calibration was successful.
- : Calibration failed. Check the O<sub>2</sub> sensor connection and check again.



# Calibrating the CO<sub>2</sub> Sensor (Zero Calibration)

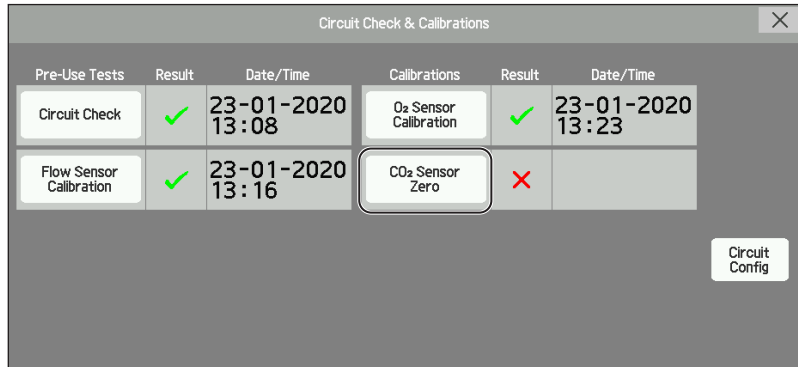
Do zero calibration of the CO<sub>2</sub> sensor before monitoring CO<sub>2</sub>.

For details on air calibration, refer to “CO<sub>2</sub> Monitoring” in Section 10.

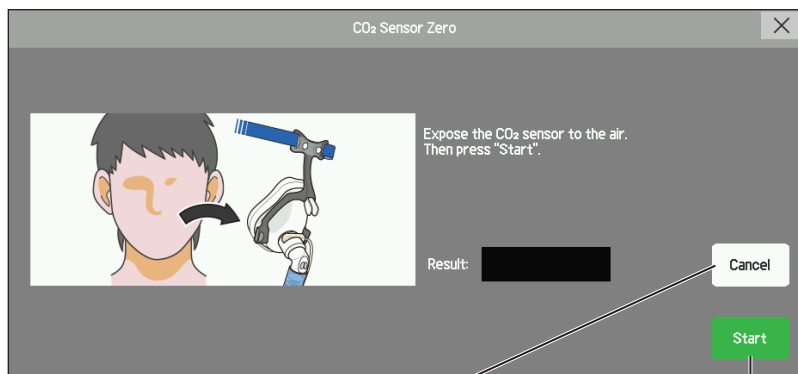
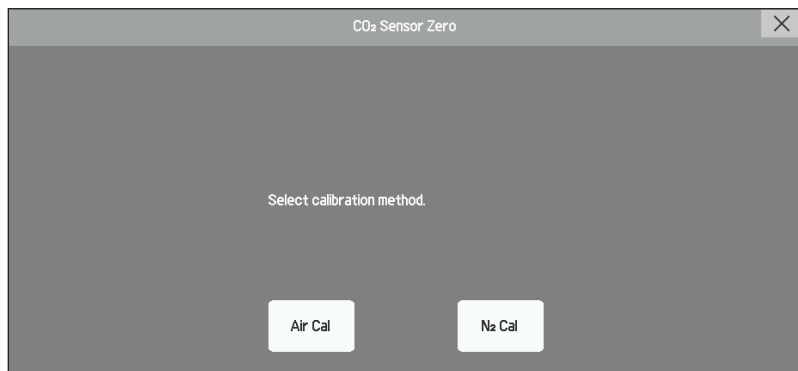


Refer to “CO<sub>2</sub> Monitoring” in Section 10.

- 1 Connect the CO<sub>2</sub> sensor to the **MULTI socket** on the right side panel of the ventilator.
- 2 Select [CO<sub>2</sub> Sensor Zero] on the Circuit Check & Calibrations window.



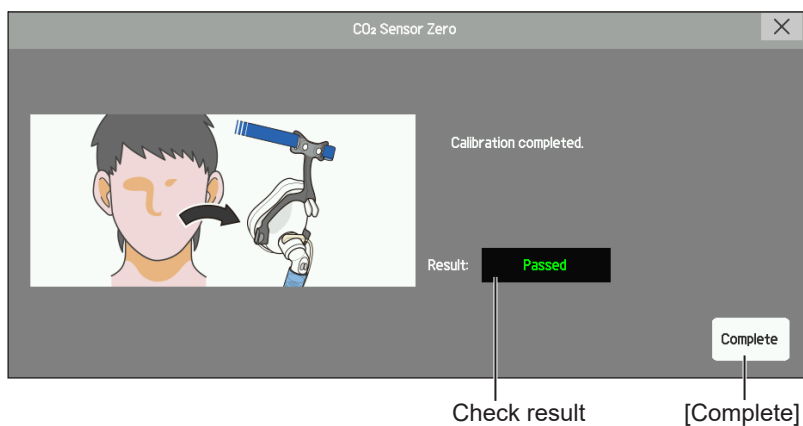
- 3 Insert the CO<sub>2</sub> sensor into the NPPV cap-ONE mask and expose the CO<sub>2</sub> sensor to the air.
- 4 On the CO<sub>2</sub> Sensor Zero window, select [Air Cal] or [N<sub>2</sub> Cal] then select [Start].



[Cancel]  
Cancels the calibration.

[Start]

When calibration is complete, the results are displayed.

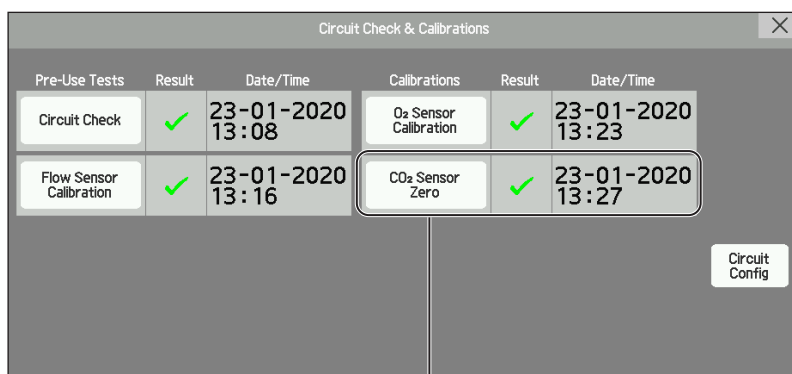


When calibration succeeds: “Passed” appears on the screen. Proceed to Step 5.

When calibration fails: The error message “Failed” appears on the screen. Check that the CO<sub>2</sub> sensor is connected and do [Air Cal] or [N<sub>2</sub> Cal] again.

**5** Select [Complete] to close the CO<sub>2</sub> Sensor Zero window.

The result and the calibration date and time are displayed beside [CO<sub>2</sub> Sensor Zero] on the Circuit Check & Calibrations window.



Result and date and time of CO<sub>2</sub> sensor calibration

**Check result**

- : Calibration was successful.
- : Calibration failed. Check the CO<sub>2</sub> sensor connection and calibrate again.

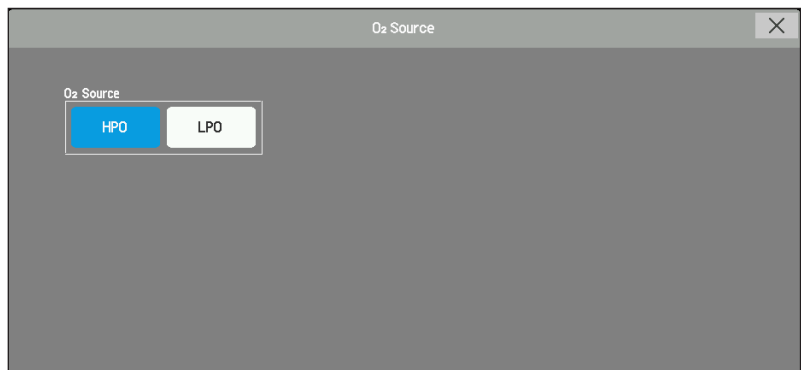
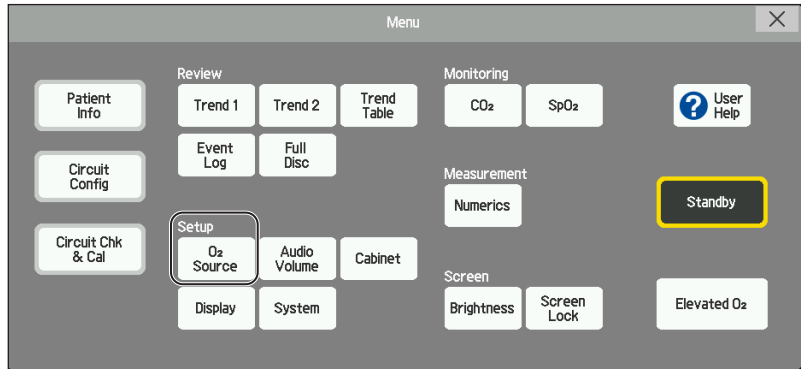


# Setting the Oxygen Supply Type

Set the type of oxygen supply to be used with this ventilator.

NOTE: When changing the oxygen supply type, be sure to check the setting.

- 1 Press the [Menu] operation key to display the Menu window.
- 2 Select [O<sub>2</sub> Source] in “Setup” to display the O<sub>2</sub> Source window.



- 3 Select the oxygen supply type.
  - HPO: Select this when a high pressure oxygen source is connected.
  - LPO: Select this when a low pressure oxygen source such as an oxygen cylinder is connected.
- 4 Select [X] to close the [O<sub>2</sub> Source] window.



## Changing Ventilator Settings

If necessary, change settings for the ventilator and display.

- 1 Select the [Menu] operation key to display the Menu window.
- 2 Select the setting items to change in “Setup”.
- 3 Change the settings on each setting window.

For details about Setup items, refer to Section 12 “Settings”.



Refer to Section 12 “Settings”.



## Performing Preoperational Checks

Make sure to use the ventilator correctly and safely by always performing the following preoperational checks before use.

If there is an abnormality, take appropriate measures by referring to Section 13 “Troubleshooting” and the Administrator’s Guide. If the ventilator is suspected to be faulty, attach a “Do Not Use” or “Under Repairs” sign to it and contact a Nihon Kohden representative.

Furthermore, make sure to order the specified accessories and consumables when stock is running low.



Refer to the following.

- “Troubleshooting” (p. 13-24)
- Administrator’s Guide

## Preoperational Checks

NOTE: Check the accuracy of the time displayed in the upper right of the screen when turning on the power or selecting a new patient. If date settings are modified during monitoring, the date for all stored data will also be modified.

| Item |  | Description  |
|------|--|--|
| 1    | Surrounding environment                  | There are no obstacles surrounding the ventilator.   |
| 2    | Alternative breathing assistance devices | There are alternative breathing assistance devices (portable or manual ventilators, resuscitators, etc.) in the surrounding area.  |
| 3    | External appearance and Connections      | There are no dirt, liquid, scratches, deformation or damage on the outside of the ventilator.  |
|      |  | The ventilator is mounted on a cart or mount plate and locked to it.   |
|      |  | All of the casters on the cart are locked.   |
|      |  | The support arms are not loose or rattling.  |
| 4    | Power                                    | The power cord and grounding lead are not damaged.   |
|      |  | The power cord and grounding lead are securely connected.  |
| 5    | Patient circuit                          | The patient circuit has been selected correctly.<br>• Exhalation port • Proximal sensor • Patient interface  |
|      |  | The patient circuit is not dirty or damaged.   |
|      |  | The patient interface is not dirty or damaged.   |
|      |  | The patient circuit, exhalation port and heated humidifier are connected as shown in the diagram. To show a diagram of the patient circuit, select [User Help] on the Menu window. |
|      |  | The result of the circuit check is normal.   |
|      |  | The result of the flow sensor calibration is normal.   |
| 6    | Oxygen supply                            | The oxygen supply type is set correctly.   |
|      |  | The high pressure oxygen hose or oxygen tube is not damaged.   |
|      |  | (When using high pressure oxygen) The high pressure oxygen hose is connected to the high pressure oxygen input port and to the oxygen supply.                                      |
|      |  | (When using low pressure oxygen) The oxygen tube is connected to the low pressure oxygen input port and to the oxygen supply.  |
|      |  | The oxygen cylinder is securely fixed to the cart.   |
|      |  | The oxygen cylinder capacity is sufficient.  |
|      |  | The result of the O <sub>2</sub> sensor calibration is normal.   |



| Item |                                       | Description   |
|------|---------------------------------------|---|
| 7    | Vital signs measurement               | There is no dirt or damage on the sensors and connection cables.<br>The sensors and connection cables are connected correctly.  |
|      |                                       | The result of the CO <sub>2</sub> sensor calibration is normal.   |
|      |                                       |   |
| 8    | Basic operation                       | The operation lamp lights.  |
|      |                                       | The touch screen is operating normally.   |
|      |                                       | The operation knob is operating normally.   |
|      |                                       | The date and time are displayed accurately.   |
| 9    | Ventilation operation <sup>1, 2</sup> | Ventilation is operating normally.<br>• Apnea ventilation is operating.<br>(Apnea ventilation operates when you stop pressing the test lung.)<br>• The measurements for the ventilation parameters are within the tolerance zone.<br>(PIP, PEEP, RR <sub>TOT</sub> , FiO <sub>2</sub> values are within the tolerance zone.)<br>• The spontaneous breaths trigger is operating.<br>(Spontaneous breaths are detected when light pressure is applied to the test lung during ventilation.) |
| 10   | Alarms <sup>1, 2</sup>                | The alarm indicators light.   |
|      |                                       | The alarm sound can be heard.   |
|      |                                       | Power supply alarm<br>1) An alarm occurs when disconnecting the AC power cord from the power line.<br>2) The alarm is cleared when reconnecting the AC power cord to the power line.  |
|      |                                       | Oxygen supply pressure alarm<br>1) An alarm occurs when the pressure-resistant oxygen hose is disconnected from the high pressure oxygen supply.<br>2) The alarm is cleared when the pressure-resistant oxygen hose is reconnected to the high pressure oxygen supply.  |
|      |                                       | Breathing circuit disconnection alarm<br>1) An alarm occurs when the test lung is disconnected from the breathing circuit.<br>2) The alarm is cleared when the test lung is reconnected to the breathing circuit.   |
|      |                                       | High PIP alarm and “Insp. Pressure Limited by High PIP Setting” message<br>1) An alarm occurs when the PIP upper alarm limit is set to a value lower than the measured value or an information message is displayed.<br>2) The alarm or the information message is cleared when the PIP upper alarm limit is set to a value sufficiently greater than the measured value.   |
|      |                                       | Breathing circuit obstruction alarm<br>1) An alarm occurs when the exhalation port is blocked.<br>2) The alarm is cleared when the exhalation port is opened.   |
|      |                                       | Minute volume alarm<br>1) An alarm occurs when the minute volume lower alarm limit is set to a higher value than the measured values.<br>2) The alarm is paused when the minute volume lower alarm limit is set to a lower value than the measured values.  |
|      |                                       | When an alarm is paused, no alarm sound is generated until the set audio pause time elapses. After the set audio pause time elapses, the alarm sound resumes. (Disconnect the test lung from the breathing circuit. The breathing circuit disconnection alarm sounds. Touch the [Audio Paused] function key to pause the alarm sound.)  |

<sup>1</sup> For the checks in 9. “Ventilator Operation” and 10. “Alarms”, refer to “Configuration and Conditions for Checks” (p. 5-22).

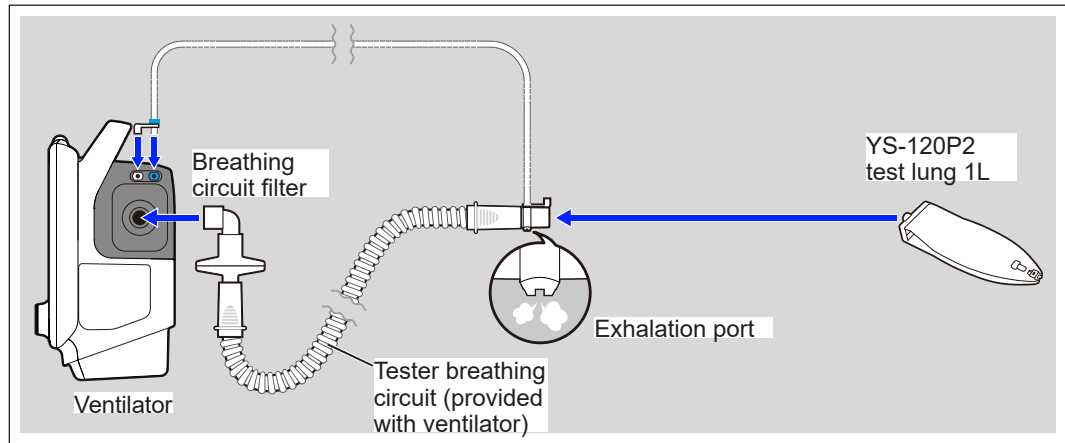
<sup>2</sup> The following alarms are not generated within the first 60 seconds after ventilation starts.

- Low PIP                      • High/Low MV                      • High/Low RR<sub>TOT</sub>
- High/Low VT                • High/Low FiO<sub>2</sub>                    • High/Low PEEP



## Configuration and Conditions for Checks

### Ventilator configuration



### Conditions

| Ventilation Mode    | SPONT-PS              |          |
|---------------------|-----------------------|----------|
| Control Settings    | Settings              |          |
| Basic Settings      | EPAP/CPAP             | 5 hPa    |
|                     | PS ( $\Delta P$ )     | 10 hPa   |
|                     | Slope                 | 2        |
|                     | FiO <sub>2</sub>      | 30%      |
|                     | Trig. Type            | Advanced |
|                     | Trig. Sens.(Advanced) | 3        |
|                     | ET%                   | 25%      |
| Additional Settings | Ti Max                | 3.00 s   |
|                     | Ti Min                | 0.30 s   |
|                     | Press. Release        | Off      |
|                     | Ramp Up Time          | Off      |
| Apnea Ventilation   | IPAP                  | 15 hPa   |
|                     | EPAP                  | 5 hPa    |
|                     | Slope                 | 2        |
|                     | RR                    | 20/min   |
|                     | Ti <sup>1</sup>       | 1.00 s   |
|                     | I:E <sup>1</sup>      | 2.0      |
|                     | Apnea Ventilation     | On       |
| Apnea               | 10 s                  |          |

<sup>1</sup> Set the item selected in "Inspiration Setting" on the System Setup ► [Parameters] tab ► [Vent] window.

### Tolerance range for ventilation parameter measurements

| Ventilation Parameter |                                  | Range        |
|-----------------------|----------------------------------|--------------|
| PIP                   | Peak inspiratory pressure        | 13 to 17 hPa |
| PEEP                  | Positive end expiratory pressure | 3 to 7 hPa   |
| RRTOT                 | Total respiratory rate           | 19 to 21/min |
| FiO <sub>2</sub>      | FiO <sub>2</sub>                 | 27 to 33%    |



# 6

## Starting Ventilation

|  |     |
|--|-----|
| 6-1 Operation to Start Ventilation ..... | 6-1 |
| 6-2 Operation During Ventilation .....   | 6-2 |



# 6-1

## Operation to Start Ventilation

6

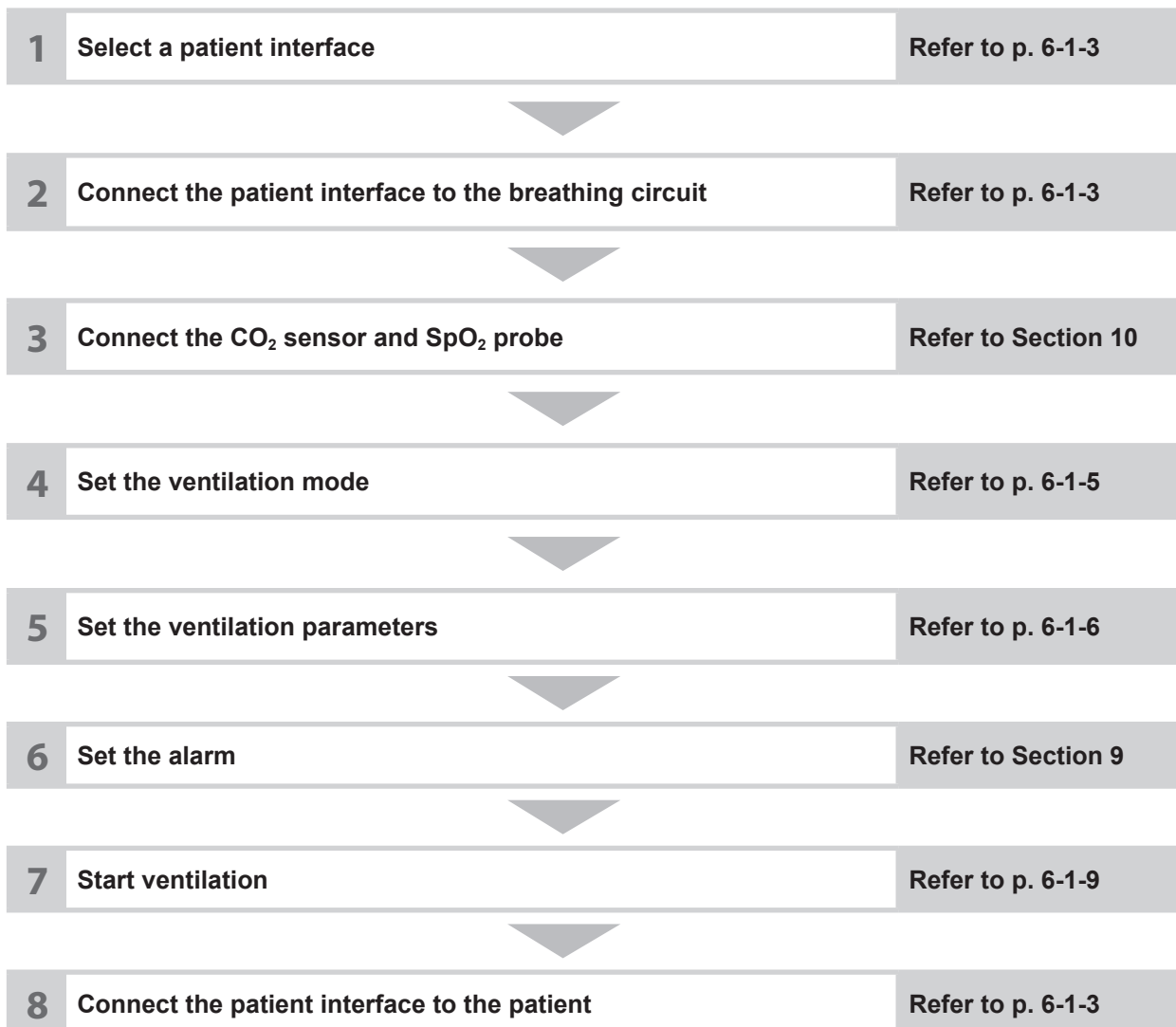
6-1

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| Selecting the Patient Interface .....                                  | 6-1-3 |
| Attaching the Patient Interface .....                                  | 6-1-3 |
| Connecting the CO <sub>2</sub> Sensor and SpO <sub>2</sub> Probe ..... | 6-1-3 |
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| Starting Ventilation.....  | 6-1-9 |



# Flow Until Starting Ventilation

Perform the following steps.





# Connecting to the Patient

## Selecting the Patient Interface

The following Nihon Kohden patient interfaces can be used with the ventilator.

- VM-310Z NPPV full face mask set L
- VM-311Z NPPV full face mask set M
- VM-312Z NPPV full face mask set S
- VM-313Z NPPV full face mask set XS
- VM-321Z Child/Infant NPPV full face mask XL
- VM-322Z Child/Infant NPPV full face mask L
- VM-330Z NPPV cap-ONE mask set L
- VM-331Z NPPV cap-ONE mask set M
- VM-332Z NPPV cap-ONE mask set S
- VM-333Z NPPV cap-ONE mask set XS

6

6-1

## Attaching the Patient Interface

Attach the patient interface to the patient.

For details on how to attach the patient interface, refer to the operator's manual for the patient interface.



Refer to the Patient Interface Operator's Manual.

## Connecting the CO<sub>2</sub> Sensor and SpO<sub>2</sub> Probe

Connect the CO<sub>2</sub> sensor and SpO<sub>2</sub> probe to monitor CO<sub>2</sub> and SpO<sub>2</sub>.

For details on how to select and connect the CO<sub>2</sub> sensor and SpO<sub>2</sub> probe, refer to Section 10 "Parameters".



Refer to Section 10 "Parameters".

# Connecting the Patient Interface to the Breathing Circuit

Connect the patient interface to the breathing circuit.

For details about connection, refer to the manuals provided with the patient interface and the breathing circuit.



Refer to the Patient Interface and Breathing Circuit Operator's Manual.



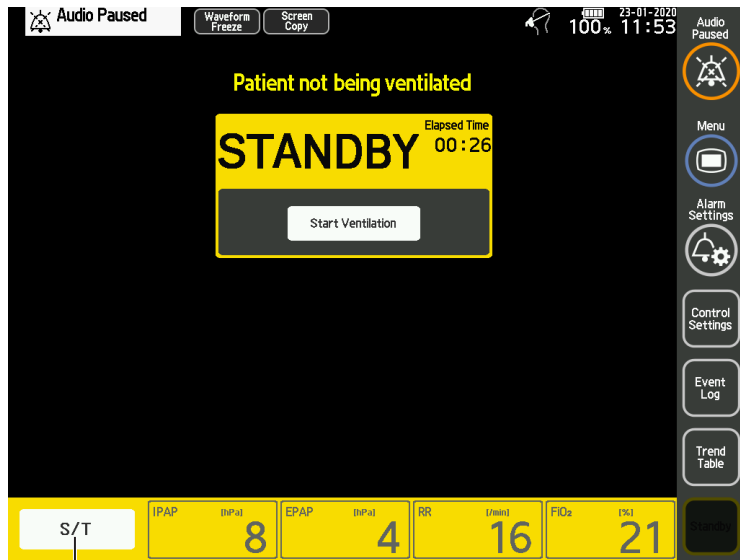
# Control Settings

Set the ventilation mode and ventilation parameters using the Control Settings windows.

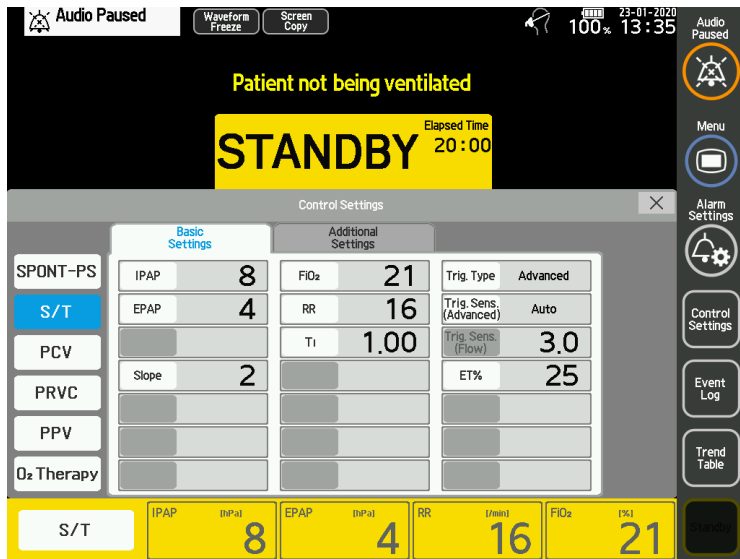
## Displaying the Control Settings Windows

Select the ventilation mode at the bottom of the Main screen to display the Control Settings window.

Control Settings windows can also be displayed by selecting [Control Settings] from the function keys. (Only when it is assigned to a function key)



Ventilation mode





## Setting the Ventilation Mode

For details on each ventilation mode, refer to “Ventilation Mode Description” in Section 16.



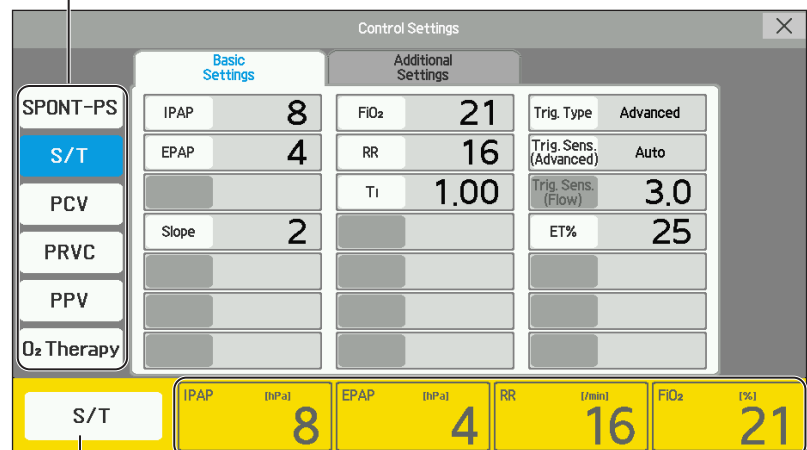
Refer to “Ventilation Mode Description” in Section 16.

- 1 Select the ventilation mode from the keys on the Control Settings window.

Ventilation mode settings keys<sup>1</sup>

Select the ventilation mode.

When the current ventilation mode is selected, it is highlighted in light blue.



Ventilation mode

Shows the selected ventilation mode.

Control settings

Shows the control settings applied to the selected ventilation mode.

“PCV”, “PRVC”, “PPV” and “O<sub>2</sub> Therapy” are only displayed when the Ventilation Mode setting is set to [On] on the [Vent] window in the System Configuration window.



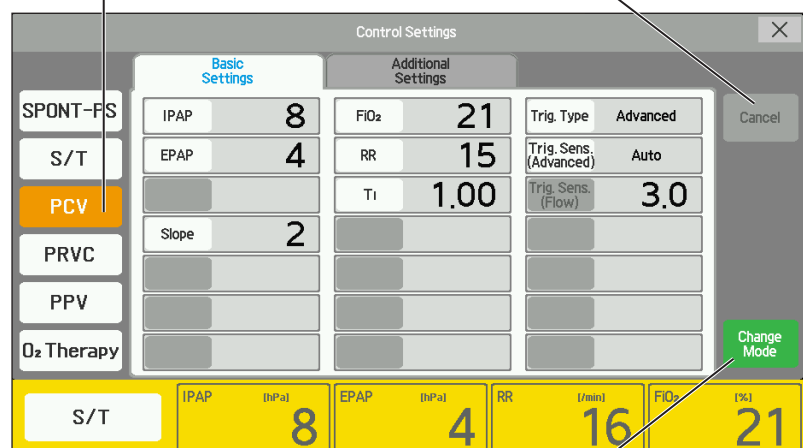
Refer to the following.  
Administrator's Guide:  
“Ventilation Settings” in Section 2

- 2 Select [Change Mode] to apply the ventilation mode change.

NOTE: The ventilation mode will not change by simply selecting a different ventilation mode settings key. [Change Mode] must be selected to enable the change.

The ventilation mode to be changed is displayed in orange.

[Cancel] Available when the ventilation mode and ventilation parameter settings are changed.



[Change Mode]

Applies change of ventilation mode.



Select [X] to cancel.



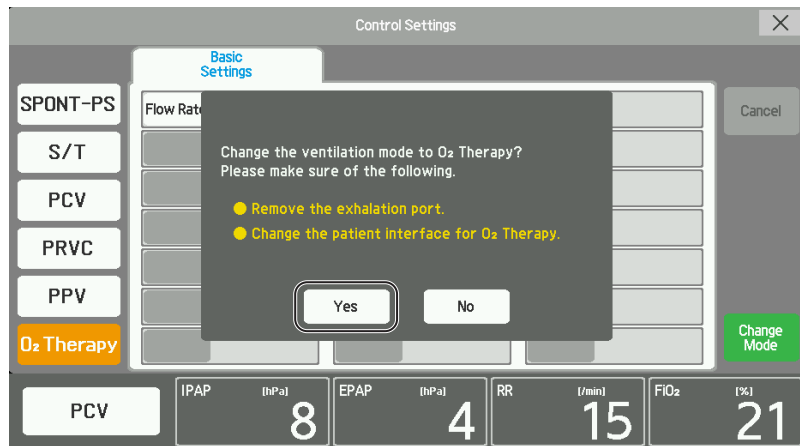
## Changing Between O<sub>2</sub> Therapy and NPPV Mode

When the ventilation mode is changed to O<sub>2</sub> Therapy mode from NPPV mode (SPONT-PS, S/T, PCV, PRVC, PPV), a confirmation screen appears.

NOTE: When the ventilation mode is changed to O<sub>2</sub> Therapy mode during ventilation, the following alarms do not occur for 30 seconds after the change.

- High/Low EtCO<sub>2</sub>
- High FiCO<sub>2</sub>
- High/Low RR (CO<sub>2</sub>)
- Apnea (CO<sub>2</sub>)

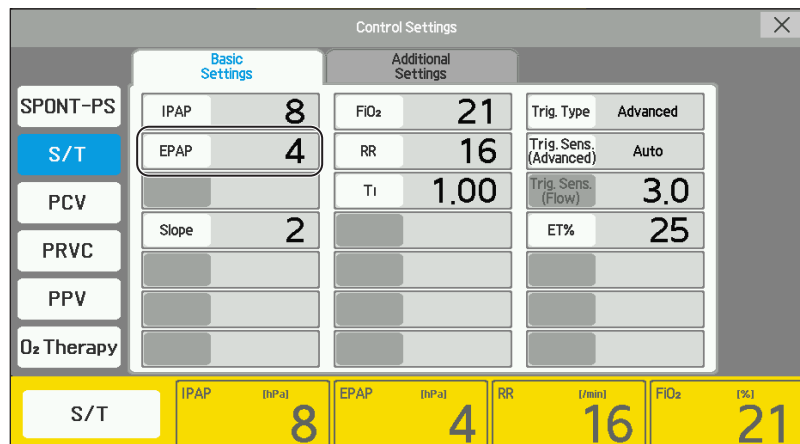
- 1 Select [O<sub>2</sub> Therapy] from the ventilation mode settings keys on the Control Settings window.
- 2 Select [Change Mode].
- 3 Select [Yes] to confirm the change.



When the ventilation mode is changed from O<sub>2</sub> Therapy to a NPPV mode, the same confirmation window appears.

## Setting the Ventilation Parameters

- 1 Display a ventilation parameter setting window by selecting the ventilation parameter in the [Basic Settings], [Additional Settings] or [Apnea Ventilation] ventilation parameter tabs.



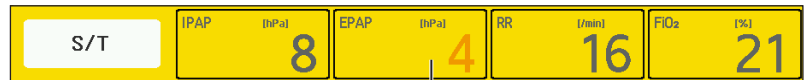
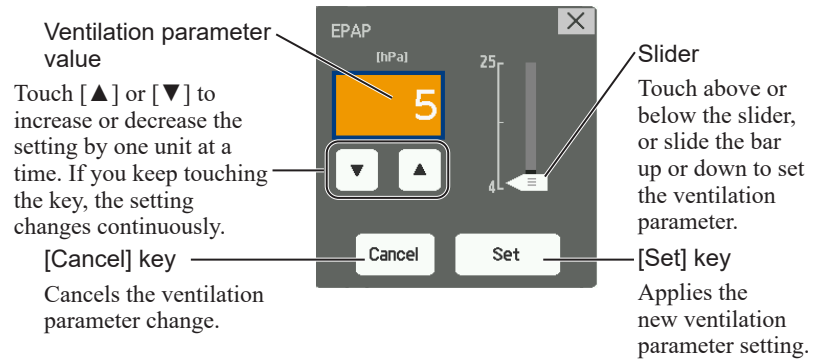
- 2 Set the ventilation parameters.



The displayed details in the ventilation parameter setting window depend on the setting item.



1) Turn the operation knob to change the ventilation parameters.



The changed ventilation parameter value in the ventilation parameter setting window turns orange.

2) Push the operation knob to apply the change.

Entered items can also be confirmed as follows:

- By touching the [Set] key
- By touching the ventilation parameter value

## Initializing the Ventilation Parameters

The ventilation parameters for each ventilation mode are initialized to the preset master settings in the following cases.

- When the ventilator is turned on and a new patient is admitted on the Patient Selection window.
- When “Yes” is selected for “New Patient?” and “Apply preset settings?” on the [Menu] window ► [Patient Info] ► [Patient Type] ► [Patient Selection] window.

The ventilation master values can be set for each patient type and each ventilation mode on the Master page of the System Setup window.



Refer to the following.

- “Selecting the Patient Type” in Section 5
- “Setting the Patient Type” in Section 8
- Administrator’s Guide: “Setting Masters” in Section 3

## Control Settings

For details on default settings, settings descriptions and parameters that can be set on Control Settings window, refer to “Control Settings” in Section 15.



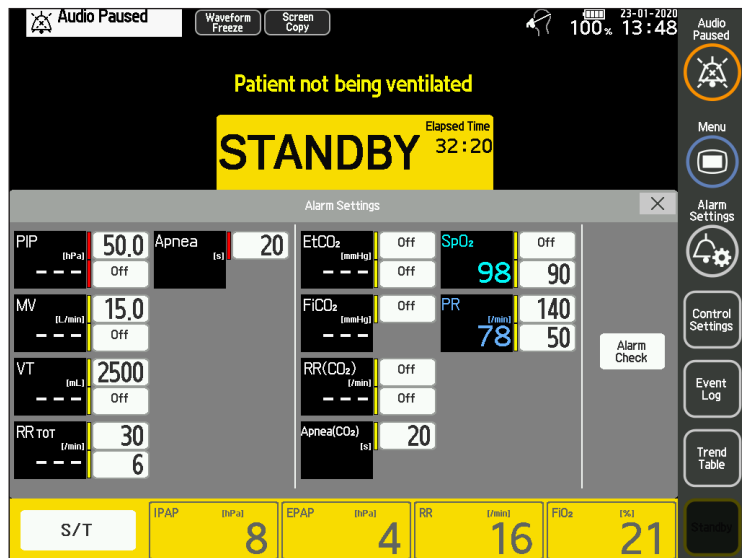
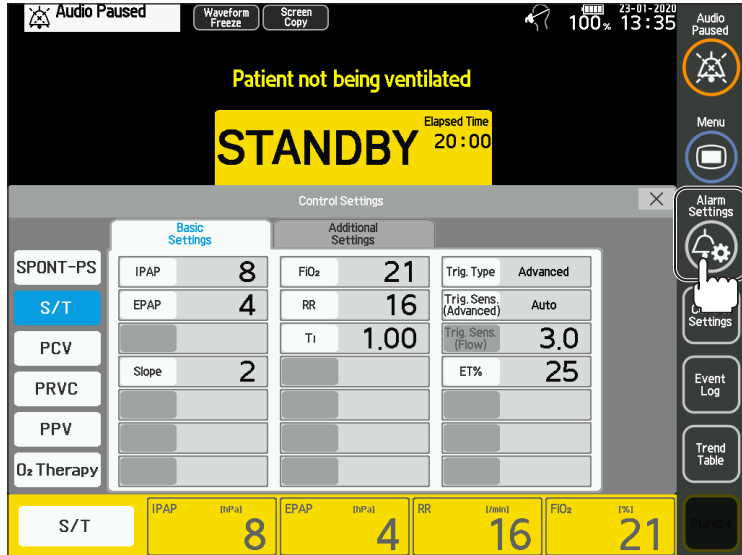
Refer to “Control Settings” in Section 15.



# Alarm Settings

Set the upper and lower alarm limits for the ventilation parameters.

Select the [Alarm Settings] operation key to display the window for setting the upper and lower alarm limits.



For details on setting upper and lower alarm limits, refer to Section 9 “Alarms”.



Refer to Section 9 “Alarms”.



# Starting Ventilation

After setting the control and alarm settings, release the ventilation standby state and start ventilation.

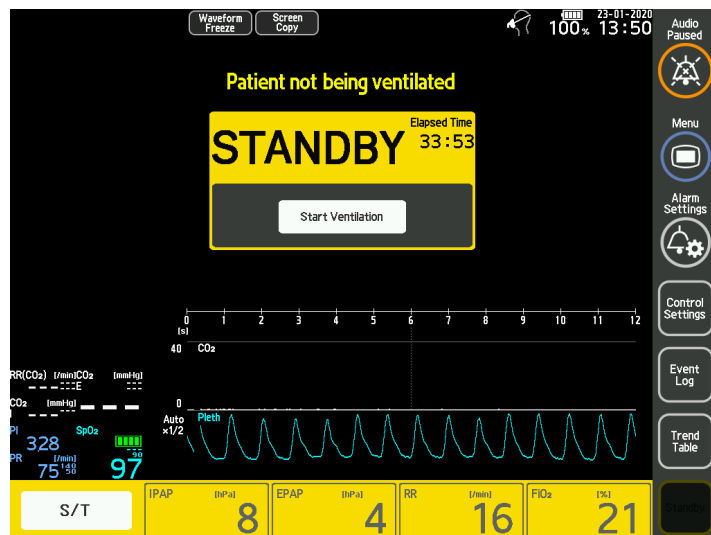
Ventilation starts even if spontaneous breathing is detected <sup>1</sup> (after 30 seconds elapse from the release of ventilation standby state).

<sup>1</sup> If the ventilation mode is set to [O<sub>2</sub> Therapy], spontaneous breathing of the patient is not detected.

NOTE: The following alarms are not generated within the first 60 seconds after ventilation starts.

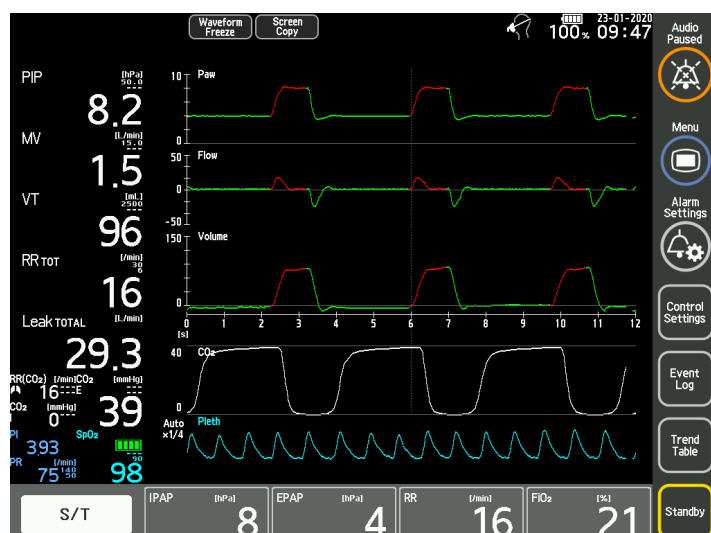
- Low PIP
- High/Low MV
- High/Low RR<sub>TOT</sub>
- High/Low VT
- High/Low FIO<sub>2</sub>
- High/Low PEEP

1 Select [Start Ventilation] on the STANDBY window.



2 Attach the patient interface to the patient.

3 Check that waveforms and numeric values are displayed on the Main screen.





# 6-2

## Operation During Ventilation

6

|  |        |
|--|--------|
| Main Screen During Ventilation .....     | 6-2-2  |
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| Ending Elevated O <sub>2</sub> .....     | 6-2-9  |
| Customizing the Layout .....             | 6-2-10 |

6-2



# Main Screen During Ventilation

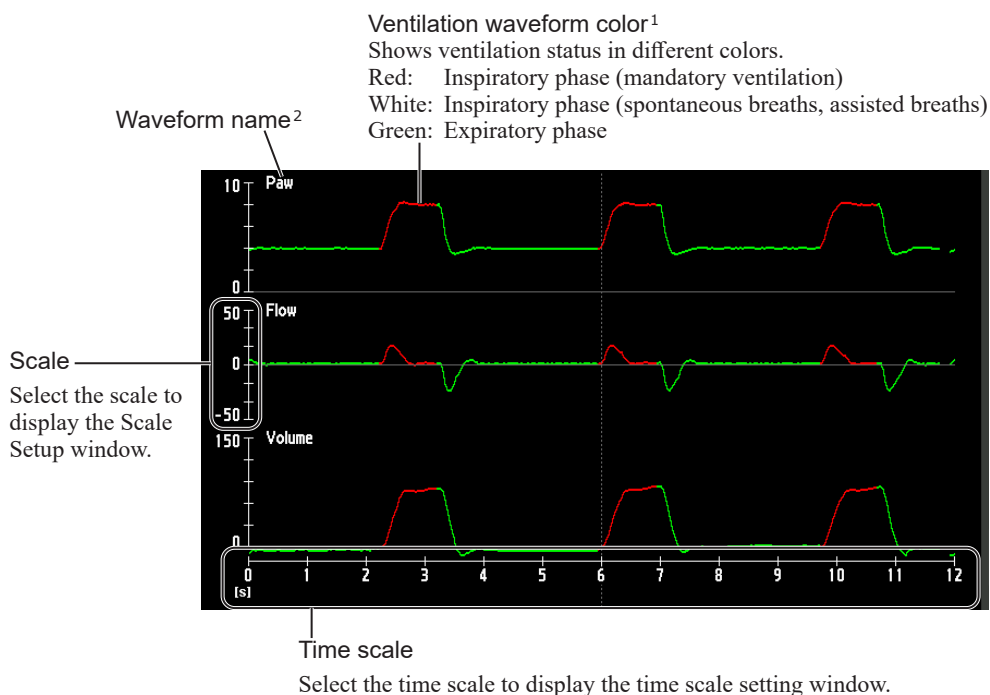
The Main screen appears as follows during patient ventilation.

The screenshot shows the main screen with the following components and labels:

- Waveform Freeze key**: Located at the top left of the screen.
- Screen Copy key**: Located at the top center of the screen.
- Patient interface icon**: Located at the top right of the screen.
- Main battery information**: Shows '100%' battery level and '09:47' time.
- Current date and time**: Shows '23-01-2020' and '09:47'.
- Ventilation parameter measurement values**: A vertical list on the left showing: PIP 8.2 (bPa), MV 1.5 (L/min), VT 96 (mL), RR TOT 16 (1/min), Leak TOTAL 29.3 (L/min), RR(CO2) 16 (1/min), CO2 39 (mmHg), SpO2 98 (%).
- Shows the measurement value such as Paw, volume and respiration rate. Select this area to display the setting window.**: Points to the parameter list.
- CO<sub>2</sub> value**: Points to the CO<sub>2</sub> value '39'.
- Shows the CO<sub>2</sub> measurement value. For details, refer to Section 10 "Parameters".**: Points to the CO<sub>2</sub> value.
- SpO<sub>2</sub> value**: Points to the SpO<sub>2</sub> value '98'.
- Shows the SpO<sub>2</sub> measurement value. For details, refer to Section 10 "Parameters".**: Points to the SpO<sub>2</sub> value.
- Ventilation mode**: Shows 'S/T' at the bottom left.
- Shows the current ventilation mode. Select it to display the Control Settings window.**: Points to the 'S/T' mode.
- Control settings**: Shows 'IPAP 8', 'EPAP 4', 'RR 16', 'FIO<sub>2</sub> 21' at the bottom.
- Shows the control settings applied to the current ventilation mode. Select it to display the ventilation parameter setting window.**: Points to the control settings.
- Ventilation waveforms**: Three stacked waveforms for Paw, Flow, and Volume.
- CO<sub>2</sub> waveform**: A CO<sub>2</sub> waveform.
- Plethysmogram**: A plethysmogram waveform.
- Event Log**: A button on the right side.
- Standby**: A button at the bottom right.



## Waveform Display Area Description



6

6-2

<sup>1</sup> The ventilation waveform color can be changed by selecting Waveform Color Type on the [Vent] tab in the [Color] page of the System Setup window.

<sup>2</sup> Airway pressure and CO<sub>2</sub> units can be changed by selecting [Units] window in the System Configuration window.



Refer to the following.

Administrator's Guide:

- "Unit Settings" in Section 2
- "Setting Colors" in Section 3



## Setting the Scale

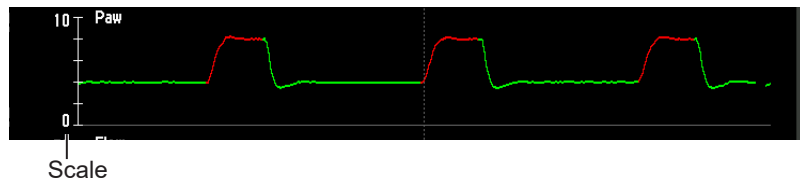
Set the waveform scale and time scale to display on the Main screen.

### Ventilation Waveform Scale

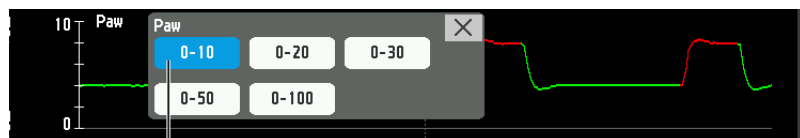
#### Settings

- Airway pressure (hPa): 0 to 10, 0 to 20, 0 to 30, 0 to 50, 0 to 100
- Flow (L/min): -10 to +10, -20 to +20, -50 to +50, -100 to +100, -200 to +200
- Volume (mL): 0 to 150, 0 to 300, 0 to 500, 0 to 1000, 0 to 3500

- 1 Select the scale on the Main screen to show the waveform scale setting window.



- 2 Select a scale key on the setting window.

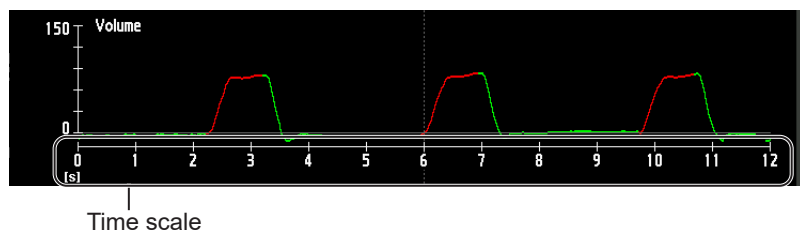


The selected item is displayed in light blue.

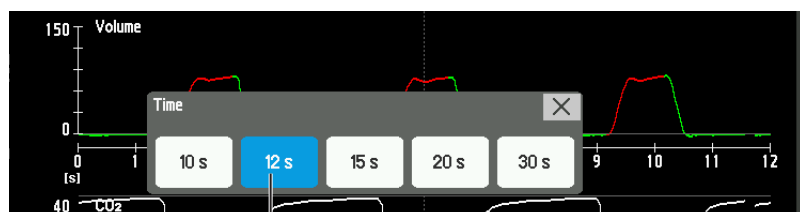
### Waveform Time Scale

Settings : 0 s, 12 s, 15 s, 20 s, 30 s

- 1 Select the time scale on the Main screen to show the time scale setting window.



- 2 Select the scale key on the time scale setting window.



The selected item is displayed in light blue.



# Waveform Freeze

Numeric data for waveforms can be viewed by freezing all the waveforms displayed on the Main screen.

## Freezing Waveforms

- 1 Select [Waveform Freeze] at the top of the Main screen.

A yellow cursor appears on the waveforms after freezing them on the Main screen.

NOTE: Cancel the waveform freeze to resume monitoring.

Selecting [Waveform Freeze] from the function keys also freezes the waveforms. (Only when the function is assigned to a function key)



Refer to the following.

Administrator's Guide:

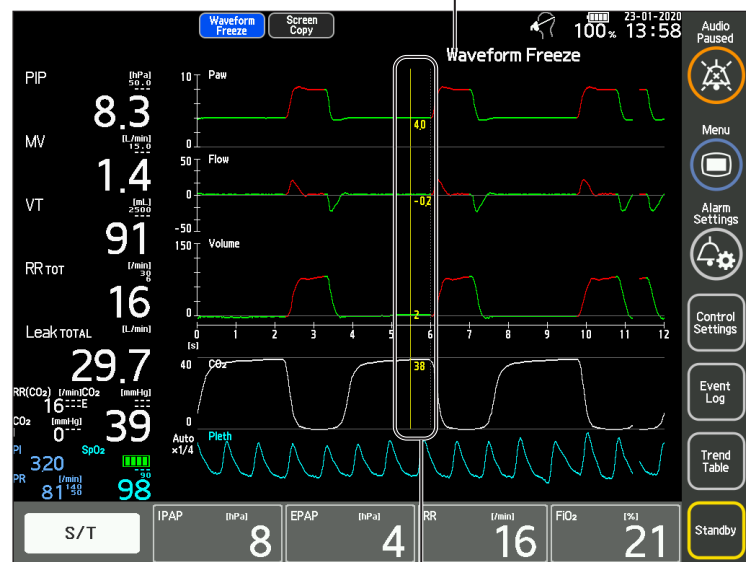
"Changing the Key Assignments" in Section 3

- 2 Turn the operation knob to the right or left to move the yellow cursor to the relevant waveform.

Measurement value is displayed beside the cursor.

The cursor can be moved by touching the waveform display area.

A "Waveform Freeze" message appears while the waveforms are frozen.



Yellow cursor

## Unfreezing Waveforms

Waveforms can be unfrozen by one of the following methods.

- Touching [Waveform Freeze] at the top of the Main screen again
- After 3 minutes elapse since the waveforms were frozen



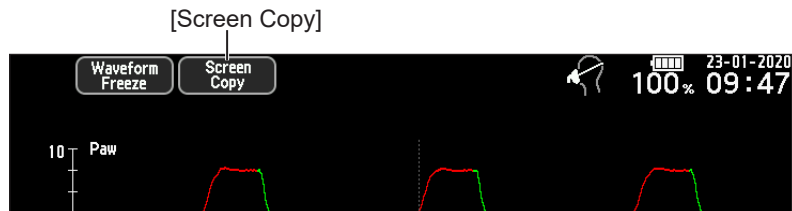
## Screen Copy Function

### Saving to an SD Card

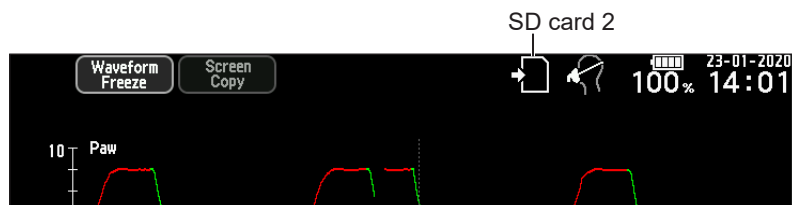
The currently displayed screen can be saved to the SD card slot 2 in bmp format.

NOTE: Up to 10 screen files can be saved. If more than 10 files are saved, the newest file is saved but overwrites the oldest file.

Select [Screen Copy] at the top of the Main screen.



The SD card 2 icon is displayed while saving.



When saving is complete, the SD card 2 icon disappears.

The files are displayed on the SD card in the following format.

File name: NKV-330\_XXXX.bmp (XXXX = 4 digit serial number starting from 0000)

### Copying a File to a USB Flash Disk

Copy all the bmp files on SD card 2 to a USB flash disk by connecting a USB flash disk to the USB socket on the right side panel of the ventilator.

Data is saved to the following location on the USB flash disk.

- Folder name: \NKV-330\ScreenCopy\
- File name: AutoCopy\_YYYYMMDD\_HHMMSS.bmp

### Saving a File to a USB Flash Disk

Files can be saved directly to a USB flash disk when a USB flash disk is already connected to the ventilator.

NOTE • When saving files directly to a USB flash disk, the files are not saved to SD card 2.

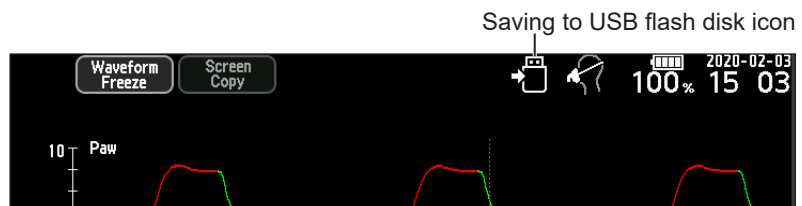
- Keep the number of files saved directly to around 1000. Delete unnecessary files in the USB flash disk save folder as required.

- 1 Connect a USB flash disk to the USB socket on the right side panel of the ventilator.



## 2 Select [Screen Copy] at the top of the Main screen.

During saving, the Saving to USB flash disk icon is displayed.



Data is saved to the following location on the USB flash disk.

- Folder name: \NKV-330\ScreenCopy\  
• File: name: YYYYMMDD\_HHMMSS.bmp



# Elevated O<sub>2</sub>

The Elevated O<sub>2</sub> function supplies oxygen to the patient for the set operating time at the set concentration during ventilation. Using the Elevated O<sub>2</sub> function before removing the mask from the patient increases patient oxygenation.

NOTE: Elevated O<sub>2</sub> cannot be used in the following cases.

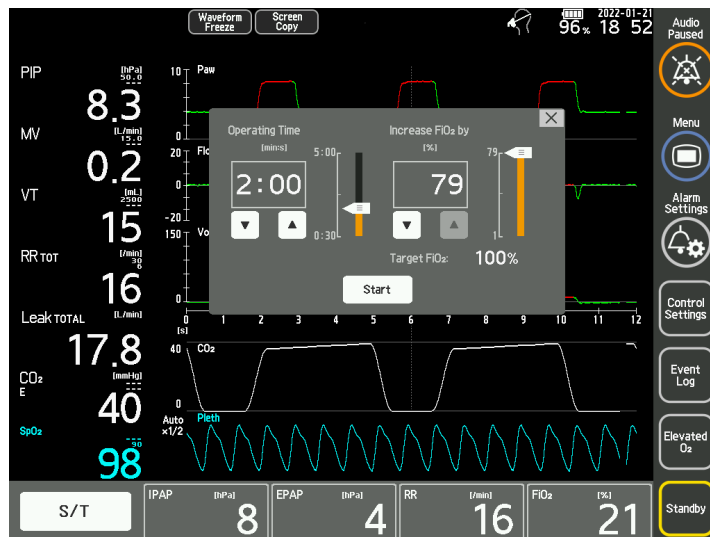
- During ventilation standby.
- When a Vent Inop. alarm occurs.
- When the O<sub>2</sub> Source is set to [LPO] on the O<sub>2</sub> Source window in “Setup” on the Menu window.

## Starting Elevated O<sub>2</sub>

1 Select [Elevated O<sub>2</sub>] in the Menu window.

The Elevated O<sub>2</sub> settings window is displayed.

Elevated O<sub>2</sub> can also be used by selecting the [Elevated O<sub>2</sub>] function key. (Only when it is assigned to a function key)



2 Set the Operating Time and Increase FiO<sub>2</sub> by settings.

Touch [▲] or [▼] to increase or decrease the setting by one unit at a time. If you keep touching the key, the setting changes continuously.

[Start] Starts Elevated O<sub>2</sub> for the set operating time at the set concentration.

Close the Elevated O<sub>2</sub> settings window. Changes to the Operating Time and Increase FiO<sub>2</sub> by settings are not saved.

Slider Touch above or below the slider, or slide the bar up or down to set the item.

Target FiO<sub>2</sub> Displays the actual concentration of oxygen supplied to the patient (Total of the FiO<sub>2</sub> in the control settings and the increase in FiO<sub>2</sub>).

### Settings

- Operating Time: Set the operating time for Elevated O<sub>2</sub>.
- Increase FiO<sub>2</sub> by: Set the amount to increase FiO<sub>2</sub> by during Elevated O<sub>2</sub>.

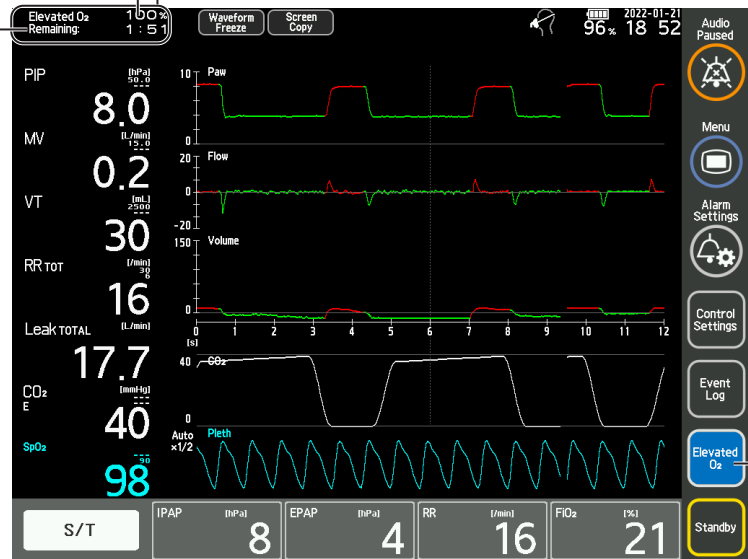


### 3 Select [Start]. Elevated O<sub>2</sub> starts.

Concentration  
Shows the supplied FiO<sub>2</sub>.

When the Ramp Up Time and Audio Pause functions are both enabled when Elevated O<sub>2</sub> is operating, these functions are displayed alternately.

Remaining time  
Shows the remaining time that Elevated O<sub>2</sub> is operating for.



This is shown in blue when Elevated O<sub>2</sub> is operating.

- NOTE
- When Elevated O<sub>2</sub> is operating, High/Low FiO<sub>2</sub> alarms are generated according to the criteria for Target FiO<sub>2</sub> set on the Elevated O<sub>2</sub> settings window.
  - High/Low FiO<sub>2</sub> alarms are not generated for 60 seconds after Elevated O<sub>2</sub> starts and ends.
  - When changing the Elevated O<sub>2</sub> settings, the changes to the settings are not saved until [Start] is selected.
  - When New Adult or New Pediatric is selected, the Elevated O<sub>2</sub> settings are initialized to their default settings.

## Ending Elevated O<sub>2</sub>

Elevated O<sub>2</sub> ends after the operating time set on the Elevated O<sub>2</sub> settings window expires.

Elevated O<sub>2</sub> also ends:

- When [Elevated O<sub>2</sub>] is selected during Elevated O<sub>2</sub> operation.
- When the ventilator enters ventilation standby.
- When a Vent Inop. Alarm occurs.
- When the O<sub>2</sub> Source is set to [LPO] on the O<sub>2</sub> Source window in “Setup” on the Menu window.



## Customizing the Layout

The layout for the Main screen can be customized according to application or preference.

The following contents can be customized.

- Display of numeric values
- Types of parameters for the numeric display
- Types of parameters for the waveform display
- Showing or hiding the cabinet
- Type of cabinet to display

For details on customization, refer to Section 12 “Settings”.



Refer to Section 12 “Settings”.



# 7

## Stopping Ventilation (Ventilation Standby)

|                              |     |
|------------------------------|-----|
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| Restarting Ventilation ..... | 7-4 |
| Turning Off the Power.....   | 7-5 |



# Ventilation Standby

Set the ventilator to “Ventilation Standby” to end patient ventilation.

When the ventilator enters ventilation standby, ventilation stops, and ventilation parameters, waveforms and ventilation alarms no longer appear on the main screen.

However, it is possible to continue CO<sub>2</sub> and SpO<sub>2</sub> monitoring while the ventilator is in ventilation standby.

## Stopping Ventilation

Set the ventilator to ventilation standby to stop patient ventilation.

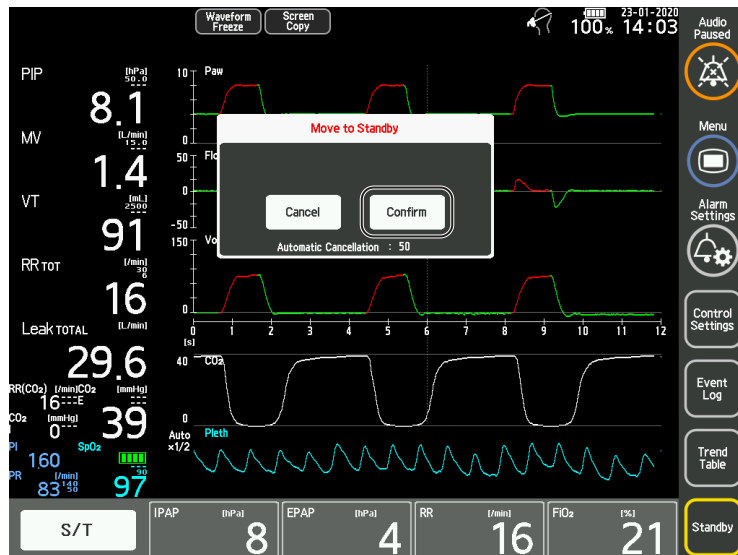
The ventilator can be changed to ventilation standby as follows.

**NOTE** • Keep the AC power connected even in ventilation standby to maintain a fully charged battery.

- The following alarms do not occur for 30 seconds after the ventilation standby state starts.

- High/Low EtCO<sub>2</sub>      - High FiCO<sub>2</sub>
- High/Low RR (CO<sub>2</sub>)    - Apnea (CO<sub>2</sub>)

- 1 Select the [Standby] operation key to display the Move to Standby window.
- 2 Select [Confirm].



- Select [Cancel] to cancel.
- After the [Move to Standby] window appears, when the touch screen is not operated for 1 minute the screen returns to the main screen.





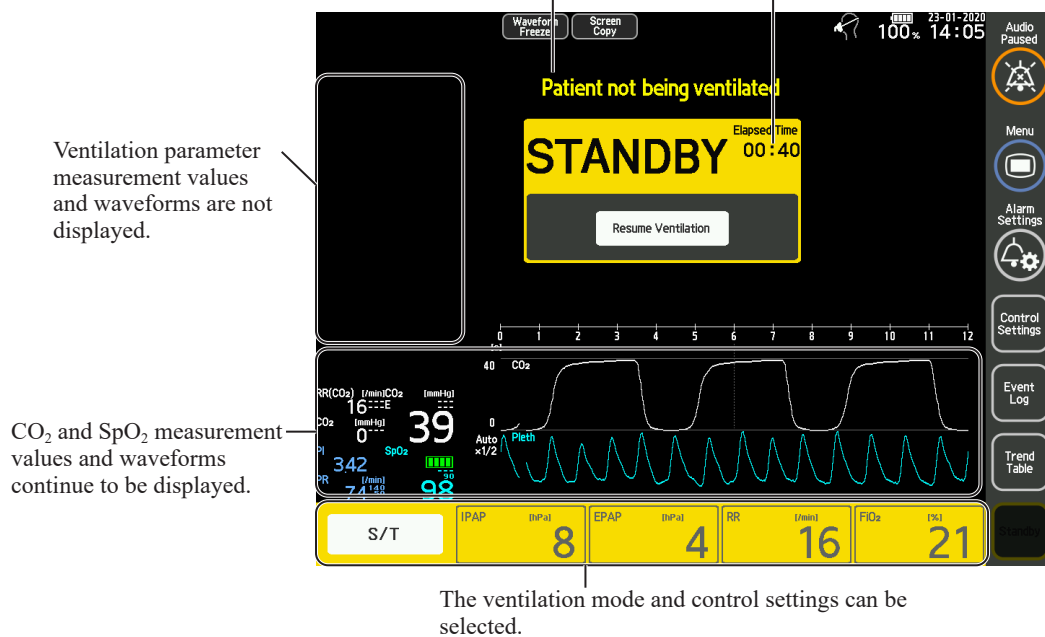
The following STANDBY window appears and the patient ventilation stops.

“Patient not being ventilated”

The ventilation operation is stopped while this message is displayed.

Elapsed time

Shows the time that has elapsed since changing to ventilation standby.



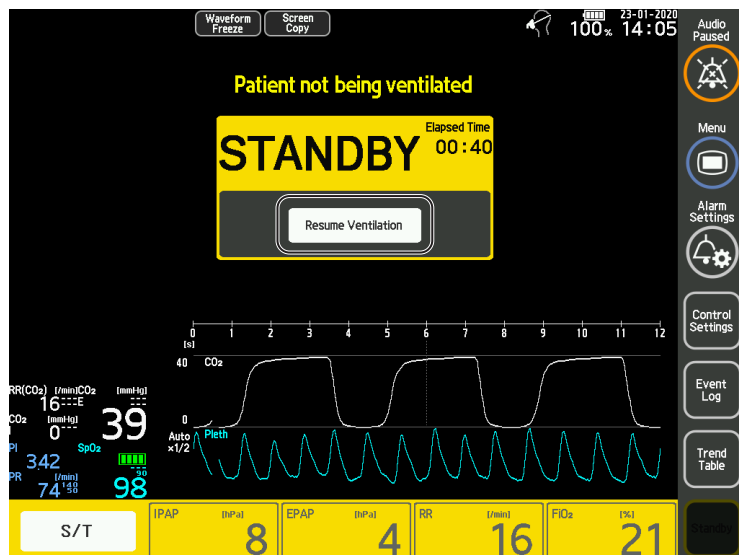
- 3 Remove the patient interface from the patient.  
Or, remove the patient interface from the breathing circuit.



## Restarting Ventilation

Select [Resume Ventilation] on the STANDBY window. Ventilation restarts.

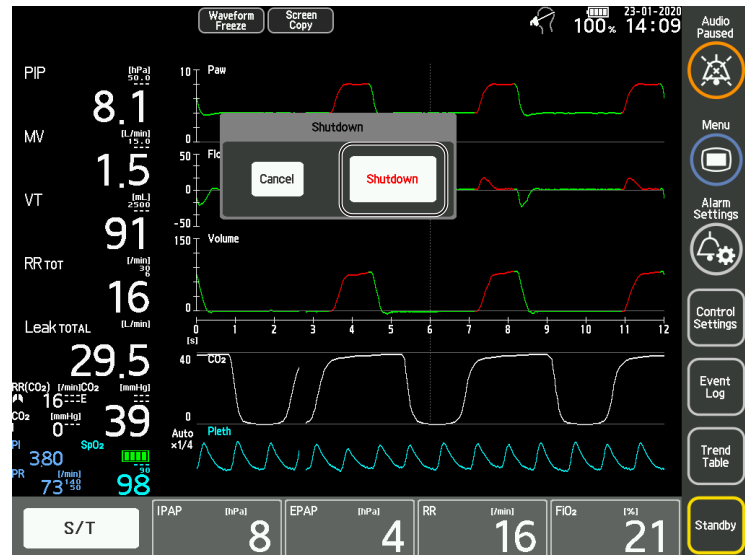
- NOTE
- Ventilation restarts when the patients spontaneous breathing is detected after 30 seconds elapse from the start of ventilation standby. Spontaneous breathing might not be detected when the breathing effort of the patient is low.
  - If the ventilation mode is set to [O<sub>2</sub> Therapy], spontaneous breathing of the patient is not detected.
  - The following alarms are not generated within the first 60 seconds after ventilation standby ends and ventilation restarts.
    - Low PIP
    - High/Low MV
    - High/Low RR<sub>TOT</sub>
    - High/Low VT
    - High/Low FiO<sub>2</sub>
    - High/Low PEEP



# Turning Off the Power

Do the following procedure to stop ventilation and turn off the ventilator power.

- 1 Press and hold the power switch on the ventilator.
- 2 Select [Shutdown] on the Shutdown window.



Select [Cancel] to cancel.



# 8

## Patient Information

|  |     |
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| Setting the Patient Type .....           | 8-4 |
| Setting the Patient Information .....    | 8-6 |
| Setting the Height .....                 | 8-6 |
| Setting the Gender .....                 | 8-7 |



# About Patient Information

## Accepting a New Patient

When accepting a new patient, enter the patient information in the ventilator. The following items can be entered on the Patient Info window.

- Patient type
- Height
- Gender

## Deleting Data of the Previous Patient

When a new patient is accepted, the data of the previous patient is deleted from the ventilator and all settings are initialized. The moment of accepting a new patient is when the data of the previous patient is deleted.

The following data is deleted.

- Review data (trend, trend table, event log, full disclosure waveforms)

### **WARNING**

Check the control settings and alarm settings when starting ventilation of a new patient. Also check the settings during ventilation and whenever the patient condition changes and change the control settings and alarm settings if necessary.

**NOTE:** When turning on the power and selecting a new patient, check that the time at the upper right of the screen is correct. If the date and time setting is changed during monitoring, the date and time of all stored data is also changed.

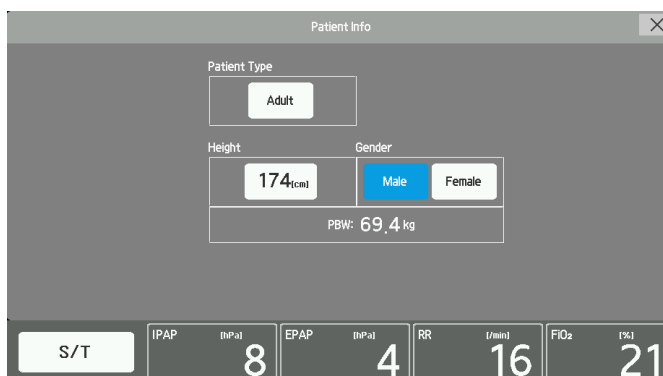
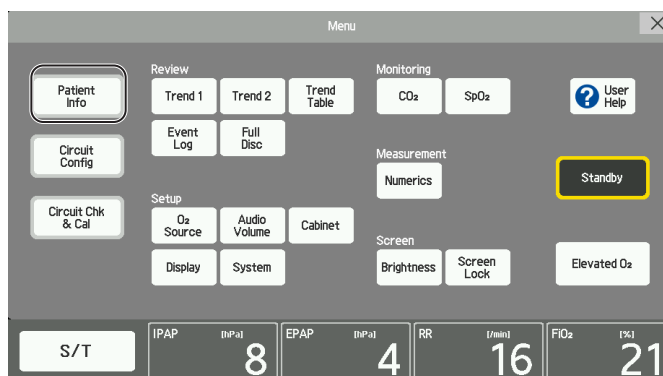


Refer to “Date and Time Settings” in Section 12.

## Displaying the Patient Info Window

Do the follow steps to display the Patient Info window.

- 1 Select the [Menu] operation key to display the Menu window.
- 2 Select the [Patient Info] key to display the Patient Info window.





# Setting the Patient Type

Set the patient type according to the following procedure.

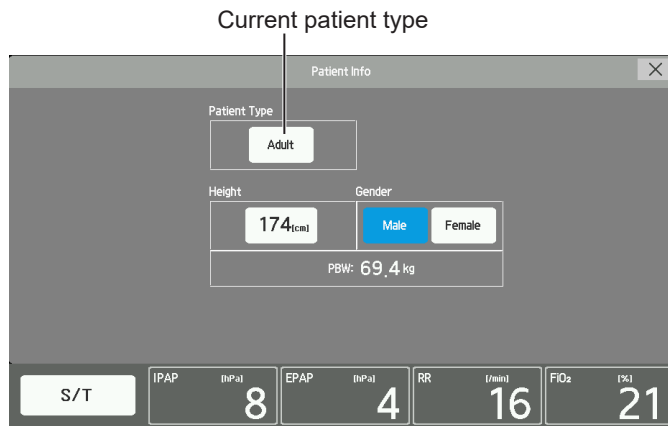
NOTE: When setting the patient type, put the ventilator into the standby state first.

- 1 Display the Patient window.

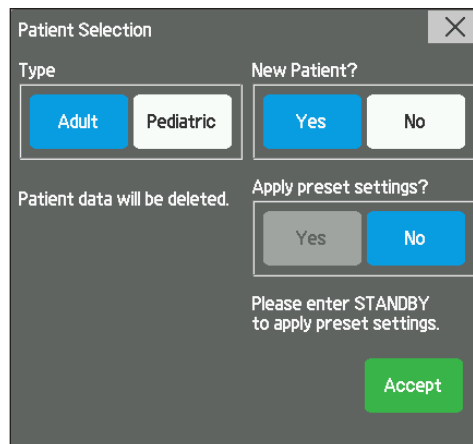


Refer to “Displaying the Patient Info Window” (p. 8-3).

- 2 Select the current patient type in “Patient Type” to display the Patient Selection window.



- 3 Set “Type” and “New Patient?”.



|                                 |                    |   |
|---------------------------------|--------------------|---|
| Type                            | Adult or Pediatric |   |
| New Patient?                    | Yes                | Admit a new patient   |
|                                 | No                 | Admit the same patient as last time   |
| Select [Yes] for “New Patient?” |                    |   |
| Apply preset settings?          | Yes                | The ventilation mode, control settings, alarm settings and display settings masters are applied to the selected patient type.<br><b>NOTE:</b> Only select [Yes] when the ventilator is in ventilation standby mode. |
|                                 | No                 | The current ventilation mode, ventilation settings, alarm settings and display settings are retained.   |



Set the masters for the ventilation mode, ventilation settings, alarm settings and display settings on the [Master] window in System Setup.

Refer to the following.

Administrator's Guide:

“Setting Masters” in Section 3

When a new patient is admitted, the following data is deleted.

- Review data (trend, trend table, event log, full disclosure waveforms)

**4** Select [Accept] to admit the patient.



# Setting the Patient Information

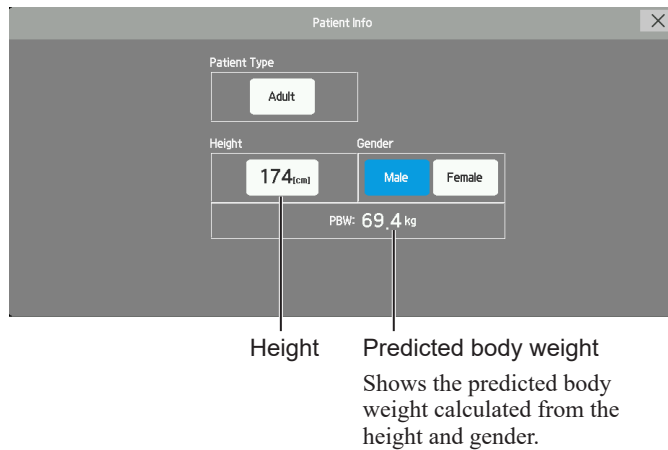
## Setting the Height

- 1 Display the Patient Info window.



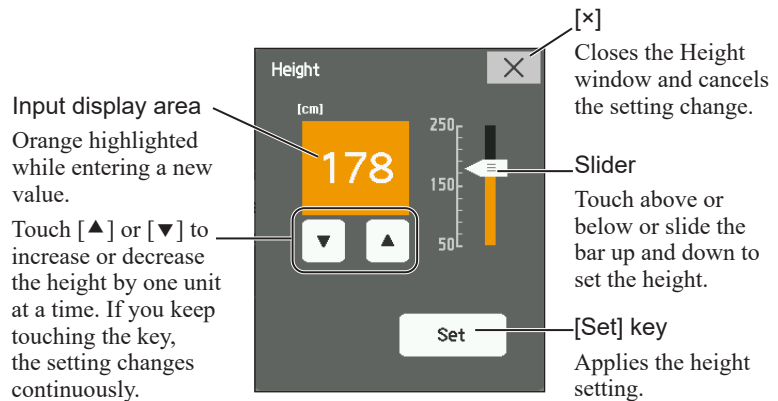
Refer to “Displaying the Patient Info Window” (p. 8-3).

- 2 Select “Height” to display the Height window.



- 3 Set the height.

- 1) Turn the operation knob to change the height.



- 2) Press the operation knob to confirm the change. The Height window closes.

Input can also be confirmed by the following operations.

- Touch the [Set] key
- Touch the input display area



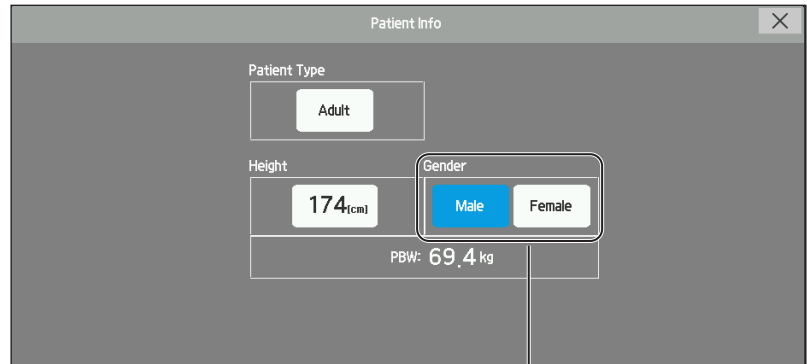
## Setting the Gender

- 1 Display the Patient Info window.



Refer to “Displaying the Patient Info Window” (p. 8-3).

- 2 Select [Male] or [Female] for “Gender”.



Gender

The selected item is displayed in light blue.



# 9

## Alarms

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## Overview of Alarms

The alarm function uses screen messages, sound, and blinking and lit alarm indicators to notify the user of abnormal measurement values for each parameter (upper and lower limit) as well as ventilator abnormality.

### **WARNING**

Use the ventilator with the monitoring devices such as a pulse oximeter or capnometer with an alarm function during ventilation. The alarm and monitoring system functions of the ventilator are not substitute for a vital sign monitor. The patient condition should be regularly checked by trained and qualified medical personnel. Otherwise, sudden changes in the patient condition may be overlooked.

### **WARNING**

When an alarm is generated, check the patient condition and secure the patient safety. Depending on the generated alarm, perform appropriate treatment as described in the operator's manual and remove the cause of alarm. If there is a problem with the alarm setting, change it to an appropriate setting.

### **WARNING**

Do not pause alarms when there are no medical personnel around the patient. This may cause critical changes in the patient condition to be overlooked.

### **WARNING**

Check the control settings and alarm settings when starting ventilation of a new patient. Also check the settings during ventilation and whenever the patient condition changes and change the control settings and alarm settings if necessary.

### **WARNING**

If the alarm sound volume is quieter than the surrounding sound, the alarm sound might not be heard and changes in the patient's condition or the operation of the ventilator may be overlooked. Set the appropriate alarm sound volume according to the environment where the ventilator is used, or frequently check the patient's condition and ventilator.

### **WARNING**

While an Audio Paused message is displayed, there is no sound for all alarms. Be careful when you pause the alarm.

### **CAUTION**

When the alarm limit is set to Off, there will be no alarm for that limit. Be careful when you set the alarm limit to Off.

## Alarm Types

Alarms on the ventilator can be mainly divided into the following types. The position of the alarm message depends on the alarm type.

| Alarm Type                          | Explanation  |
|-------------------------------------|--|
| <b>Upper and lower limit alarms</b> | An upper or lower limit alarm occurs when the measured value of a parameter exceeds the upper alarm limit or drops below the lower alarm limit.  |
| <b>Technical alarms</b>             | Technical alarms indicate abnormality and connection status of the ventilator, battery, breathing circuit and sensors. (Circuit Disconnect, O <sub>2</sub> Supply Low, Main Battery Low, etc.)                 |
| <b>Technical Fault alarms</b>       | This occurs when abnormality of the ventilator is detected. The ventilation operation continues.   |
| <b>Vent Inop. alarms</b>            | This occurs when abnormality of the ventilator is detected and ventilation cannot continue.<br><br>When a ventilation stop alarm occurs, immediately stop ventilation and display the ventilation stop window. |



Unlike alarms, information (notification) of the patient measurement condition and ventilator condition is displayed as messages.

### Power Abnormality Alarms

Unlike other alarms, the power abnormality alarm occurs when the power supply of the ventilator fails or when a system failure occurs. There is a buzzer sound from the ventilator and the alarm indicator blinks in red.

9

## Alarm Priority

Alarms are categorized as follows according to priority.

The operation of the ventilator at the time of alarm as well as the occurrence priority of alarms depends on the priority.

| Priority                          | Explanation   |
|-----------------------------------|---|
| High<br>↑<br>Priority<br>↓<br>Low | <b>Crisis</b><br><br>This is the highest priority alarm. It is generated when the patient's life is at risk or there is a risk of injury.<br><br>It is also generated in cases that may affect the maintenance of the ventilator or system.               |
|                                   | <b>Warning</b><br><br>This is the next priority below Crisis. It is generated when the patient's life is at risk or there is risk of injury or discomfort.<br><br>It is also generated in cases that may affect the function of the ventilator or system. |
|                                   | <b>Advisory</b><br><br>This is the next priority below Warning. It is generated when there is a risk of minor injury or discomfort to the patient.<br><br>It is also generated when measurement is not possible.  |
|                                   | <b>Information</b><br><br>This is a screen message that informs the user of the measurement status of the patient and the status of the ventilator.<br><br>There is no alarm sound and the alarm indicator does not light.                                |



The ventilator has an alarm escalation function that can raise the priority of an upper/lower limit alarm or technical alarm depending on the duration or value of the alarming parameter.



Alarm Escalation Settings

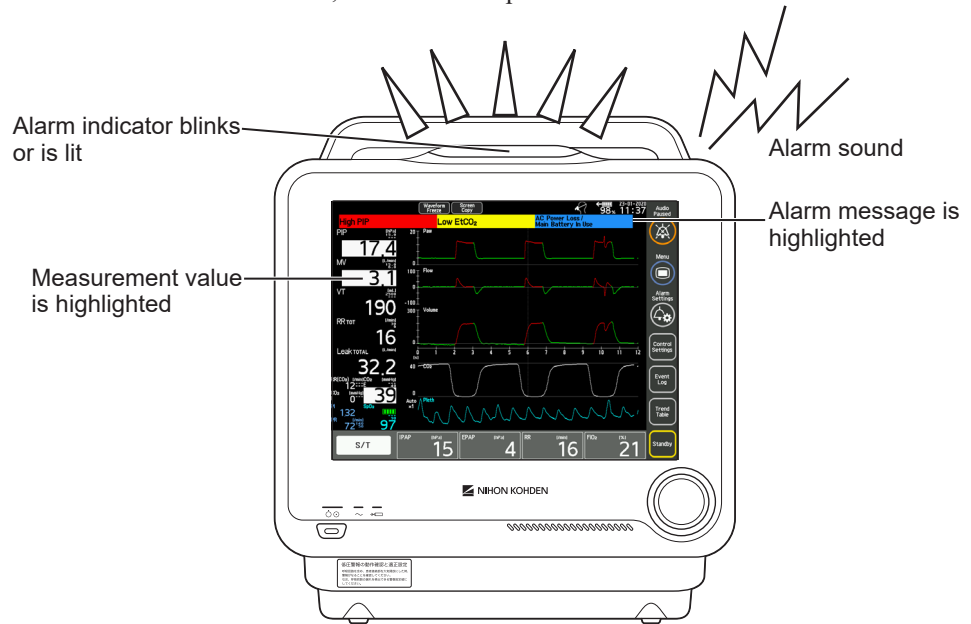
Refer to the following.

Administrator's Guide:

“Setting the Alarm Escalation Conditions” in Section 3

## Ventilator Operation When an Alarm Occurs

When an alarm occurs, the ventilator operates as follows.



The ventilator operation for each alarm priority is shown in the following table.

The initial values are shown in gray highlighting.

| Priority                 | Alarm Sound <sup>1</sup>                  | Alarm Message on the Screen <sup>1</sup>   | Alarm Indicator <sup>1</sup> |
|--------------------------|---|--|------------------------------|
| Crisis                   | IEC standard<br>caf-af                    | Highlighted red message                    | Blinking red                 |
|                          | NK1 sound<br>Continuous pip sound         |  |                              |
|                          | NK2 sound<br>Continuous ping sound        |  |                              |
| Warning                  | IEC standard<br>caf                       | Highlighted yellow<br>or<br>orange message | Blinking yellow              |
|                          | NK1 sound<br>Continuous bing bong sound   |  |                              |
|                          | NK2 sound<br>Continuous ding ding sound   |  |                              |
| Advisory                 | IEC standard<br>“af” every 20 seconds     | Highlighted cyan<br>or<br>yellow message   | Cyan or yellow message       |
|                          | NK1 sound<br>Single beep every 20 seconds |  |                              |
|                          | NK2 sound<br>Single beep every 20 seconds |  |                              |
| Information <sup>2</sup> | No sound                                  | White                                      | Not lit                      |

- <sup>1</sup> The alarm sound and display color can be changed in Alarm Sound Type and Alarm Priority Color on the [Display/Sound] page in the [Alarm] window in System Setup window.






Refer to the following.  
Administrator's Guide:  
"Alarm Settings - [Display/Sound] Page" in Section 3

- <sup>2</sup> Notifications are different from alarms. Notifications are messages with information about the measurement status of the patient and the status of the ventilator.

## Alarm Control Icons

If you pause the sound of a currently generated alarm or turn off the alarm function, the following alarm control icons are displayed on the window.

| Screen Icon   | Name                         | Explanation  |
|---|------------------------------|--|
|    | <b>Audio paused</b>          | Alarm sounds are temporarily paused.<br>After the [Audio Paused] key is selected, an audio pause icon is displayed beside the alarm messages for alarms that occur during the audio pause.<br>While the alarms are paused, an "Audio Paused" message and the remaining pause time (00:00) are displayed at the upper left of the screen. |
|  | <b>Audio off</b>             | Alarm sounds are paused indefinitely.<br>After the [Audio Paused] key is selected, if there is a technical alarm which has the "Silence" operation type <sup>1</sup> , an audio pause icon is displayed beside the alarm message.  |
|  | <b>Alarm off<sup>2</sup></b> | When an upper or lower limit alarm is set to Off, this icon is displayed next to its measurement value.  |

- <sup>1</sup> For the operation type after alarm pause, refer to the following.



Refer to "Operation After Audio Pause" (p. 9-13).

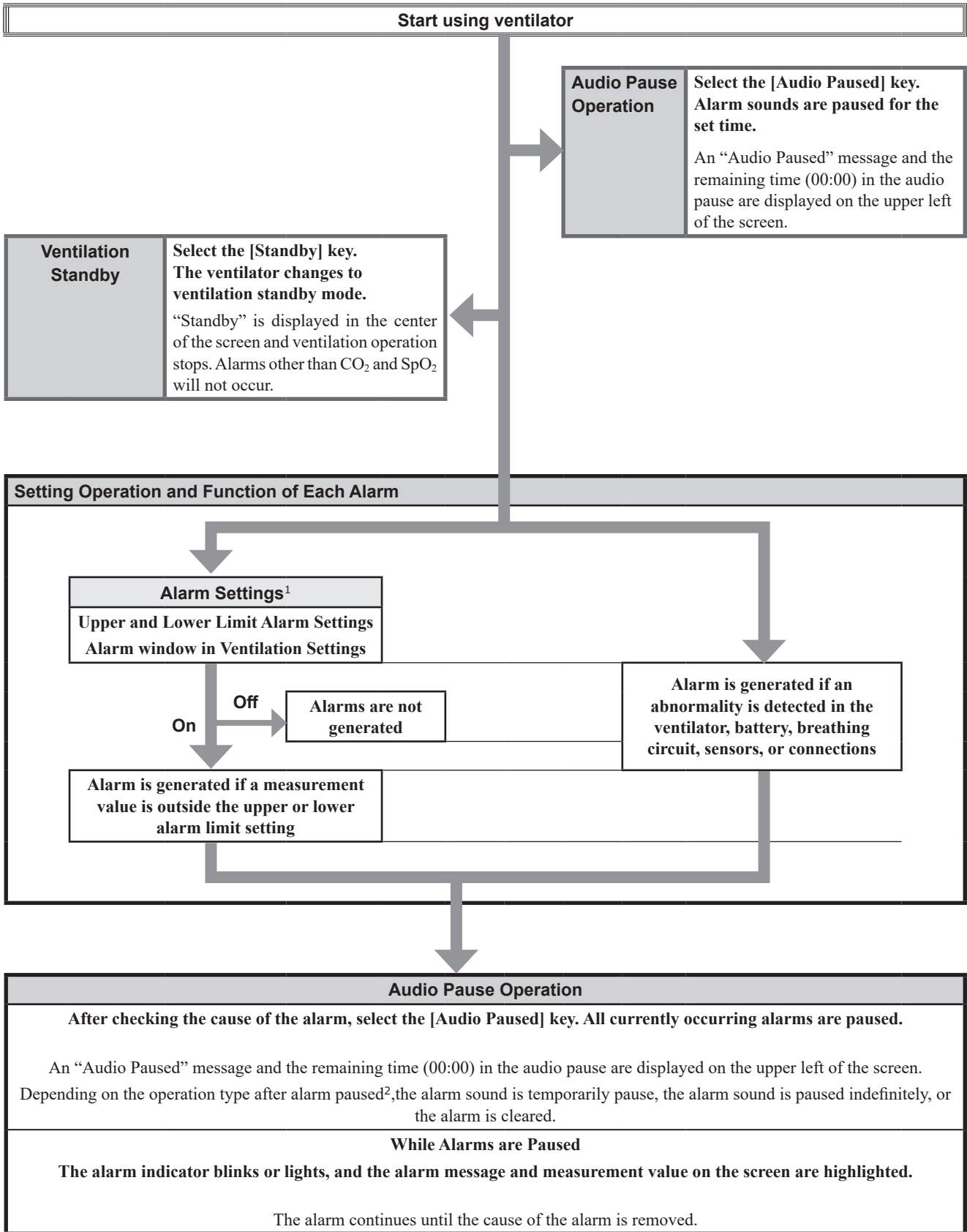
- <sup>2</sup> The Alarm off icon is displayed when the Limit Display is set to any setting other than Values on the [Display/Sound] page in the [Alarm] window in System Setup window.



Refer to the following.  
Administrator's Guide:  
"Alarm Settings - [Display/Sound] Page" in Section 3



# Flow of Alarm Generation



<sup>1</sup> The upper and lower limit alarm settings are fixed for some parameters depending on the control settings.



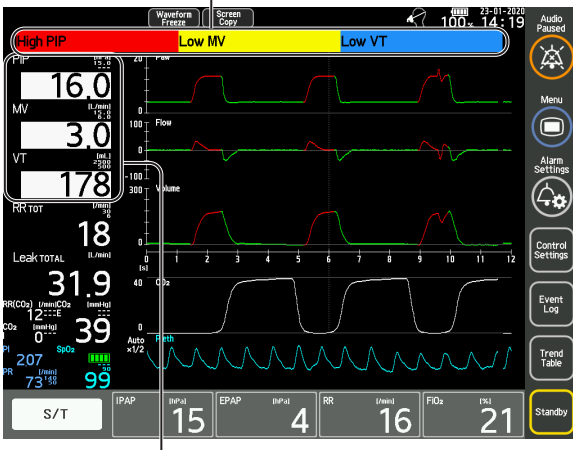
<sup>2</sup> For the operation type after alarm pause, refer to the following.



Refer to "Operation After Audio Pause" (p. 9-13).

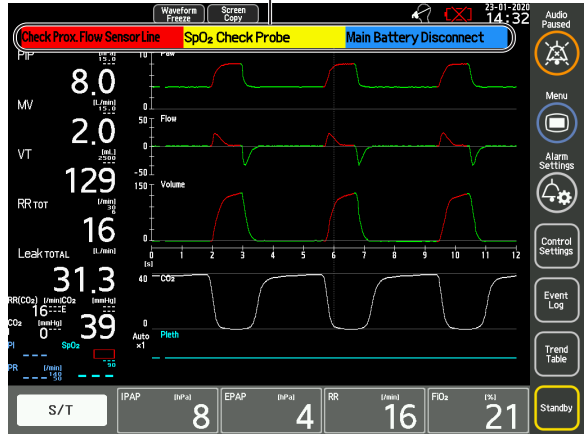
# List of Alarms—Ventilator Operation and Screen Display Examples

## Upper and Lower Limit Alarms

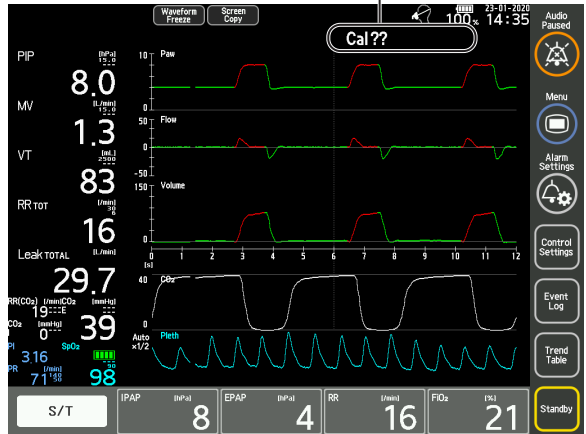
| Explanation  | Screen Examples   |
|--|---|
| <p>An upper or lower limit alarm occurs when the measured value of a parameter exceeds the preset upper or lower limit alarm.</p> <p>Some parameters have fixed upper and lower limits.</p> <p>When an upper or lower limit alarm occurs, the measured value is highlighted and the alarm message is highlighted at the top of the screen.</p> <p>The position of the alarm message depends on the priority of the alarm.</p> <p>The color or highlight color of the measurement value and alarm message can be set in System Setup window.</p> <p> Refer to the following.<br/>Administrator's Guide:</p> <ul style="list-style-type: none"> <li>• “[Display] Page - ‘Highlight Color’” in Section 3</li> <li>• “[Display/Sound] Page - Alarm Priority Color” in Section 3</li> </ul> <p>The alarm priority of each parameter can be selected in System Setup window.</p> <p> Refer to the following.</p> <ul style="list-style-type: none"> <li>• “Alarm Types” (p. 9-3)</li> <li>• “Screen Messages” in Section 13</li> <li>• Administrator's Guide: <ul style="list-style-type: none"> <li>• “[Display] Page” in Section 3</li> <li>• “[Vent Alarm Priority] Page” in Section 3</li> <li>• “[Vital Alarm Priority] Page” in Section 3</li> </ul> </li> </ul> | <p>Messages are highlighted</p>  <p>Measurement values are highlighted</p> <p>Messages and measured values are highlighted</p> |



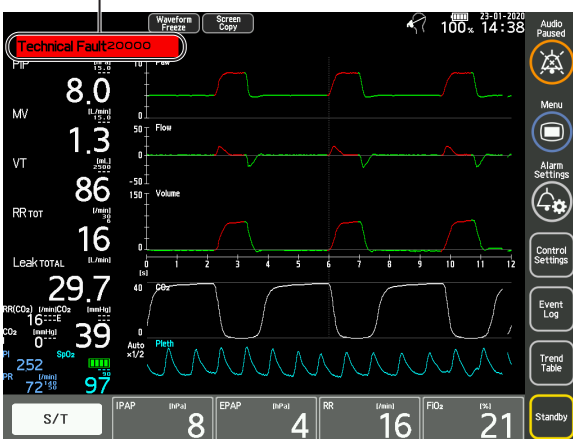
# Technical Alarms

| Explanation  | Screen Examples  |
|--|--|
| <p>Technical alarms are related to abnormality in the ventilator, battery, breathing circuit and sensor as well as connection status.</p> <p>When a technical alarm occurs, a highlighted alarm message is displayed at the top of the screen.</p> <p>The position of the alarm message depends on the priority of the alarm.</p> <p>The color or highlight color of the measurement value and alarm message can be set in System Setup window.</p> <p>Refer to the following.<br/>Administrator's Guide:</p> <ul style="list-style-type: none"> <li>• “[Display] Page - Highlight Color” in Section 3</li> <li>• “[Display/Sound] Page - Alarm Priority Color” in Section 3</li> </ul> <p>The priority of each item can be selected in System Setup window.</p> <p>Refer to the following.</p> <ul style="list-style-type: none"> <li>• “Alarm Types” (p. 9-3)</li> <li>• “Screen Messages” in Section 13</li> <li>• Administrator's Guide: “[Technical Priority] Page” in Section 3</li> </ul> | <p>Messages are highlighted</p>  <p>Messages are highlighted</p> |

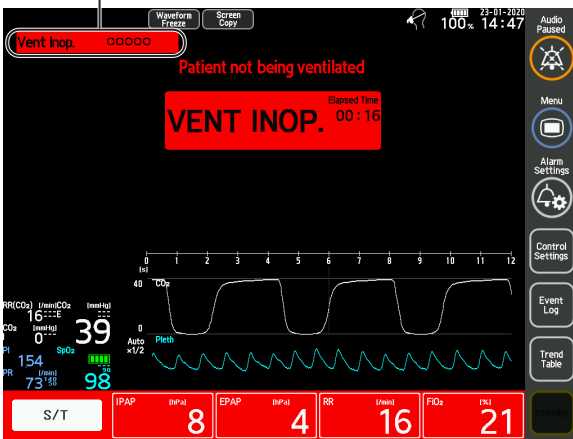
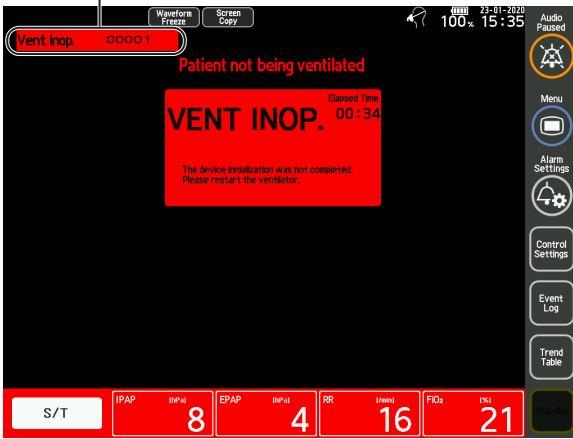
# Information (Notifications)

| Explanation  | Screen Examples  |
|--|--|
| <p>Information (notifications) related to the ventilator, battery, breathing circuit, sensor, and connection condition is displayed in white letters in the low priority position at the top of the screen.</p> <p>There is no alarm sound, blinking alarm indicator, or message highlighting.</p> <p>However, if there are two or more information items, the messages are displayed alternately.</p> <p>For details about information messages (notifications), refer to Section 13 “Troubleshooting”.</p> | <p>Displays in white letters in the low priority position.</p>  <p>Messages are displayed in white letters</p> |

## Technical Fault Alarms

| Explanation  | Screen Examples  |
|--|--|
| <p>This occurs when abnormality of the ventilator is detected.</p> <p>The alarm sound and alarm indicator operate as high priority and the “Technical Fault xxxxx” message and error code are displayed in the high priority position.</p> <p>NOTE: When a Technical Fault alarm occurs, secure the patient respiration with an alternative means of breathing assistance. Inform the Nihon Kohden representative of the error code on the screen.</p> <p>Ventilation operation continues even while a Technical Fault alarm occurs.</p> | <p>High priority position is highlighted</p>  <p>Message and error code is highlighted</p> |

## Vent Inop. Alarm

| Explanation  | Screen Examples   |
|--|---|
| <p>This occurs when abnormality in the ventilator is detected and ventilation cannot continue.</p> <p>When a Vent Inop. alarm occurs, immediately stop ventilation and display the VENT INOP. window.</p> <p>The alarm sound and alarm indicator operate as high priority and the “Vent Inop. xxxxx” message and error code are displayed in the high priority position.</p> <p>NOTE</p> <ul style="list-style-type: none"> <li>When a Vent Inop. alarm occurs, secure the patient respiration with an alternative means of breathing assistance. Inform the Nihon Kohden representative of the error code on the screen.</li> <li>When a message recommending restarting the ventilator is displayed at the same time as the Vent Inop. alarm, immediately restart the ventilator.</li> </ul> <p>If a Vent Inop. alarm occurs during an audio pause period, the audio pause is ended.</p> | <p>High priority position is highlighted</p>  <p>Message and error code is highlighted</p> <p>High priority position is highlighted</p>  <p>Message and error code are highlighted<br/>Message recommending restarting the ventilator</p> |



# Alarm Priority—When More than One Alarm Occurs at the Same Time

The ventilator operates as follows according to the alarm priority.

## Alarm Sound and Alarm Indicator

If alarms with different priorities occur at the same time, the alarm sounds for the highest priority alarm and the alarm indicator blinks or lights.

## Alarm Messages on the Screen

Messages are displayed on the main screen as shown below in the position corresponding to the alarm priority.

**Crisis**  
(Message is highlighted)

**Warning**  
(Message is highlighted)

**Advisory (Message is highlighted)**  
or Information (Notification)

Upper or lower limit alarm (Measured value is highlighted)

## Temporarily Pausing the Alarm Sound

The alarm sound can be temporarily paused in advance when an alarm is expected to occur, for example, when replacing or temporarily removing the breathing circuit from the patient. When the set alarm pause time elapses, the alarm sound resumes.

Alarm functions other than alarm sound (alarm indicator blinking and lighting, alarm messages, and highlighted display of measured value) are not paused.

### WARNING

While an Audio Paused message is displayed, there is no sound for all alarms. Be careful when you pause the alarm.

## Audio Paused Time Setting

On the [Audio Paused] page in the [Alarm] window in System Setup window, set the Audio Paused Time (1 or 2 min).



Refer to the following.

Administrator's Guide:

“Alarm Settings - [Audio Paused] Page” in Section 3

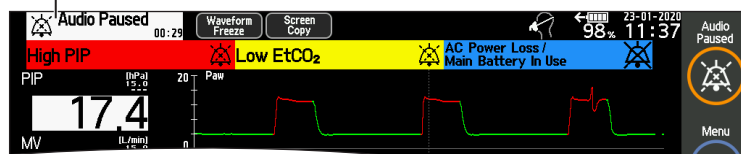
9

## How To Pause Alarm Sound

Select the [Audio Paused] operation key to temporarily<sup>1</sup> pause the currently occurring alarm sound.

The operation after audio pause depends on the alarm.<sup>2</sup>

Audio paused icon and the remaining pause time are displayed.



The “Audio Paused” message is displayed at the top of the screen until audio pause is canceled or the remaining pause time elapses.

If a Vent Inop. alarm occurs while audio is paused, the audio pause ends.

<sup>1</sup> On the [Audio Paused] page in the [Alarm] window in System Setup window, set the Audio Paused Time (1 or 2 min).



Refer to the following.

Administrator's Guide:

“Alarm Settings - [Audio Paused] Page” in Section 3

<sup>2</sup> The operation after audio pause depends on the alarm that occurred. Refer to the following section for details about operation after audio pause.




Refer to “Operation After Audio Pause” (p. 9-13).




## If Another Alarm Occurs during Alarm Pause

Alarms that occur during audio pause are displayed as follows regardless of the operation type after audio pause.

| Notified by     | Operation  |
|-----------------|--|
| Alarm sound     | Pause  |
| Alarm indicator | Blinking or lit with the color of the highest priority   |
| Alarm message   | <ul style="list-style-type: none"> <li>• Displayed in the position and color for the priority of the alarm</li> <li>• The audio paused icon () is displayed beside the message</li> </ul> |

### Alarm cleared during audio paused

If an alarm occurs during the alarm pause period and the cause of the alarm is removed during the pause period, the alarms are cleared and there is no notification by alarm sound. For those alarms, an alarm non-notification icon () is displayed on the Event Log window of the review window.



Refer to “Event Log” in Section 11.




## Ending the Audio Pause

The audio pause ends when any of the following conditions are met.

- The set pause time (1 or 2 minutes) has passed
- The [Audio Paused] key is selected again while the alarms are paused
- A Vent Inop. alarm occurs

## Operation After Audio Pause

If you select the [Audio Paused] key when an alarm occurs (notification by alarm sound, alarm indicator and alarm message), the alarm notification function of the ventilator operates as follows for each alarm operation type.

|                          | Alarm Notification Function | Operation  |   |             |
|--------------------------|-----------------------------|--|---|-------------|
|                          |                             | Re-alarm   | Silence   | Termination |
| During Alarm Pause       | Alarm Sound                 | Paused temporarily   | Paused indefinitely   | Paused      |
|                          | Alarm Indicator             | Blinking or lit  |   | Not lit     |
|                          | Alarm Message               | Display<br><b>Low RR<sub>TOT</sub></b>  | Display<br><b>SpO<sub>2</sub> Check Probe</b>  | Termination |
|                          | Measurement Value           | Highlighted  | —   | —           |
| After Audio Pause Period | Alarm Sound                 | If the alarm condition continues, the notification by alarm sound returns.   | The audio pause continues for as long as the alarm condition continues.   | —           |
|                          | Alarm Indicator             | Blinking or lit  |   | —           |
|                          | Alarm Message               | Display<br><b>Low RR<sub>TOT</sub></b>   | Display<br><b>SpO<sub>2</sub> Check Probe</b>  | —           |
|                          | Measurement Value           | Highlighted  | —   | —           |

The operation depends on the alarm that occurred. For the operation of each alarm, refer to Section 13 “Troubleshooting”.



Refer to “Screen Messages” in Section 13.



## Alarm Sound Suppression at Startup

When the ventilator is turned on, it starts in the audio paused condition.

The audio pause ends when any of the following conditions are met.

| Alarm Activation Delay Setting | Condition  |
|--------------------------------|--|
| Auto                           | <ul style="list-style-type: none"><li>• Ventilation operation starts</li><li>• CO<sub>2</sub> and/or SpO<sub>2</sub> is measured normally (measurement value is displayed)</li></ul>   |
| 1 min, 2 min                   | <ul style="list-style-type: none"><li>• Ventilation operation starts</li><li>• One or both of the following conditions continue for the set time<ul style="list-style-type: none"><li>- CO<sub>2</sub> is measured normally</li><li>- SpO<sub>2</sub> is measured normally</li></ul></li></ul> |

The automatic alarm return conditions depend on Alarm Activation Delay on the [Audio Paused] page in the [Alarm] window in System Setup window.



Refer to the following.

Administrator's Guide:

"Alarm Settings - [Audio Paused] Page" in Section 3

# Alarm Settings and Alarm Off Icon

## Alarm Setting

The upper and lower alarm limits are displayed on the right side of the measurement value of each ventilation parameter and vital sign parameter.

When the alarm function is set to Off, the alarm setting is displayed as “---”.

NOTE: When starting ventilation operation, be sure to confirm the settings on the Alarm Settings window.



- To change upper and lower limit alarm settings, select the [Alarm Settings] key to display the Alarm Settings window.
- To display the upper and lower alarm limit settings, set this to Limit Display on the [Display/Sound] page in the [Alarm] window in System Setup window.

Refer to the following.

Administrator's Guide:

“Alarm Settings - [Display/Sound] Page” in Section 3

## Alarm Off Icon

When display of the upper alarm limit and/or lower alarm limit is set to Off, a bright or dim alarm Off mark can be displayed instead.



The alarm Off mark is set in Limit Display on the [Display/Sound] page in the [Alarm] window in System Setup window.

Refer to the following.

Administrator's Guide:

“Alarm Settings - [Display/Sound] Page” in Section 3

| Upper and Lower Alarm Limit Settings | Alarm Off Icon Display   |
|--------------------------------------|--|
| Mark Bright                          | <p>The image shows a black display with white text. At the top, 'RR(CO<sub>2</sub>) [l/min]CO<sub>2</sub> [mmHg]' is displayed. Below this, '12' and 'E' are shown. In the center, a large '38' is shown. To the right of '38' is a bright alarm off icon (a star with a slash). A line points from the text 'Alarm off icon (bright)' to this icon. Other parameters shown include 'PI 278', 'SpO<sub>2</sub>' with a green bar, and 'PR 80'.</p> |
| Mark Dim                             | <p>The image shows a black display with white text, identical to the one above. However, the alarm off icon (a star with a slash) is dimmed. A line points from the text 'Alarm off icon (dim)' to this icon.</p>  |



## Changing Upper and Lower Limit Alarms

The upper and lower limit alarms of ventilation parameters and vital sign parameters can be changed on the [Alarm Settings] window. The [Alarm Settings] window shows the upper and lower limit alarms for all parameters.

In addition, an alarm master for each patient type can be set in advance. The upper and lower limit alarms are initialized to the preset alarm master settings when [New Adult] or [New Pediatric] is selected on the Patient Selection window after startup.



Refer to the following.

- “Selecting the Patient Type” in Section 5
- Administrator’s Guide: “Setting Masters” in Section 3

### Measurement Precautions

If you try to set the upper limit to a value above the maximum, or a lower limit to a value below the minimum, the alarm for that limit is set to Off.

#### Example: Setting the upper and lower limit alarms for total respiratory rate

Upper limit: ... → 148 → 149 → 150 → Off

Lower limit: ... → 2 → 1 → 0 → Off

#### CAUTION

When the alarm limit is set to Off, there will be no alarm for that limit. Be careful when you set the alarm limit to Off.



The alarm cannot be set to Off for some parameters.

---

## Setting the Upper and Lower Alarm Limits

The upper and lower limit alarms are set individually for each parameter.

- 1 Select the [Alarm Settings] operation key to display the Alarm Settings window.

## 2 Set the upper and lower limit alarms.

- 1) Select the upper or lower limit for the parameter item to be set. The upper and lower limit alarms setting window is displayed.

**Example: High PIP alarm setting**

The Alarm Settings window displays the following parameters and values:

|                |      |                      |    |                              |     |                             |     |
|----------------|------|----------------------|----|------------------------------|-----|-----------------------------|-----|
| PIP (mPa)      | 50.0 | Apnea (s)            | 20 | EtCO <sub>2</sub> (mmHg)     | Off | SpO <sub>2</sub>            | Off |
| MV (L/min)     | 7.9  | FiO <sub>2</sub> (%) | 28 | FiCO <sub>2</sub> (mmHg)     | Off | PR (mmHg)                   | 140 |
| VT (mL)        | 15.0 | RR (1/min)           | 18 | RR(CO <sub>2</sub> ) (1/min) | Off | Apnea(CO <sub>2</sub> ) (s) | 20  |
| VT (mL)        | 1.5  | RR TOT (1/min)       | 20 |                              |     |                             |     |
| VT (mL)        | 2.0  |                      |    |                              |     |                             |     |
| VT (mL)        | 2500 |                      |    |                              |     |                             |     |
| VT (mL)        | 92   |                      |    |                              |     |                             |     |
| RR TOT (1/min) | 16   |                      |    |                              |     |                             |     |
|                | 6    |                      |    |                              |     |                             |     |

The callout box for MV shows: Measurement value display (1.5), Upper limit (15.0), Alarm priority (1.5), and Lower limit (2.0).

- 2) Turn the operation knob to set the upper or lower limit.

### Upper and lower limit alarms setting window

Current measurement value

The setting window for High MV (L/min) shows a current measurement value of 2.4. The upper limit area is highlighted in orange with a value of 16.0. The slider ranges from 0.2 to 30.0.

**Upper or lower limit area**  
Orange highlighted while entering a new value.

Touch [▲] or [▼] to increase or decrease the setting by one unit at a time. If you keep touching the key, the setting changes continuously.

**[Cancel] key**  
Cancels and returns to the previous upper or lower limit alarm.

**[Set] key**  
Applies the upper or lower limit alarm.

**Measurement value display**  
Shows the current measurement value.

**Slider**  
Touch above or below the slider, or slide the bar up or down to set the upper or lower limit.



To turn off the upper limit alarm, touch [▲] to set the value above the upper limit range. To turn off the lower alarm limit, touch [▼] to set the value below the lower limit range. This turns the upper limit alarm or lower limit alarm to Off.

- 3) Press the operation knob to confirm the change and close the upper and lower limit alarms setting window.

The upper and lower limits can also be confirmed by the following operations.

- Touch the [Set] key
- Touch the upper or lower limit area

- 4) Repeat steps 1) to 3) to confirm the upper and lower limits of other parameters.

## 3 Select [X] to close the Alarm Settings window and return to the Menu window.

Or, touch anywhere outside the Alarm Settings window to return to the Menu window.



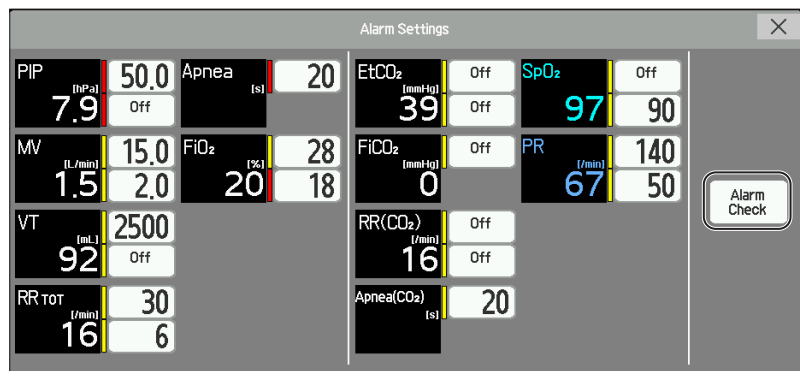
## Testing the Alarms

The alarm indicator lighting and the alarm sound can be tested.

### ⚠ CAUTION

When the ventilator is turned on and periodically thereafter, check that the red, yellow, cyan and green alarm indicator lamps blink and there is a sound produced when an alarm occurs.

- 1 Select the [Alarm Settings] operation key to display the Alarm Settings window.
- 2 Select the [Alarm Check] key to start the alarm check.



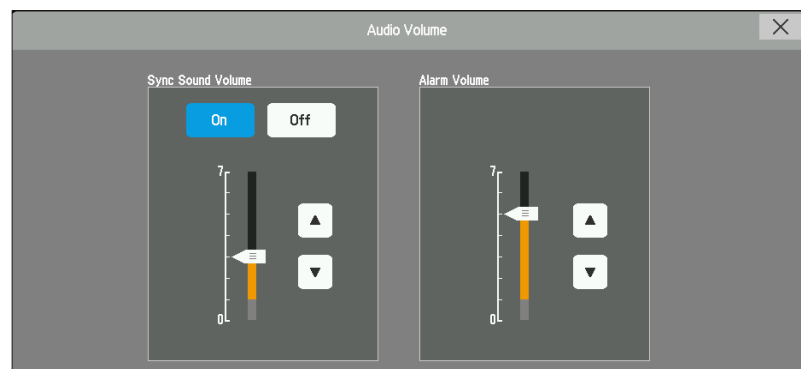
- 3 Check that the alarm indicator lights and that an alarm sound is generated.
  - Check that the alarm indicator lights in red → yellow → cyan → green.
  - Check that an alarm sound is generated.

When the nurse call connection cable is connected, alarms generated when checking the alarm are also output as a nurse call.

## Setting the Alarm Sound Volume


The alarm sound volume can be set on the Audio Volume window in “Setup”.

Set an alarm volume which is appropriate for the environment of use.



 Refer to “Setting the Alarm Sound” in Section 12.


The minimum alarm volume which can be set is limited by Alarm Minimum Volume on the [Audio Volume] page in System Setup window.

 Refer to the following.  
Administrator's Guide  
“System Settings - [Audio Volume] Page” in Section 3

## Displaying the Alarm Log

Alarms that occurred, alarm setting changes and other items are recorded in the alarm event log.

For details about the event log, refer to “Event Log” in Section 11.

 Refer to “Event Log” in Section 11.

## Alarm Messages

For the message list of generated alarms, refer to “Screen Messages” in Section 13.

 Refer to “Screen Messages” in Section 13.



# 10

## Parameters

|   |       |   |       |
|---|-------|---|-------|
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| Inspection of Measuring Accuracy<br>(Precise Method) .....  | 10-13 |   |       |



## CO<sub>2</sub> Monitoring

The ventilator uses the mainstream method to measure and monitor CO<sub>2</sub>. The mainstream method measures CO<sub>2</sub> by connecting to the MULTI socket on the ventilator after a CO<sub>2</sub> sensor kit (TG-900P, TG-920P or TG-980P) is attached to the patient's breathing circuit using the patient interface (mask), airway adapter or nasal adapter.

CO<sub>2</sub> can be measured during ventilation and during ventilation standby. The CO<sub>2</sub> sensor kits used with the ventilator can measure CO<sub>2</sub> by either of the following 2 measurement methods.

- Semi-quantitative method
- Quantitative method

When using a CO<sub>2</sub> sensor kit, refer to the operator's manual of the CO<sub>2</sub> sensor kit.



Refer to the CO<sub>2</sub> Sensor Kit Operator's Manual.

### CO<sub>2</sub> Monitoring Precautions

Precautions differ depending on the CO<sub>2</sub> sensor kit being used. Refer to the operator's manual of the CO<sub>2</sub> sensor kit.

#### **⚠ WARNING**

When using the airway adapter or nasal adapter on a patient with low ventilatory volume, the CO<sub>2</sub> may mix in the inspiration due to the airway adapter's or nasal adapter's dead space, resulting in inaccurate measured values or difficulty in detecting no breath. Take the dead space into account when performing ventilation. If that dead space is too much for this patient, appropriate ventilation might be impossible.

#### **⚠ CAUTION**

When the "Sensor Fault" or "Module Fault" message is displayed, check the CO<sub>2</sub> sensor kit and replace it if necessary. CO<sub>2</sub> cannot be monitored while the message is displayed.

#### **⚠ WARNING**

Position the cable so that it cannot wind around the face or the neck of the patient.

#### **⚠ CAUTION**

Follow the CAUTION label on the CO<sub>2</sub> gas cylinder.

#### **⚠ CAUTION**

Select an airway adapter or nasal adapter that is appropriate for the patient weight and ventilation volume. If an inappropriate airway adapter or nasal adapter is used, the resistance in the respiratory circuit may increase and it may cause incorrect measurement value.

CO<sub>2</sub> monitoring precautions  
TG-900P CO<sub>2</sub> sensor kit

#### **⚠ CAUTION**

Supply adequate oxygen when measuring CO<sub>2</sub> partial pressure of a patient connected to a Jackson Rees, Mapleson D or any other breathing circuit where CO<sub>2</sub> gas may be present during inspiration. The inspiration zero compensation method measures CO<sub>2</sub> partial pressure based on the assumption of no CO<sub>2</sub> gas in the inspired air; it assumes CO<sub>2</sub> partial pressure 0 mmHg (0 kPa) in the inspiration of every respiration. If the inspired air contains CO<sub>2</sub> gas, the displayed CO<sub>2</sub> value is lower than the actual value.

#### **⚠ CAUTION**

The CO<sub>2</sub> data may be inaccurate when monitoring a patient with an extremely high respiration rate or irregular respiration. Read the measured values carefully.

#### **⚠ CAUTION**

The measured value may be incorrect when the operating temperature changes greatly.

CO<sub>2</sub> monitoring precautions  
TG-980P CO<sub>2</sub> sensor kit

**⚠ CAUTION**

The measured value may be incorrect when the operating temperature changes greatly.

CO<sub>2</sub> monitoring precautions  
TG-920P CO<sub>2</sub> sensor kit

**⚠ CAUTION**

Supply adequate oxygen when measuring CO<sub>2</sub> partial pressure of a patient connected to a Jackson Rees, Mapleson D or any other breathing circuit where CO<sub>2</sub> gas may be present during inspiration. The inspiration zero compensation method measures CO<sub>2</sub> partial pressure based on the assumption of no CO<sub>2</sub> gas in the inspired air; it assumes CO<sub>2</sub> partial pressure 0 mmHg (0 kPa) in the inspiration of every respiration. If the inspired air contains CO<sub>2</sub> gas, the displayed CO<sub>2</sub> value is lower than the actual value.

**⚠ CAUTION**

When measuring CO<sub>2</sub> partial pressure of a patient with an oxygen mask, set the oxygen supply to 5 L/min or more. If CO<sub>2</sub> gas remains in the oxygen mask and mixes with the inspired air, the measured value may be lower than the actual value.

**⚠ CAUTION**

The measured value may be incorrect when the operating temperature changes greatly.

CO<sub>2</sub> monitoring precautions  
Precautions when using the YG-122T nasal adapter

**⚠ WARNING**

The only oxygen cannula that can be used with YG-122T is #1103 manufactured by Hudson RCI. Do not use any other oxygen cannula. Other oxygen cannulas cannot be attached and oxygen cannot be delivered to the patient through the nostrils.

**⚠ WARNING**

- When you use YG-122T together with an oxygen cannula, check that the oxygen cannula is correctly attached on the patient by referring to other parameters and by observing the patient periodically.
- If arterial oxygen partial pressure does not increase, immediately stop using the oxygen cannula with the CO<sub>2</sub> sensor kit and select another way to supply oxygen.

**⚠ WARNING**

Check that the oxygen cannula tube is not bent, broken, or blocked by the nasal tube. If the ends of the oxygen cannula tube turn too far up or down, it causes insufficient O<sub>2</sub> supply or the CO<sub>2</sub> value may be incorrect.

**⚠ CAUTION**

When using the YG-121T or YG-122T nasal adapter on a patient, observe the patient condition all the time. The mouth guide touches the mouth and may cause pressure sores.

Precautions when using the YG-221T or YG-231T nasal adapter

**⚠ WARNING**

Before and during use, check that the oxygen cannula tube is firmly connected to the oxygen supply unit and that the oxygen tube is not bent, broken, or blocked. Failure to do so may cause insufficient oxygen delivery to the patient.

**⚠ WARNING**

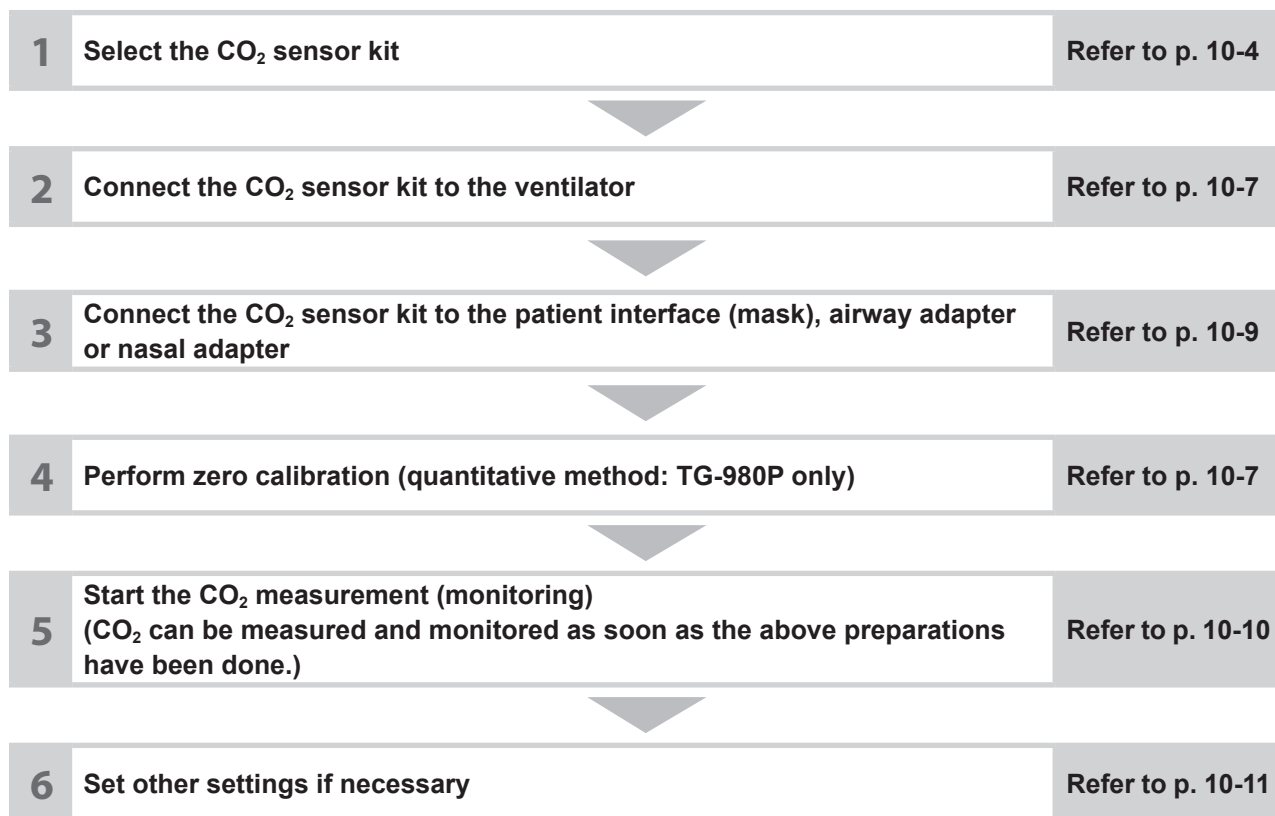
If arterial oxygen partial pressure does not increase when using the YG-221T or YG-231T nasal adapter to deliver oxygen to the patient, immediately stop using the nasal adapter and select another way to deliver oxygen. Failure to do so may cause insufficient oxygen delivery to the patient.

NOTE: Measurement inaccuracies may occur if the CO<sub>2</sub> sensor kit is used as follows:

- In an environment containing high-concentration N<sub>2</sub>O anesthetic gas (nitrogen oxide gas)
- In an environment with sudden temperature changes
- In an environment with excess condensation
- When used with patients with irregular spontaneous breathing



## Measurement Flow



## Selecting the CO<sub>2</sub> Sensor Kit

### **WARNING**

Only use parts and consumables specified by Nihon Kohden for the ventilator. Refer to the operator's manual of the parts and consumables to handle and use them. Otherwise, the performance and safety of the ventilator cannot be guaranteed.

The TG-900P, TG-920P or TG-980P mainstream method CO<sub>2</sub> sensor kit contains an integrated sensor and measurement circuit for measuring CO<sub>2</sub>.

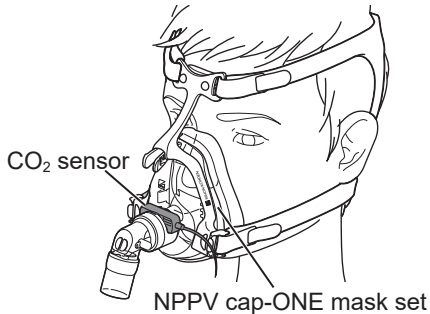
Select the CO<sub>2</sub> sensor kit and patient interface according to the ventilation operation (ventilation start time/ventilation standby time), applicable body weight, dead space volume, and purpose of ventilation.



Refer to "Sensors and Probes" in Section 16.

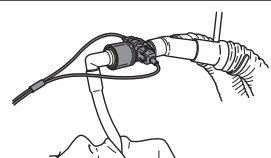
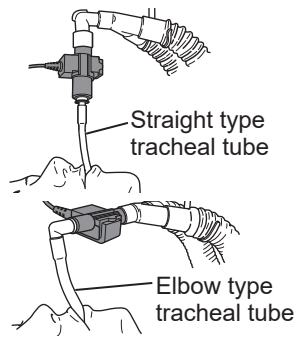
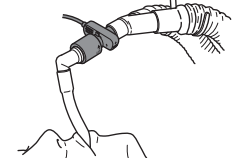
## Attachment Examples of the CO<sub>2</sub> Sensor Kits

### During Ventilation Operation (Noninvasive Positive Pressure Ventilation)

| Measurement Method  | CO <sub>2</sub> Sensor Kit Attachment Example |  | Patient Interface (Mask) (NPPV Mask) |
|---------------------|---|--|--------------------------------------|
| Quantitative Method | TG-980P                                       |  | VM-330Z NPPV cap-ONE mask set L      |
|                     |   |  | VM-331Z NPPV cap-ONE mask set M      |
|                     |   |  | VM-332Z NPPV cap-ONE mask set S      |
|                     |   |  | VM-333Z NPPV cap-ONE mask set XS     |

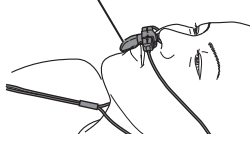
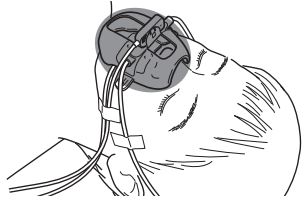
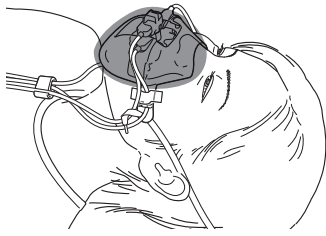
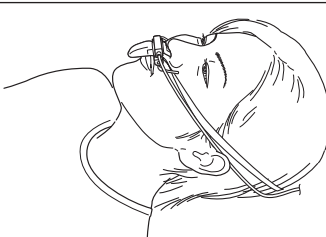
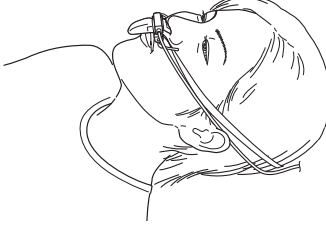
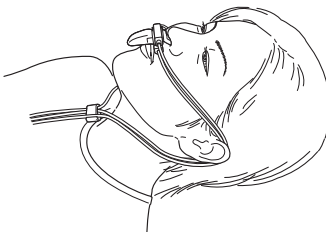
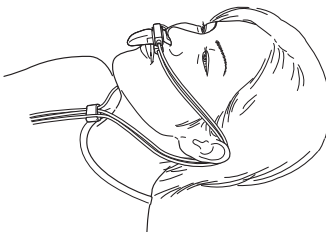

### During Ventilation Operation (Invasive Positive Pressure Ventilation)

NOTE: Make sure the CO<sub>2</sub> sensor does not touch the patient when installing during tracheal intubation.

| Measurement Method       | CO <sub>2</sub> Sensor Kit Attachment Example  | Airway Adapter or Nasal Adapter | Patient (Approximate Weight) | Dead Space Volume |
|--------------------------|--|---------------------------------|------------------------------|-------------------|
| Semi-quantitative Method | TG-920P<br> | YG-111T airway adapter          | 7 kg or more                 | 4 mL              |
|                          | TG-900P<br> | YG-101T airway adapter          | 10 kg or more                | 5 mL              |
| Quantitative Method      | TG-980P<br> | YG-211T airway adapter          | 7 kg or more                 | 4 mL              |

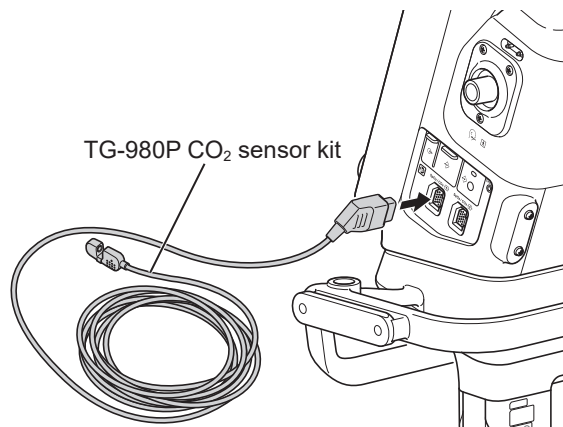


**During Ventilation Standby**

| Measurement Method       | CO <sub>2</sub> Sensor Kit Attachment Example |  | Airway Adapter or Nasal Adapter   | Patient (Approximate Weight) | Dead Space Volume |
|--------------------------|---|--|---|------------------------------|-------------------|
| Semi-quantitative Method | TG-920P                                       | YG-121T nasal adapter<br> | YG-120T nasal adapter (for nasal breathing)   | 10 kg or more                | 1.2 mL            |
|                          |   |  | YG-121T nasal adapter (for naso-oral breathing)                                     |                              |                   |
|                          |   |  | YG-122T nasal adapter (for oxygen cannula adjustment)                               |                              |                   |
| Quantitative Method      | TG-980P                                       |                           | YG-232T pediatric cap-ONE mask  | 20 to 40 kg                  | 3.5 mL            |
|                          |   |                          | YG-272T adult cap-ONE mask  | 30 kg or more                | 7 mL              |
|                          |   |                         | YG-282T large adult cap-ONE mask  | 40 kg or more                | 10 mL             |
|                          |   |                         | YG-220T adult cap-ONE nasal adapter   | —                            | —                 |
|                          |   |  |  |                              |                   |
|                          |   |                         | YG-221T adult cap-ONE nasal adapter   |                              |                   |
|                          |   |  |  |                              |                   |

## Connecting the CO<sub>2</sub> Sensor Kit to the Ventilator

When connecting the TG-980P CO<sub>2</sub> sensor kit



Connect the CO<sub>2</sub> sensor kit to the **MULTI socket** on the ventilator.

**NOTE:** The ventilator has 2 MULTI sockets, so connect the CO<sub>2</sub> sensor kit to either socket. The other socket can be used for measuring SpO<sub>2</sub>.



The composition shown in the illustration is an example. Refer to “Selecting the CO<sub>2</sub> Sensor Kit” (p. 10-4) for adapters and sensors that can be used in combination with each CO<sub>2</sub> sensor kit.

## Performing Zero Calibration Using a TG-980P CO<sub>2</sub> Sensor Kit

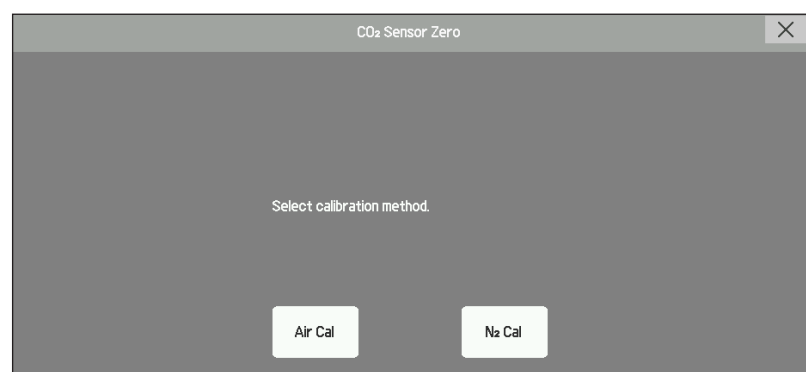
When using the TG-980P CO<sub>2</sub> sensor kit to perform quantitative method measurements, make sure to perform zero calibration in the following conditions.

- Before use
- Once a day
- When replacing any of the following:
  - Patient interface (mask)
  - Airway adapter
  - Nasal adapter
- When the operating environment temperature changes
- When the operating locations change

In addition to the above examples, perform zero calibration whenever necessary.

There are 2 zero calibration methods, “Air Cal” and “N<sub>2</sub> Cal”.

Perform zero calibration on the CO<sub>2</sub> Sensor Zero window.



### Air Cal

Expose the CO<sub>2</sub> sensor or airway adapter which is attached to the patient interface (mask) to the air and do zero calibration.

Use 0.5 mmHg as the CO<sub>2</sub> partial pressure in the air when performing zero calibration.



## N<sub>2</sub> Cal

Perform zero calibration by supplying N<sub>2</sub> gas to the airway adapter.

The method for supplying N<sub>2</sub> gas to the airway adapter depends on type of N<sub>2</sub> gas cylinder.

Refer to the manual for the N<sub>2</sub> gas cylinder.



Refer to N<sub>2</sub> Gas Cylinder Operator's Manual.

NOTE: N<sub>2</sub> calibration is not available when using the patient interface (mask). Perform air calibration instead.

## Calibrating by Air

Perform air calibration on the Circuit Check & Calibrations window ► CO<sub>2</sub> Sensor Zero window.



Refer to “Calibrating the CO<sub>2</sub> Sensor (Zero Calibration)” in Section 5.

- 1 Expose the CO<sub>2</sub> sensor or airway adapter which is attached to the patient interface (mask) to the air.
- 2 Select [Circuit Chk & Cal] on the Menu window ► [CO<sub>2</sub> Sensor Zero].
- 3 Select [Air Cal].
- 4 When the “Expose the CO<sub>2</sub> sensor to the air. Then press “Start”.” message appears, select [Start] to perform air calibration. When air calibration is complete, a message appears.

After zero calibration, when the CO<sub>2</sub> sensor or airway adapter which is attached to the patient interface (mask) is returned to the breathing circuit, CO<sub>2</sub> is ready to be measured and the ventilator starts monitoring the CO<sub>2</sub>.

## Calibrating by N<sub>2</sub> Gas

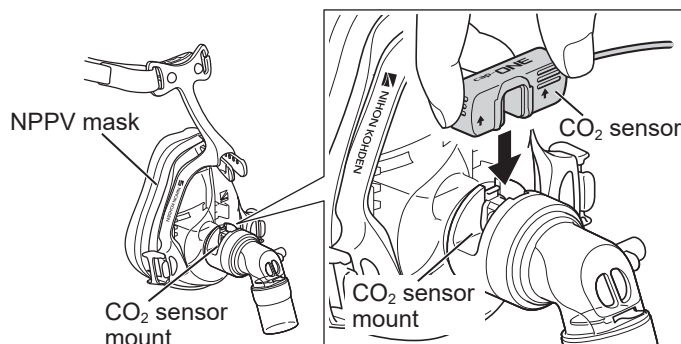
- 1 Connect the airway adapter that is fitted to the CO<sub>2</sub> sensor kit to the N<sub>2</sub> gas cylinder.
- 2 Select [Circuit Chk & Cal] on the Menu window ► [CO<sub>2</sub> Sensor Zero].
- 3 Select [N<sub>2</sub> Cal].
- 4 Flow the N<sub>2</sub> gas from the N<sub>2</sub> gas cylinder to the airway adapter.
- 5 When the “Flow N<sub>2</sub> Gas. Then press “Start”.” message appears, select [Start] to perform N<sub>2</sub> calibration. When N<sub>2</sub> calibration is complete, a message appears.

After zero calibration, when the airway adapter is returned to the breathing circuit, CO<sub>2</sub> is ready to be measured and the ventilator starts monitoring the CO<sub>2</sub>.

## Connecting the CO<sub>2</sub> Sensor Kit to the Patient Interface (Mask)

### During Ventilation Operation (Noninvasive Positive Pressure Ventilation)

Fit the CO<sub>2</sub> sensor to the NPPV mask's CO<sub>2</sub> sensor mount until a click is heard.  
The CO<sub>2</sub> sensor can be fit in either direction.



### During Ventilation Operation (Invasive Positive Pressure Ventilation) and Ventilation Standby

Refer to the operator's manual of the CO<sub>2</sub> sensor kit for airway adapter and nasal adapter connection methods.



Refer to CO<sub>2</sub> Sensor Kit Operator's Manual.



## Starting the CO<sub>2</sub> Measurement (Monitoring)

After the above preparations are finished, CO<sub>2</sub> will enter the measurement state and measurement and monitoring will begin.

### Measurement Precautions

#### CAUTION

When the “CO<sub>2</sub> Sensor Fault” or “CO<sub>2</sub> Adapter Fault” message is displayed, check the CO<sub>2</sub> sensor kit and replace it if necessary. CO<sub>2</sub> cannot be monitored while the message is displayed.

### Inspiration Zero Compensation Method Using the TG-900P or TG-920P CO<sub>2</sub> Sensor Kit

When atmospheric pressure decreases by 3.3 kPa, the measurement value will decrease by about 0.13 kPa (1 mmHg) at a CO<sub>2</sub> gas pressure of 5.33 kPa (40 mmHg).

- NOTE
- The ventilator automatically calibrates the sensor on a periodic basis. The sensor is also automatically calibrated in the following situations:
    - At the moment of exhaling during power on
    - When signals change suddenly due to temperature changes
  - When calibrating the sensor, the calibration waveform will be represented by a step-wise CO<sub>2</sub> waveform, but this has no impact on respiration rates and measurements.

### Single Wave Spectroscopic Method (Quantitative Method) Using the TG-980P CO<sub>2</sub> Sensor Kit

NOTE: Make sure to calibrate the CO<sub>2</sub> sensor in the following situations:

- When replacing the airway adapter
- When changing the type of airway adapter used
- When the operating environment temperature changes
- When operating locations change

Do it whenever necessary.

## Main Screen Example

CO<sub>2</sub> value  
Shows the CO<sub>2</sub> measurement value. Select the value to display the CO<sub>2</sub> window.

CO<sub>2</sub> waveform

Scale  
Shows the scale for the CO<sub>2</sub> waveform. Select the display area to display the scale setting window.

## Changing the CO<sub>2</sub> Settings

Change settings related to CO<sub>2</sub> monitoring.

Select [CO<sub>2</sub>] on the Menu window and change settings on the CO<sub>2</sub> window.

The CO<sub>2</sub> window can be displayed by selecting the CO<sub>2</sub> value on the main screen.

| Setting                                 | Description  |
|---|--|
| EtCO <sub>2</sub> Max Hold <sup>1</sup> | Sets the EtCO <sub>2</sub> maximum display holding time. |
| Scale                                   | Sets the CO <sub>2</sub> waveform scale.                 |

<sup>1</sup> This can be set when using the TG-980P.

- CO<sub>2</sub> units (mmHg and kPa) can be changed on the [Units] window in the System Configuration window.
- The display color for measurement values and CO<sub>2</sub> waveform can be set on the [Vital] tab in the [Color] page of the System Setup window.



Refer to the following.

Administrator's Guide:

- "Unit Settings" in Section 2
- "Setting Colors" in Section 3

Displays the waveform being measured.

The selected item is displayed in light blue.



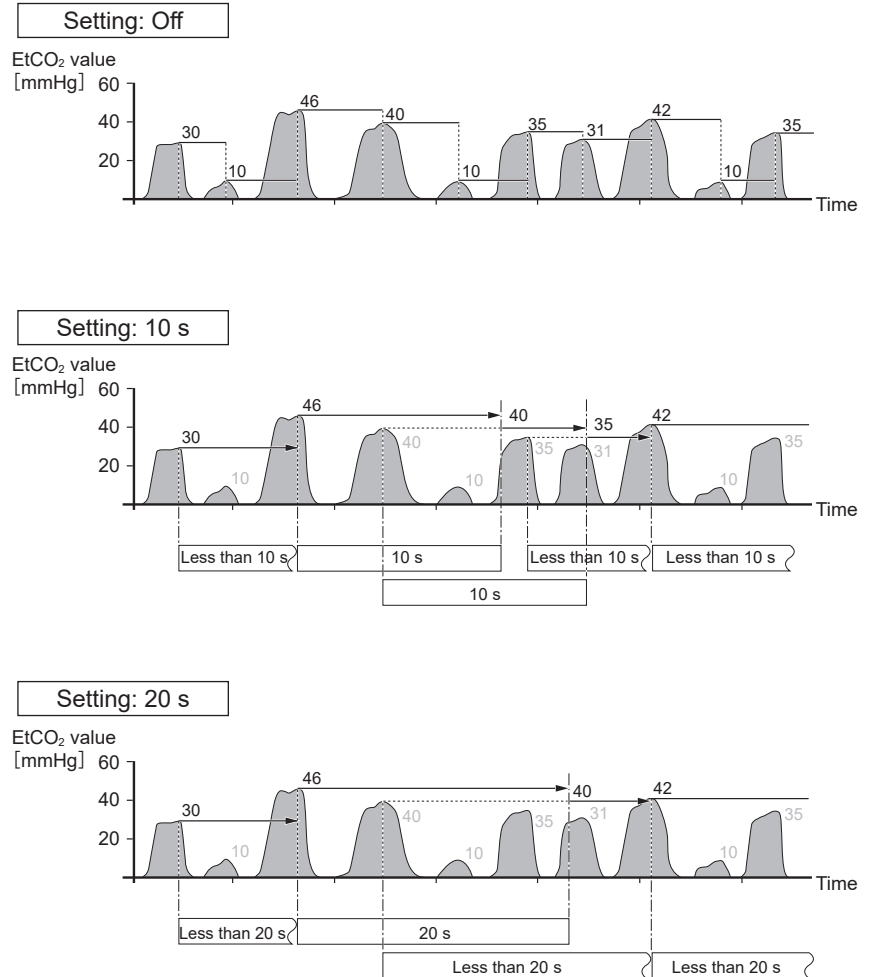
## EtCO<sub>2</sub> Max Hold: 10 s, 20 s, Off

This can be set only when TG-980P is connected.

Set the duration for holding the maximum EtCO<sub>2</sub> values.

### Maximum value display

The maximum value is held and displayed on the window during the set period. When a value larger than the maximum value is measured, the new maximum value replaces the previous maximum.



### Scale

- **mmHg display:** 0-40, 0-60, 0-80, 0-120, 0-150
- **kPa display:** 0.0-5.5, 0.0-8.0, 0.0-10.5, 0.0-16.0, 0.0-20.0

Set the scale for the CO<sub>2</sub> waveform by selecting the scale key to change or by moving the slider.

## Inspection of Measuring Accuracy

### Daily Inspection of Measuring Accuracy

For daily inspections, check the accuracy of the ventilator by breathing into it.

Place the mount on the thick side of the airway adapter (side that connects to the patient's mask or tracheal tube) into the mouth, adjust your breathing and breathe normally at a speed of approximately one breath every 5 seconds (12 times a minute).

Breathing too fast or too deep makes it difficult to obtain correct measurements.

The standard EtCO<sub>2</sub> value is 40 mmHg. Confirm that a CO<sub>2</sub> gas concentration of 35 to 45 mmHg is displayed.

### Inspection of Measuring Accuracy (Precise Method)

If there seems to be a significant error in the CO<sub>2</sub> measurement, use the sensitivity calibration gas to confirm the accuracy. Perform the same inspection once every 6 months to ensure a stable measurement accuracy.

For details on how to perform the inspection, refer to Section 4 “Maintenance and Inspection” of the Administrator's Guide.



Refer to the following.  
Administrator's Guide:  
Section 4 “Maintenance and Inspection”



# SpO<sub>2</sub> Monitoring

To monitor SpO<sub>2</sub>, attach the probe to the patient, connect the probe to the MULTI socket using a SpO<sub>2</sub> adapter and then measure the plethysmogram and SpO<sub>2</sub> values.

## SpO<sub>2</sub> Monitoring Precautions

### ⚠ WARNING

- When using the finger probe, do not fasten the probe and cable to the finger by wrapping with tape. This may cause burn, congestion or skin problems from poor blood circulation.
- When using probes other than the finger probe, to avoid poor circulation, do not wrap the tape too tight. Check the blood circulation condition by observing the skin color and congestion at the skin peripheral to the probe attachment site. Even for short-term monitoring, there may be burn or skin problems from poor blood circulation.

### ⚠ WARNING

SpO<sub>2</sub> measurement may be incorrect in the following cases.

- When the patient's carboxyhemoglobin or methemoglobin increases abnormally.
- When dye is injected in the blood.
- During CPR.
- When measuring at a site with venous pulse.
- When there is body movement.
- When the plethysmogram is small (insufficient peripheral circulation).

### ⚠ WARNING

Check the circulation condition by observing the skin color at the measurement site and plethysmogram. Change the measurement site every

8 hours for disposable probes and every 4 hours for reusable probes. The skin temperature may increase at the attached site by 2 or 3°C (4 or 5°F) and cause a burn or skin problems. When using the probe on the following patients, take extreme care and change the measurement site more frequently according to symptoms and degree.

- Elderly patient
- Unconscious patient
- Patient with a fever
- Patient with insufficient peripheral circulation

### ⚠ WARNING

When not monitoring SpO<sub>2</sub>, disconnect the SpO<sub>2</sub> connection cord from the ventilator. Otherwise, noise from the probe sensor may cause interference and incorrect data may be displayed on the screen.

### ⚠ WARNING

After use, clean the reusable SpO<sub>2</sub> probe. Failure to follow this warning may cause cross infection.

### ⚠ WARNING

When monitoring SpO<sub>2</sub> of a patient who is receiving photodynamic therapy, the light from the probe sensor may cause a burn where the probe is attached. Photodynamic therapy uses a photosensitizing agent that may cause photosensitive side effects.

The SpO<sub>2</sub> probe manufactured by Nihon Kohden have two wavelengths with peaks in the range of 650 and 950 nm. The maximum light intensity is 5.5 mW/s or less.

### ⚠ CAUTION

While a patient is on medication which causes vasodilation, the plethysmogram may change and in rare cases the SpO<sub>2</sub> value might not be displayed.

### ⚠ CAUTION

Turn off the power of mobile phones, small wireless devices and other devices which produce strong electromagnetic interference around a patient (except for devices allowed by the hospital administrator). Radio waves from devices such as mobile phones or small wireless devices may be mistaken as plethysmogram and the displayed data may be incorrect.

### ⚠ CAUTION

When measuring SpO<sub>2</sub> under strong light such as surgical light or sunlight, cover the measuring site with a blanket to block the light. Otherwise measurement accuracy may be affected.

**⚠ CAUTION**

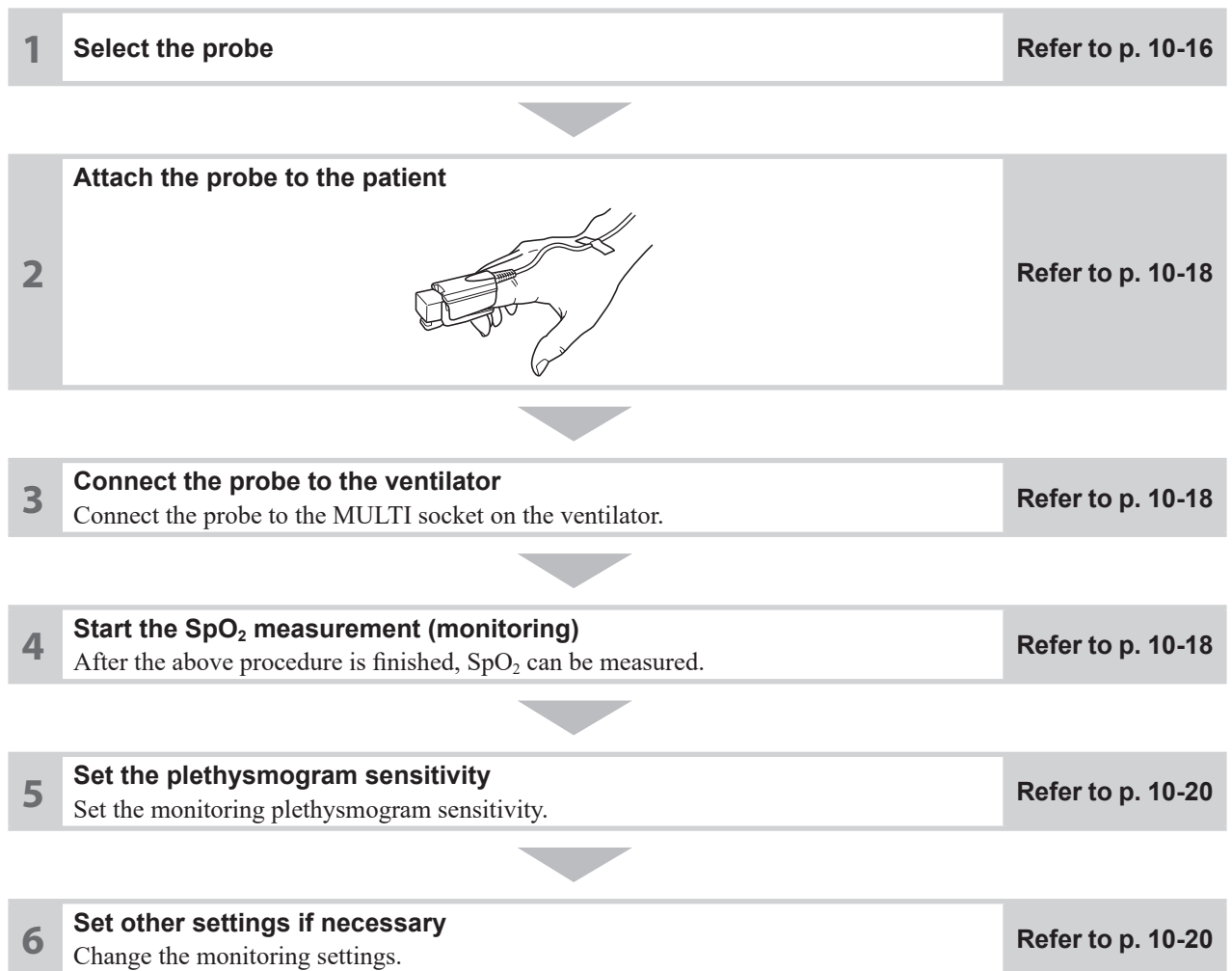
When monitoring the patient only with the ventilator, turn on both the upper and lower limit alarms for PR and SpO<sub>2</sub>. If the patient's pulse is not detected during asystole or other condition, a "Cannot Detect Pulse" or "Check Probe" alarm occurs instead of an SpO<sub>2</sub> limit alarm. Furthermore, if the patient has no pulse, noise from probe movement could be misjudged as a pulse and cause an incorrect PR or SpO<sub>2</sub> value to be displayed.

**⚠ CAUTION**

If the patient requires respiration monitoring, monitor the respiration. Oxygen saturation (SpO<sub>2</sub>) is measured by pulse oximetry which cannot be used for respiration monitoring.

NOTE: Unlike ECG monitoring, detection of arrhythmia and asystole is not available when monitoring SpO<sub>2</sub> only. If SpO<sub>2</sub> is monitored without ECG, PR and SpO<sub>2</sub> alarms do not occur during asystole because PR and SpO<sub>2</sub> values are not measured when there is no pulse. Furthermore, if the patient has no pulse, noise from probe movement could be misjudged as a pulse and cause an incorrect PR or SpO<sub>2</sub> value to be displayed.

## Measurement Flow





## Selecting the Probe

### ⚠ WARNING


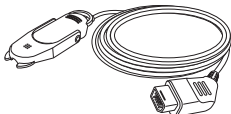
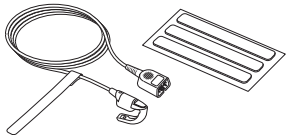
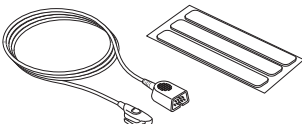
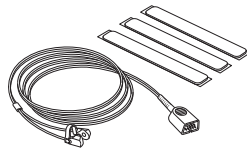
Only use the Nihon Kohden specified probes. If an unspecified probe is used, maximum performance from the ventilator cannot be satisfied.

Refer to “Sensors and Probes” in Section 16 when selecting the probe.



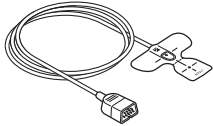
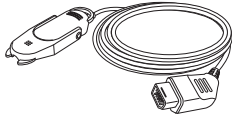
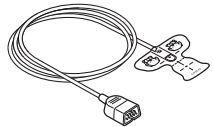
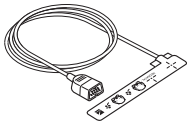
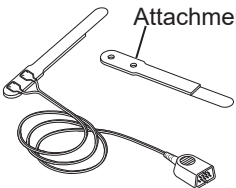
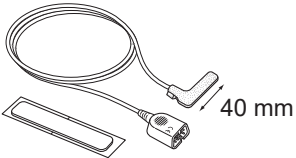
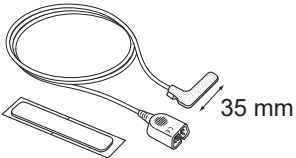
Refer to “Sensors and Probes” in Section 16.

## Reusable Probes

| Reusable Probes  | Patient (Weight)                            | Attachment Site | SpO <sub>2</sub> Adapter  |
|--|---|-----------------|---|
| TL-201T finger probe (0.6 m, 1.6 m)<br>                               | Adults, pediatric<br>(Weight 20 kg or more) | Finger          | JL-500P1, JL-500P2 SpO <sub>2</sub> adapter <sup>1</sup><br> |
| TL-630T1 finger probe (0.6 m),<br>TL-630T3 finger probe (1.6 m)<br>  | Adults, pediatric<br>(Weight 50 kg or more) |                 |   |
| TL-631T1 finger probe (0.6 m),<br>TL-631T3 finger probe (1.6 m)<br> | Adults, pediatric<br>(Weight 20 kg or more) | Finger or toe   |   |
| TL-220T multi-site probe<br>  | Adults, pediatric<br>(Weight 3 kg or more)  |                 |   |

<sup>1</sup> For the differences between JL-500P1 and JL-500P2, contact your Nihon Kohden representative.

## Disposable Probes

| Disposable Probes   | Patient (Weight)                             | Attachment Site |                   | SpO <sub>2</sub> Adapter  |
|---|--|-----------------|-------------------|---|
| TL-271T (0.8 m), <b>TL-271T3</b> (1.6 m)<br>   | Adults<br>(Weight 30 kg or more)             | Finger or toe   |                   | JL-500P1, JL-500P2 SpO <sub>2</sub> adapter <sup>1</sup><br> |
| TL-272T (0.8 m), <b>TL-272T3</b> (1.6 m)<br>   | Pediatric<br>(Weight from 10 to 50 kg)       |                 |                   |   |
| TL-273T (0.8 m), <b>TL-273T3</b> (1.6 m)<br>   | Adults<br>(Weight 40 kg or more)             | Finger or toe   |                   |   |
| TL-260T multi-site Y probe<br>Attachment tape<br><br>The attachment tape type differs depending on the patient. | Pediatric, neonates<br>(Weight 3 kg or more) | Finger or toe   | Attachment tape S |   |
| TL-051S (0.8 m), TL-052S (1.6 m)<br><br>40 mm  | Adults<br>(Weight 50 kg or more)             | Finger          |                   |   |
| TL-061S (0.8 m), TL-062S (1.6 m)<br><br>35 mm  | Pediatric<br>(Weight from 15 to 50 kg)       | Finger          |                   |   |

<sup>1</sup> For the differences between JL-500P1 and JL-500P2, contact your Nihon Kohden representative.



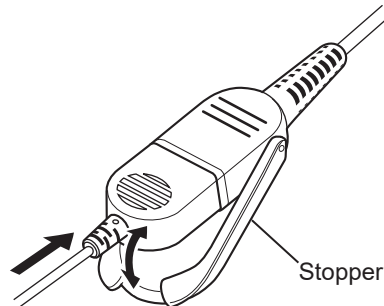
## Attaching the Probe to the Patient

Refer to the operator's manual of the probe for how to attach the probe.

## Connecting the Probe to the Ventilator

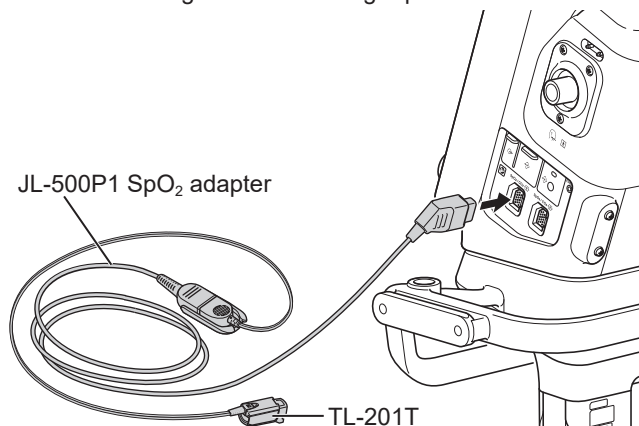
Connect the selected probe to the **MULTI socket** by using the JL-500P1 or JL-500P2 SpO<sub>2</sub> adapter.

- 1 Open the stopper of the SpO<sub>2</sub> adapter and connect the probe connector firmly.
- 2 Close the stopper.



When connecting the TL-201T finger probe

- 3 Connect the SpO<sub>2</sub> adapter to the **MULTI socket**.



## Starting the SpO<sub>2</sub> Measurement (Monitoring)

After the above procedure is finished, SpO<sub>2</sub> can be measured.

### Measurement Precautions

#### ⚠ CAUTION

When the probe is attached on an appropriate site with sufficient circulation and an error message about probe attachment repeatedly appears, the probe may be deteriorated. Replace it with a new one.

#### ⚠ CAUTION

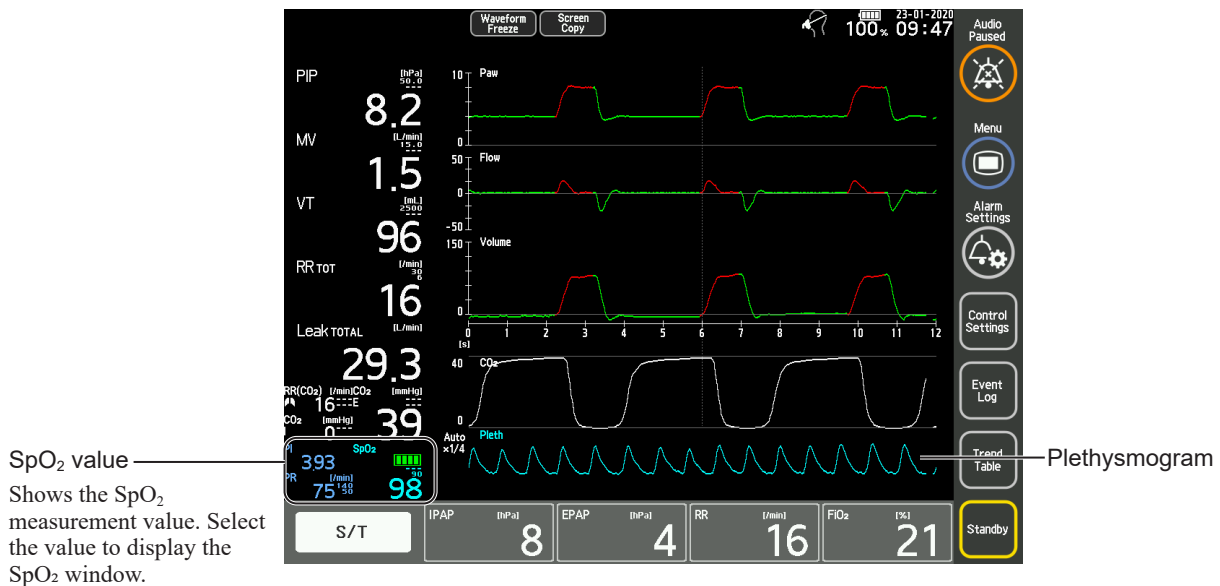
If the attachment site is dirty with blood or bodily fluids, clean the attachment site before attaching the probe. If there is nail polish on the attachment site, remove the polish. Otherwise, the amount of transmitted light decreases, and the measured value may be incorrect or measurement cannot be performed.

#### ⚠ CAUTION

When a message indicates a faulty probe or faulty SpO<sub>2</sub> connection cord, stop monitoring and replace the probe or SpO<sub>2</sub> connection cord with a new one.

**NOTE:** In order to maintain sufficient blood circulation, keep the measurement site warm by covering with a blanket or something similar. Warming the site is effective, especially for a patient with a small pulse amplitude.

## Main Screen Example



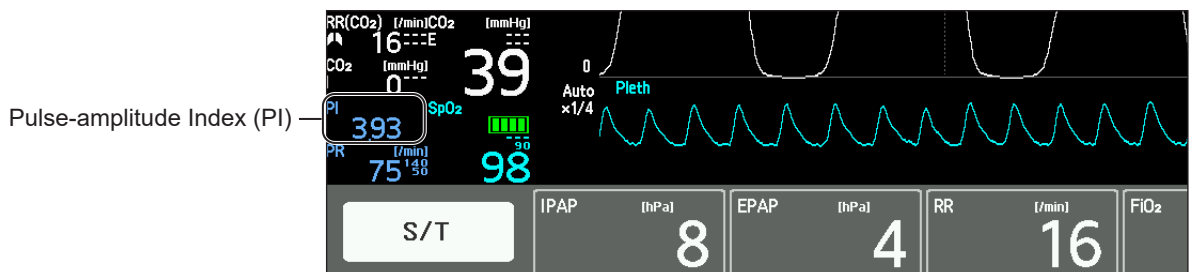
## Pulse-amplitude Index (PI)

The pulse-amplitude index (PI) is displayed on the ventilator.

### Pulse-amplitude Index






This indicates the percentage of the pulsation component in the entire transmitted IR signal.

This index may be affected by artifacts.



### SQI Bar Graph

This shows the plethysmogram signal quality for SpO<sub>2</sub> measurement using a bar graph.

| SQI Bar Graph  | Plethysmogram Signal Quality for SpO <sub>2</sub> Measurement   |
|--|---|
|  (4 green bars)               | The signal quality is high.   |
|  (3 green bars)               | There may be some artifacts.  |
|  (2 yellow bars) <sup>1</sup> | The signal quality is reduced due to a large artifact. If this state continues for a long time, check the patient and probe attachment. |
|  (1 red bar) <sup>1</sup>     | The signal quality is very low. Check the patient and probe attachment.   |
|  (0 bars)                     | Cannot measure.   |

<sup>1</sup> If the SQI bar graph shows 1 or 2 bars, the “Low Quality Signal” message appears on the screen.



## Changing the SpO<sub>2</sub> Settings

Change settings related to SpO<sub>2</sub> monitoring.

Select [SpO<sub>2</sub>] on the Menu window and change settings on the SpO<sub>2</sub> window.

The SpO<sub>2</sub> window can be displayed by selecting the SpO<sub>2</sub> value on the main screen.

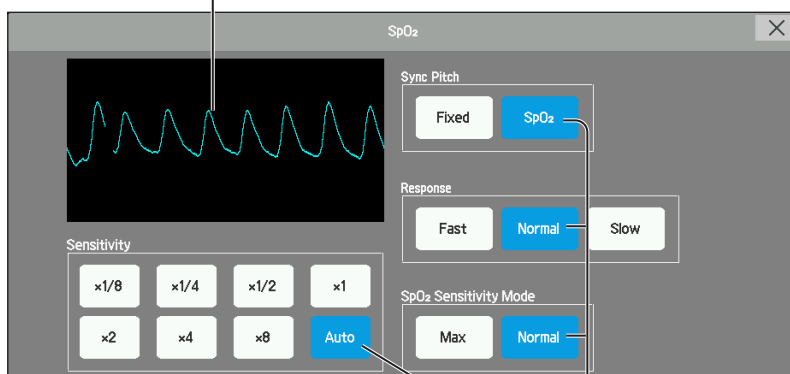
| Setting                           | Description   |
|-----------------------------------|---|
| Sensitivity                       | Sets the SpO <sub>2</sub> plethysmogram sensitivity.                                      |
| Sync Pitch                        | Sets the pulse sync sound type.   |
| Response                          | Sets the speed of the display response to changes in the patient SpO <sub>2</sub> values. |
| SpO <sub>2</sub> Sensitivity Mode | Sets the sensitivity for the SpO <sub>2</sub> measurement.                                |

The display color for measurement values can be set on the [Vital] tab in the [Color] page of the System Setup window.



Refer to the following.  
Administrator's Guide:  
"Setting Colors" in Section 3

Displays the plethysmogram being measured.



The selected item is displayed in light blue.

### Sensitivity: ×1/8, ×1/4, ×1/2, ×1, ×2, ×4, ×8, Auto

Set the monitoring plethysmogram sensitivity.

NOTE: The plethysmogram amplitude varies according to the ratio of the pulsation component to the entire transmitted IR signal. When the pulsation component ratio is 1%, the plethysmogram amplitude is about 10 mm at ×1 sensitivity on the display.

### Sync Pitch

Changes the sync pitch based on SpO<sub>2</sub> measurement values. This allows changes in SpO<sub>2</sub> values to be heard without looking at the screen.

### Settings

- Fixed: The pitch is constant. It is set in Pulse Sync Sound in the System Setup window.<sup>1</sup>
- SpO<sub>2</sub>: The pitch moves higher or lower to match the change in SpO<sub>2</sub> value.

<sup>1</sup> The pitch can be set in Pulse Sync Sound on the [SpO<sub>2</sub>] page in the [Parameters] window of the System Setup window.



Refer to the following.  
Administrator's Guide:  
"Parameter Settings" in Section 3

### Response: Fast, Normal, Slow

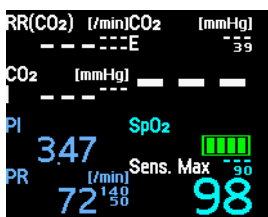
Response mode for SpO<sub>2</sub> can be set for change in patient SpO<sub>2</sub> values.

NOTE: When the measurement condition is unstable due to strenuous movement of the patient or for other reasons, response may become slower in all modes.



Example of Response Time according to Each Setting:  
Refer to "Response Time" in Section 16.

### SpO<sub>2</sub> Sensitivity Mode



Sets the sensitivity for the SpO<sub>2</sub> measurement.

- Max: Set to [Max] when it is difficult to detect pulse or pulse is unusual, such as when monitoring a patient with peripheral circulation insufficiency or when an IABP is used and SpO<sub>2</sub> cannot be measured.
- Normal: For normal monitoring, set to [Normal].



When [Max] is set, "Sens. Max" appears above the SpO<sub>2</sub> value on the main screen.

NOTE: When [Max] is set, a waveform and numeric value for SpO<sub>2</sub> may appear even when the probe is detached from the patient.



# 11

## Review

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# Overview of Review Window

Review windows display past vital sign data for patients. The following review windows are available.

- Trend window
- [Trend Table] window
- [Event Log] window
- [Full Disc] window



## Synchronizing the Display Time

When you change to another review window while the first review window is displayed, the time of the data in each window is synchronized. By changing review windows, you can view various types of vital sign data for the patient at the time you want to check.

## Review data

The following types of review data can be saved.

| Review Data               | Files/Hours  |
|---------------------------|--------------|
| Trend graph               | 72 hours     |
| Trend table               | 72 hours     |
| Event log                 | 32,768 items |
| Full disclosure waveforms | 72 hours     |

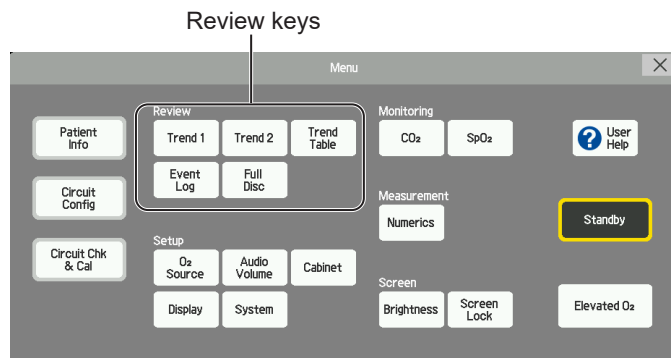
- NOTE
- When the data is full, the oldest data is deleted to create a new file.
  - If the main battery and backup battery are not installed in the ventilator, do not remove the AC power cord from the outlet while the ventilator is on. Otherwise, data loss may occur.
  - Select a New Patient to delete the data for previous patient.

## Displaying a Review Window

### Displaying a Review Window from the [Menu] Window

- 1 Select [Menu] to display the [Menu] window.
- 2 Select the review keys from the [Menu] window to display each type of review window.

The review windows can also be displayed by selecting each review key from the function keys. (Only when they are assigned to function keys)



### Displaying a Review Window from another Review Window

When a review window is displayed, select one of the tabs at the top of the review window to change to another review window.

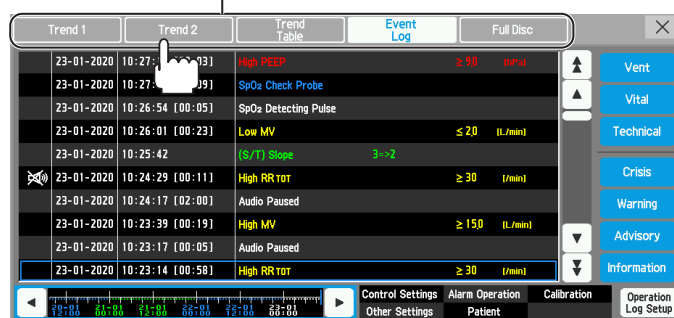


When changing to another review window, the time for each type of data is synchronized.

#### Example: Displaying the [Trend 2] window

Select the [Trend 2] tab while displaying another review window.

Tabs for changing review windows





# Displaying a Review Window in Other Ways

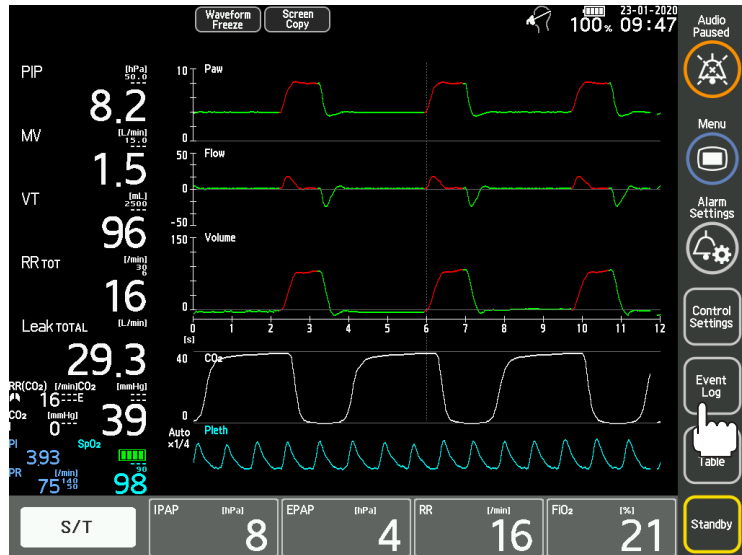
## Display the Review window using the function keys

Assign review keys as functions keys by selecting [Keys] in the System Setup window to directly display review windows from the main screen.



Refer to the following.  
Administrator's Guide:  
"Changing the Key Assignments" in Section 3

### Assigning [Event Log] to a function key



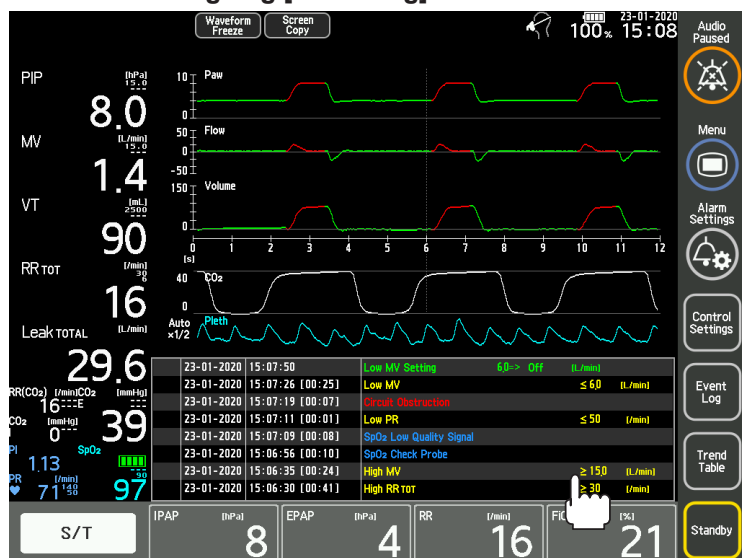
## Displaying the Review window from the cabinet

The Review window can be displayed by selecting it from inside the cabinet area. To do this, first add the Review window in Menu window ► Setup ► [Cabinet] window.



Refer to "Setting the Cabinet Type" in Section 12.

### Assigning [Event Log] to the cabinet

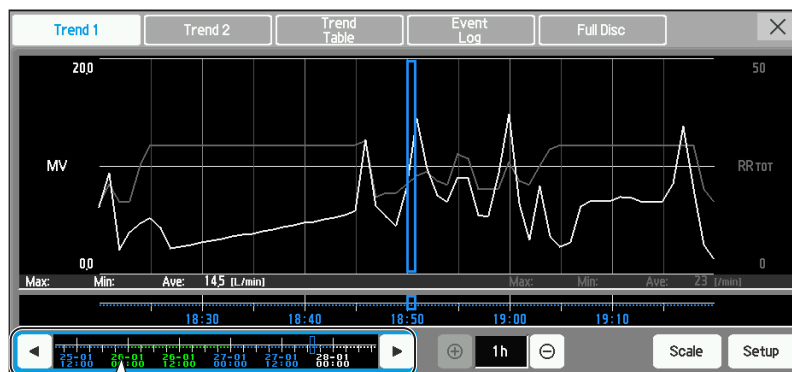


## Time Scale Bar

The Time Scale Bar appears at the bottom of each review window.

The Time Scale Bar displays all data saved on the ventilator.

Adjust the position of the cursor using the forward and back keys to move through the data one item at a time or when changing detailed settings.



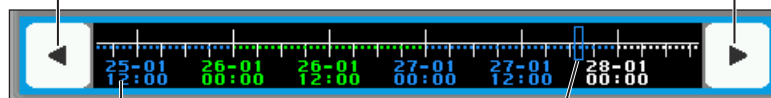
### Time scale bar

Touch any position on the time scale bar to display the data for that time.

[◀], [▶]

[◀]: Moves the cursor in the review window to previous data.

[▶]: Moves the cursor in the review window to next data.



#### Date display

Shows the date (top) and time (bottom) in the trend window.

#### Window display frame

Shows the position of the displayed review window.



# Trend

Trend windows show past patient measurement values in a graph.

There are two types of trend windows, [Trend 1] and [Trend 2] and each window can display trend graphs with up to 4 parameters.

- Trend graph data is displayed for each type of data at the following intervals for each displayed time scale.

| Time Scale                | Interval       |
|---------------------------|----------------|
| 1 hours, 2 hours, 4 hours | 1 min interval |
| 8 hours, 24 hours         | 2 min interval |
| 72 hours                  | 6 min interval |

- Touch [+] or [-] to change between trend graph display time scales.
- Use the time scale bar at the bottom of the screen to scroll through data not displayed on the window.

## Trend Window Description

Trend windows can show trend graphs for the past 72 hours with up to 4 parameters.

NOTE: Depending on scale settings, it might not be possible to display the entire graph on the screen.

To display a trend window, select [Trend 1] or [Trend 2] in the [Menu] window.

Trend windows can also be displayed as follows:

- By selecting [Trend 1] or [Trend 2] from the function keys (Only when they are assigned to function keys)
- By selecting a trend window from the cabinet (Only when it is set to the cabinet)

**Cursor**  
The cursor shows the position of the selected data on the time scale. The position of the cursor is linked to the cursor in the list window.

**Scale upper limit** 200

**Parameter name** MV

**Trend waveform**

**Scale lower limit** 00

**Measurement values**  
Shows the measurement values in the window display frame.

**Time scale bar**  
Refer to "Time Scale Bar" (p. 11-5).

**Time scale**  
Shows the time scale of the trend graph on the window. The time scale can be increased or decreased by using [+] and [-]. Increase or decrease trends as follows:  
[+] [-]  
1 h ↔ 2 h ↔ 4 h ↔ 8 h ↔ 24 h ↔ 72 h

**[Scale]**  
Sets the scale for each parameter.

**[Setup]**  
Sets the parameters to display on trend windows.

# Changing the Trend Graph Settings

## Setting the Parameters

Set the parameters to display on the trend graph.

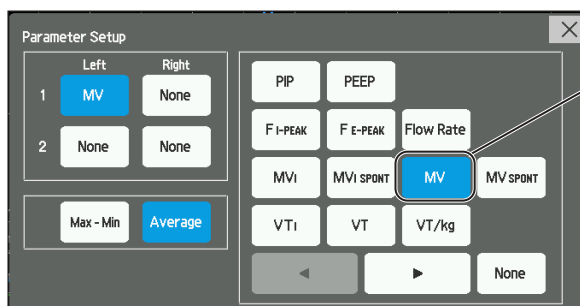
- 1 Select [Setup] on the [Trend 1] or [Trend 2] window in the [Menu] window to display the Parameter Setup window.


The Parameter Setup window can also be displayed by selecting the parameter name on the trend window.

- 2 Select the position for displaying the parameters.



- 3 Select the parameters to display from the list of parameters.



- 4 Repeat Steps 2 and 3 to set the other parameters.
- 5 Select [] to close the Parameter Setup window.



## Setting the Scale

Set the trend graph display scale for each parameter.

- 1 Select [Scale] on the [Trend 1] or [Trend 2] window in the [Menu] window to display the Scale Setup window.

---

The Scale Setup window can also be displayed by selecting the upper or lower limit of the scale on the trend window.

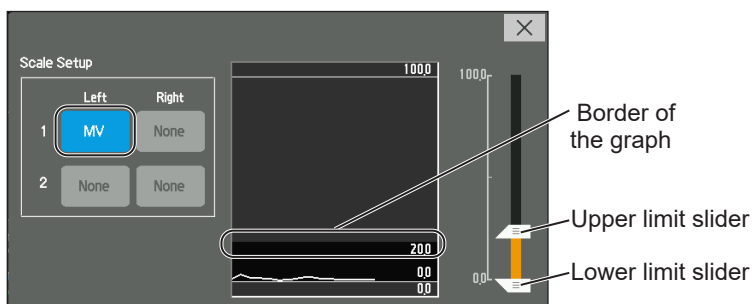
---

- 2 Select the parameters to set the scale for.
- 3 Move the upper and lower limit sliders to adjust the range of values displayed on the trend graph.

---

Values can also be changed by dragging the border of the graph up and down.

---



- 4 Repeat Steps 2 and 3 to set the scale of other parameters.
- 5 Select  to close the Scale Setup window.

## Trend Types and Scales

The following trends can be displayed on the ventilator. Furthermore, the scale for each trend parameter is also shown.

| Item                             | Description                           | Unit  | Scale                  | Default Setting      |           |
|----------------------------------|---------------------------------------|---|------------------------|----------------------|-----------|
|                                  |                                       |   |                        | Adult                | Pediatric |
| PIP                              | Peak inspiratory pressure             | hPa (cmH <sub>2</sub> O, mbar) <sup>1</sup> | 0.0 to 100.0           | 0.0 to 50.0          |           |
| PEEP                             | Positive end expiratory pressure      | hPa (cmH <sub>2</sub> O, mbar) <sup>1</sup> | 0.0 to 100.0           | 0.0 to 30.0          |           |
| FI-PEAK                          | Peak inspiratory flow                 | L/min                                       | 0.0 to 200.0           | 0.0 to 50.0          |           |
| FE-PEAK                          | Peak expiratory flow                  | L/min                                       | -200.0 to 0.0          | -50.0 to 0.0         |           |
| Flow Rate                        | Flow rate                             | L/min                                       | 0.0 to 100.0           | 0.0 to 50.0          |           |
| MVI                              | Total inspiratory minute volume       | L/min                                       | 0.0 to 100.0           | 0.0 to 20.0          |           |
| MVISPONT                         | Spontaneous inspiratory minute volume | L/min                                       | 0.0 to 100.0           | 0.0 to 20.0          |           |
| MV                               | Total expiratory minute volume        | L/min                                       | 0.0 to 100.0           | 0.0 to 20.0          |           |
| MVSPONT                          | Spontaneous expiratory minute volume  | L/min                                       | 0.0 to 100.0           | 0.0 to 20.0          |           |
| VTi                              | Inspiratory tidal volume              | mL  | 0 to 3500              | 0 to 1000            |           |
| VT                               | Expiratory tidal volume               | mL  | 0 to 3500              | 0 to 1000            |           |
| VT/kg                            | Expiratory tidal volume /kg           | mL/kg                                       | 0.0 to 50.0            | 0.0 to 20.0          |           |
| RRTOT                            | Total respiratory rate                | /min  | 0 to 150               | 0 to 50              |           |
| RRSPONT                          | Spontaneous respiration rate          | /min  | 0 to 150               | 0 to 50              |           |
| T <sub>I</sub>                   | Inspiratory time                      | s   | 0.0 to 100.0           | 0.0 to 10.0          |           |
| T <sub>E</sub>                   | Expiratory time                       | s   | 0.0 to 100.0           | 0.0 to 10.0          |           |
| T <sub>I</sub> /T <sub>TOT</sub> | Inspiratory duty cycle                | %   | 0 to 90                | 0 to 50              |           |
| I:E                              | I:E ratio                             | —   | 0.0 to 10.0            | 0 to 5.0             |           |
| LeakTOTAL                        | Total leakage flow                    | L/min                                       | 0.0 to 200.0           | 0.0 to 50.0          |           |
| LeakPATIENT                      | Patient leakage flow                  | L/min                                       | 0.0 to 200.0           | 0.0 to 50.0          |           |
| Leak%                            | Leakage volume ratio                  | %   | 0 to 100               | 0 to 100             |           |
| Pt. Trig.                        | Spontaneous breathing ratio           | %   | 0 to 100               | 0 to 100             |           |
| O <sub>2</sub> Gas Usage         | O <sub>2</sub> gas usage              | L/min                                       | 0.0 to 100.0           | 0.0 to 50.0          |           |
| FiO <sub>2</sub>                 | FiO <sub>2</sub>                      | %   | 15 to 100              | 15 to 50             |           |
| SpO <sub>2</sub>                 | SpO <sub>2</sub>                      | —   | 0 to 100               | 80 to 100            |           |
| PR                               | Pulse rate                            | /min  | 0 to 300               | 0 to 100             |           |
| PI                               | Pulse-amplitude index                 | %   | 0.01 to 100.00         | 0.01 to 100.00       |           |
| EtCO <sub>2</sub>                | EtCO <sub>2</sub>                     | mmHg (kPa) <sup>1</sup>                     | 0 to 150 (0.0 to 20.0) | 0 to 40 (0.0 to 5.5) |           |
| FiCO <sub>2</sub>                | FiCO <sub>2</sub>                     | mmHg (kPa) <sup>1</sup>                     | 0 to 100 (0.0 to 13.0) | 0 to 5 (0.0 to 0.5)  |           |
| RR (CO <sub>2</sub> )            | Respiratory rate (CO <sub>2</sub> )   | /min  | 0 to 150               | 0 to 50              |           |

<sup>1</sup> The unit can be set on the [Units] window in the System Configuration window.



Refer to the following.  
Administrator's Guide:  
"Unit Settings" in Section 2



## Trend Table

The [Trend Table] window shows past patient measurement values in a table. Use the time scale bar at the bottom of the screen to scroll through data not displayed on the window.

### Trend Table Window Description

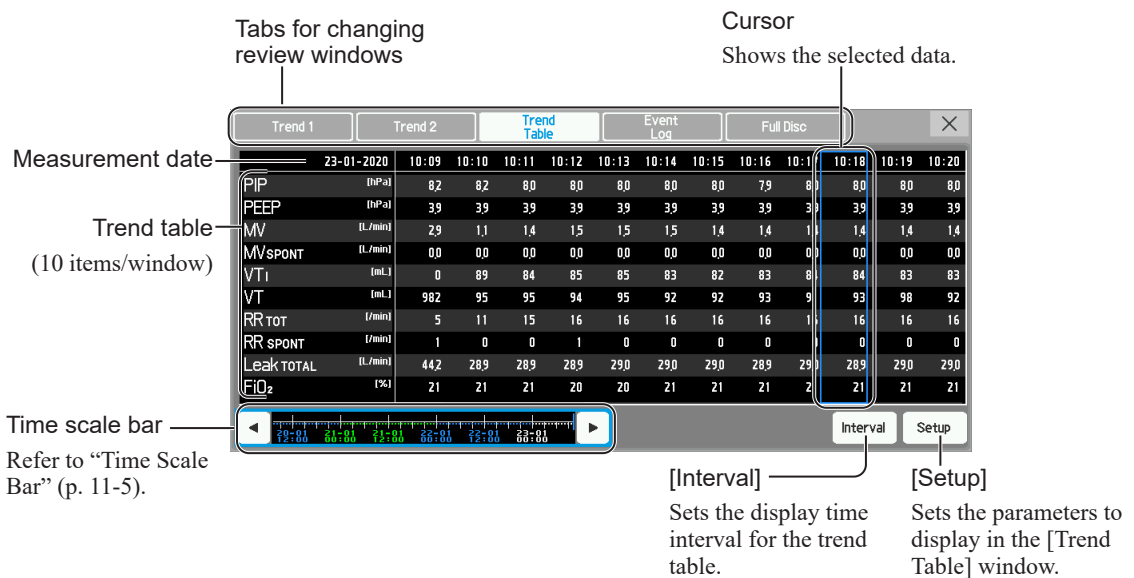
The [Trend Table] window displays all of the measurement values for the past 72 hours in a list for each set time period (1 min, 5 min, 10 min, 15 min, 30 min, 1 h).

The [Trend Table] window can show various parameters (up to 10).

Select [Trend Table] in the [Menu] window to display the [Trend Table] window.

Trend Table window can also be displayed as follows:

- By selecting [Trend Table] from the function keys (Only when it is assigned to a function key)
- By selecting the [Trend Table] window from the cabinet (Only when this is set in the cabinet)



### Changing the Time Scale Interval

Change the time interval for displaying data in the Trend Table.

#### Setting:

1 min, 5 min, 10 min, 15 min, 30 min, 1 h

- 1 Select [Interval] on the [Trend Table] window to display the Interval window.

The [Interval] window can also be displayed by selecting the measurement date in the [Trend Table] window.

- 2 Select the display time interval.

## Setting Parameters for the Trend Table

Select the parameters to display in the [Trend Table] window.

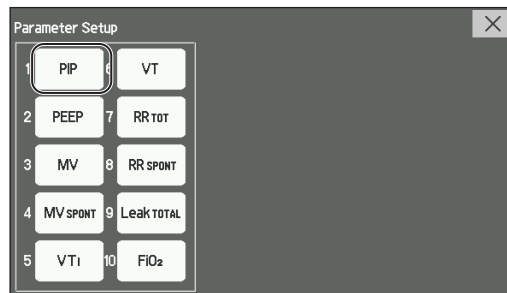
### Setting:

Refer to “Types of Trend Tables” (p. 11-11).

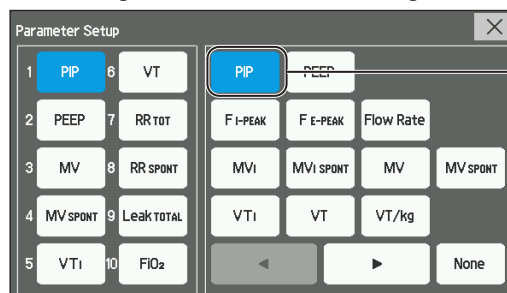
- 1 Select [Setup] on the [Trend Table] window in the [Menu] window to display the Parameter Setup window.

The Setup window can also be displayed by selecting the parameter name in the [Trend Table] window.

- 2 Select the Trend Table position from the Parameter Setup.



- 3 Select the parameters from the list of parameters.



The selected item is displayed in light blue.



- If the desired parameter does not appear, select [◀] or [▶] to display other parameter choices.
- Select [None] to delete a set parameter.

- 4 Repeat Steps 2 and 3 to set the other parameters.
- 5 Select [✕] to close the Parameter Setup window.

## Types of Trend Tables

The types of parameters that can be shown on the [Trend Table] window are the same as those on the trend windows.



Refer to “Trend Types and Scales” (p. 11-9).



## Event Log

The [Event Log] window shows all of the alarm history and other events (time and content of occurrences and time and content at alarm pausing) and operation logs in a table.



“Alarm Settings” in Section 6-1

A maximum of 72 hours of data or a total of 32,768 individual records can be saved. 10 of those data can be displayed on the Event History window at any one time.

Use the time scale bar at the bottom of the screen to scroll through data not displayed on the window.

The operations are displayed on the window in green, the alarms are displayed in the color of their priority<sup>1</sup>, and other information is displayed in white.

<sup>1</sup> The display color for the alarm can be set by selecting [Alarm Priority Color] on the [Display/Sound] page in the Alarm window of the System Setup window.



Refer to the following.

Administrator's Guide:

“Alarm Settings - [Display/Sound] Page” in Section 3

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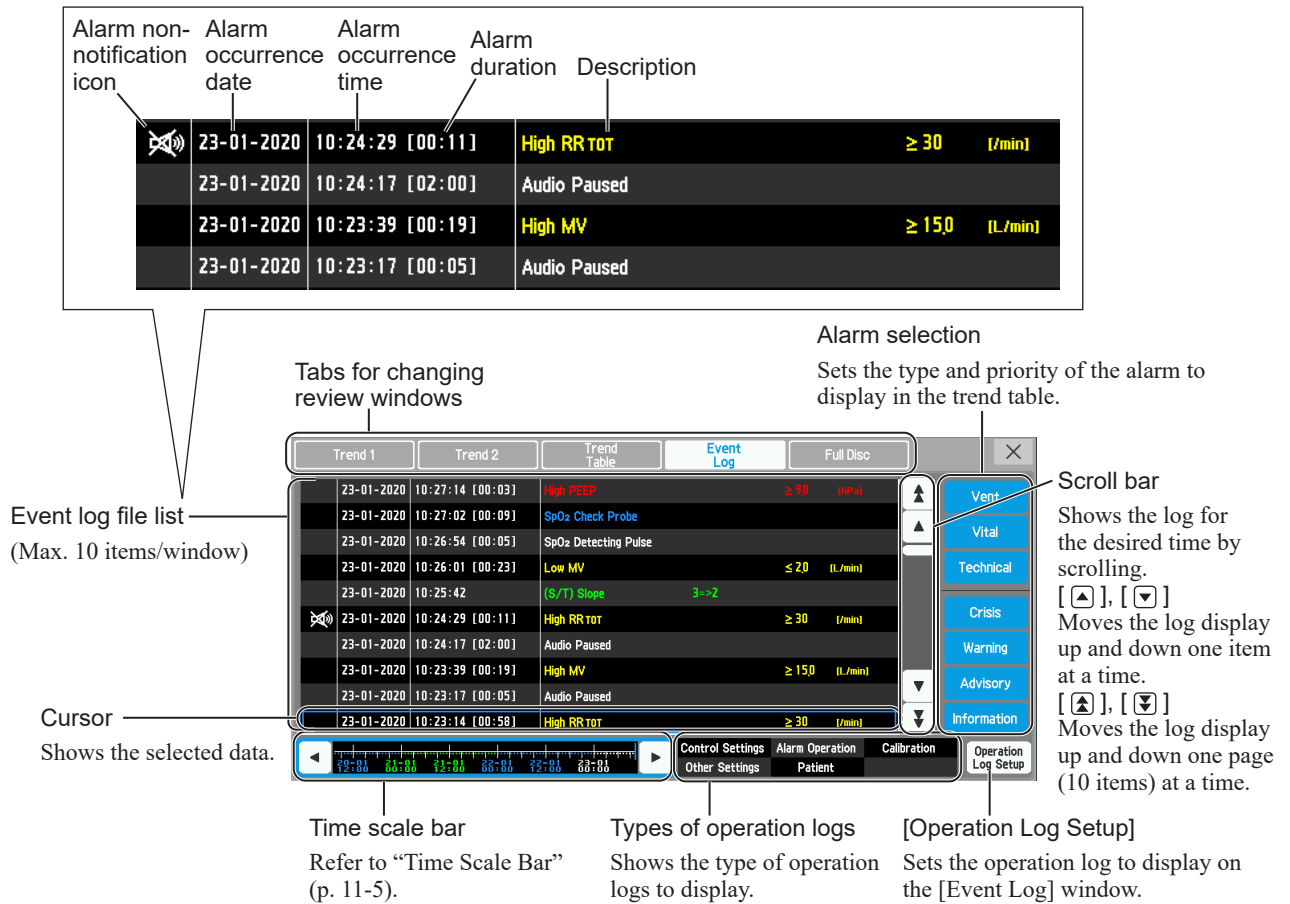
## Event Log Window Description

Select [Event Log] in the [Menu] window to display the [Event Log] window.

---

The [Event Log] window can also be displayed as follows:

- By selecting [Event Log] from the function keys (Only when it is assigned to a function key)
  - By selecting the [Event Log] window from the cabinet (Only when it is set to the cabinet)
-



Alarm non-notification icon

Alarm occurrence date

Alarm occurrence time

Alarm duration

Description

| Alarm non-notification icon | Alarm occurrence date | Alarm occurrence time | Alarm duration | Description        |
|-----------------------------|-----------------------|-----------------------|----------------|--------------------|
|                             | 23-01-2020            | 10:24:29 [00:11]      | ≥ 30           | High RR TOT (/min) |
|                             | 23-01-2020            | 10:24:17 [02:00]      |                | Audio Paused       |
|                             | 23-01-2020            | 10:23:39 [00:19]      | ≥ 15.0         | High MV (L/min)    |
|                             | 23-01-2020            | 10:23:17 [00:05]      |                | Audio Paused       |

Alarm selection  
Sets the type and priority of the alarm to display in the trend table.

Scroll bar  
Shows the log for the desired time by scrolling.  
[↑], [↓]  
Moves the log display up and down one item at a time.  
[↑], [↓]  
Moves the log display up and down one page (10 items) at a time.

Event log file list  
(Max. 10 items/window)

Cursor  
Shows the selected data.

Time scale bar  
Refer to "Time Scale Bar" (p. 11-5).

Types of operation logs  
Shows the type of operation logs to display.

[Operation Log Setup]  
Sets the operation log to display on the [Event Log] window.

Time scale bar

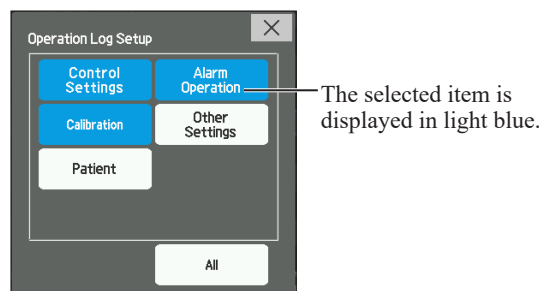
Types of operation logs

[Operation Log Setup]

## Setting the Event Log

Set the parameters to display in the event logs.

- 1 Select [Operation Log Setup] on the [Event Log] window in the [Menu] window to displayed the Operation Log Setup window.
- 2 Select the parameters to display from the list.



Select [All] to display all parameters.

- 3 Select [X] to close the Operation Log Setup window.



# Full Disclosure Waveforms

The ventilator can store full disclosure waveforms for up to 72 hours for five display parameters (Paw waveform, Flow waveform, Volume waveform, CO<sub>2</sub> waveform and plethysmogram).

The Full Disc window consists of Compressed Waveform and Actual Waveform windows.

## [Full Disc] Window

A single trace full disclosure waveform of 60, 20, 12 or 4<sup>1</sup> seconds (changeable) is displayed on the Actual Waveforms window.

<sup>1</sup> A single 4-second trace is displayed on the Actual Waveforms window.

Select [Full Disc] in the [Menu] window to display the [Full Disc] window.

The [Full Disc] window can also be displayed as follows:

- By selecting [Full Disc] from the function keys (Only when it is assigned to a function key)
- By selecting the [Full Disc] window from the cabinet (Only when it is set to the cabinet)

**Cursor**  
Encloses the waveform for 4 seconds. When changing from a compressed waveform to an actual waveform, the actual waveform for the enclosed area is displayed.

**Start time for waveform sweep**  
23-01-2020 10:32:00 - 10:32:59

**Compressed waveform area**  
Shows up to 5 compressed waveform parameters for a single trace of 60 s, 20 s, 12 s or 4 s<sup>1</sup> (selectable).  
<sup>1</sup> A single trace of 4 s is displayed in the Actual Waveforms window.

**Measurement values**  
Shows the measurement values in the window display frame.  
PIP 84 (mPa) MV 1.7 (L/min) VT 107 (mL) RR TOT 16 (/min)

**Time scale bar**  
Refer to "Time Scale Bar" (p. 11-5).

**Display time for single trace**  
60 (s/trace)  
Select [+] or [-] to set the display time.

**Parameter name**  
Paw, Flow, Volume, CO<sub>2</sub>, Pleth

**Scroll bar**  
Shows the waveform for the desired time by scrolling.  
[▲], [▼]  
Moves the waveform display forward or back by the set display time.  
[▲], [▼]  
Moves the waveform display up and down one page at a time.

**[Setup]**  
Sets the parameters to display on the [Full Disc] window.

**Start time for waveform sweep**  
Starts the waveform sweep.

**Compressed waveform area**  
Shows up to 5 compressed waveform parameters for a single trace of 60 s, 20 s, 12 s or 4 s<sup>1</sup> (selectable).

**Measurement values**  
Shows the measurement values in the window display frame.

**Time scale bar**  
Refer to "Time Scale Bar" (p. 11-5).

**Display time for single trace**  
60 (s/trace)  
Select [+] or [-] to set the display time.

**Parameter name**  
Paw, Flow, Volume, CO<sub>2</sub>, Pleth

**Scroll bar**  
Shows the waveform for the desired time by scrolling.  
[▲], [▼]  
Moves the waveform display forward or back by the set display time.  
[▲], [▼]  
Moves the waveform display up and down one page at a time.

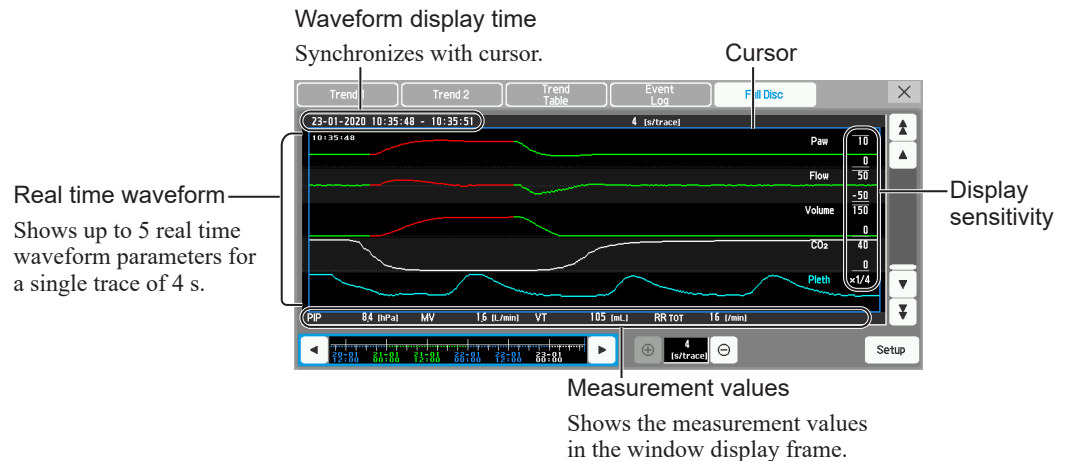
**[Setup]**  
Sets the parameters to display on the [Full Disc] window.

## Actual Waveforms Window

To view the actual uncompressed waveforms, select the selection display frame in the compressed waveforms area to display the Actual Waveforms window.

The Actual Waveforms window shows full disclosure waveforms for a single trace of 4 s, while additionally displaying other information such as the sensitivity of the waveforms.

Turn the operation knob to the right or left to show waveforms for a particular time.



After touching a compressed waveform to display the Actual Waveforms window, touch the cursor in the Actual Waveforms window to return to the Compressed Waveforms display.

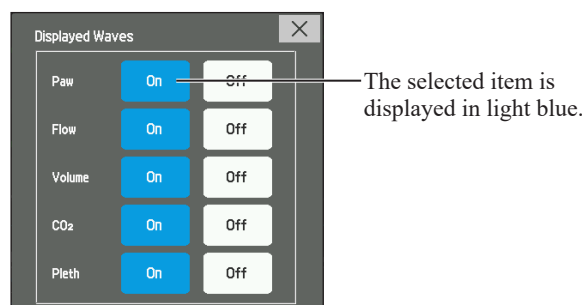
## Changing the Full Disclosure Waveform Settings

### Setting the Displayed Waveforms


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Set the waveform parameters to display on the full disclosure waveforms.

- 1 Select [Setup] on the [Full Disc] window in the [Menu] window to display the Displayed Waves window.
- 2 Select whether to display a waveform for each parameter.



- On: Displays the waveform.
- Off: Does not display the waveform.

- 3 Select [] to close the Displayed Waves window.



# 12

## Settings

|  |       |
|--|-------|
| Overview.....                                | 12-2  |
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| Brightness Settings.....                     | 12-5  |
| O <sub>2</sub> Source Settings .....         | 12-5  |
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## Overview

This chapter explains how to change settings related to the ventilator and screen displays.

NOTE: If any settings were changed, check the settings.

---

## List of Settings

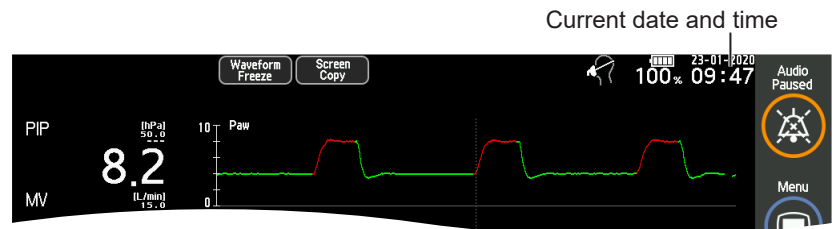
| Item                  | Details  | Reference  |
|-----------------------|--|--|
| Date/Time             | Set the current date and time.                             | p. 12-3  |
| Brightness            | Set the screen brightness.                                 | p. 12-5  |
| O <sub>2</sub> Source | Set the oxygen supply.                                     | p. 12-5  |
| Audio Volume          | Set the sync sound on/off, sync volume, and alarm volume.  | p. 12-6  |
| Cabinet               | Set the content to be displayed in the cabinet area.       | p. 12-8  |
| Display Configuration | Set the parameters and waveforms to display on the screen. | p. 12-10   |
| System                | These are settings for the administrator.                  | Administrator's Guide: Section 3 "System Setup Settings" |

# Date and Time Settings

Set the current date and time.

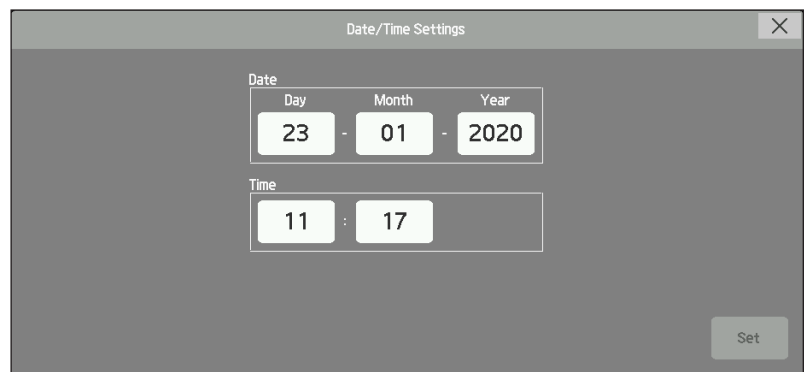
NOTE: If the date and time settings are changed during monitoring, the date and time of all stored data is also changed.

- 1 Select the date and time on the upper right of the Main screen to display the Date/Time window.



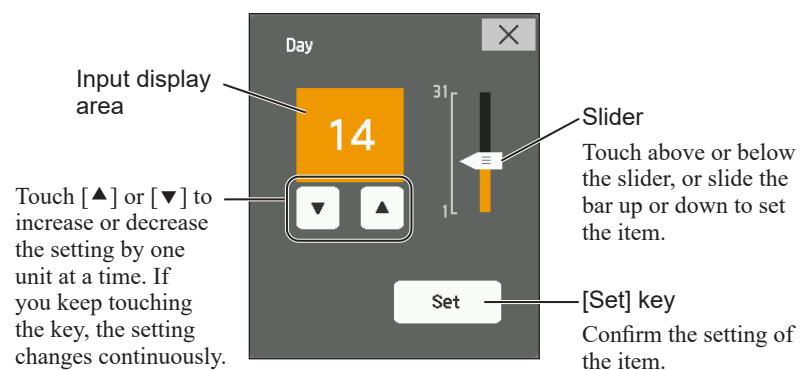
- 2 Enter the date and time.

- 1) Select the item to set (year, month, day, hour, minute).



- 2) Turn the operation knob to enter the item.

- Year: Enter a 4-digit year
- Month - Day - Hour - Minute: Enter 1 or 2 digits



- 3) Press the operation knob to confirm the entered item.

The entered items can be confirmed by the following operations.

- Touch the [Set] key
- Touch the entry column

- 4) Repeat Steps 1) and 2) to confirm all items.



### 3 Confirm the date and time.

- 1) After setting all items, select [Set] and confirm the date and time.
- 2) Select [×] to close the Date/Time Settings window.

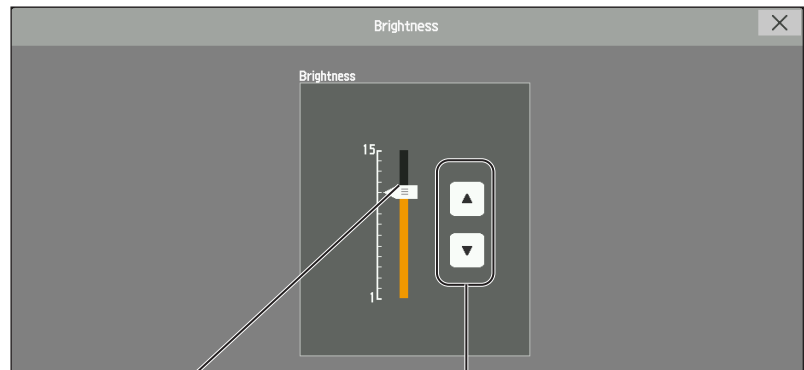
The screenshot shows a 'Date/Time Settings' dialog box. It contains two main sections: 'Date' and 'Time'. The 'Date' section has three input fields labeled 'Day', 'Month', and 'Year' with values '14', '01', and '2020' respectively. The 'Time' section has two input fields labeled 'Hour' and 'Minute' with values '15' and '25' respectively. A green 'Set' button is located in the bottom right corner of the dialog box.

- NOTE
- If an entered value is outside the setting range, an “Out of Range.” message appears.
  - If you change to another screen before selecting [Set], the setting is not changed.

## Brightness Settings

Set the screen brightness.

- 1 Select the [Menu] operation key to display the Menu window.
- 2 Select [Brightness] in “Screen” to display the Brightness window.
- 3 Set the brightness.



Slider

Touch above or below the slider, or slide the bar up or down to set the brightness.

Select [▲] or [▼] to increase or decrease the setting by one unit. If you keep touching the key, the setting changes continuously.

- 4 Select [×] to close the Brightness window.

## O<sub>2</sub> Source Settings

Set the oxygen supply connected to the ventilator.

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- 1 Select the [Menu] operation key to display the Menu window.
- 2 Select [O<sub>2</sub> Source] in “Setup” to display the O<sub>2</sub> Source window.
- 3 Set [HPO] or [LPO].



The selected item is displayed in light blue.

- HPO: Set this when connecting a high pressure oxygen source.
- LPO: Set this when connecting a low pressure oxygen source such as an oxygen cylinder.

- 4 Select [×] to close the [O<sub>2</sub> Source] window.



# Audio Volume Settings

Set the pulse sync sound on/off and alarm sound volume.

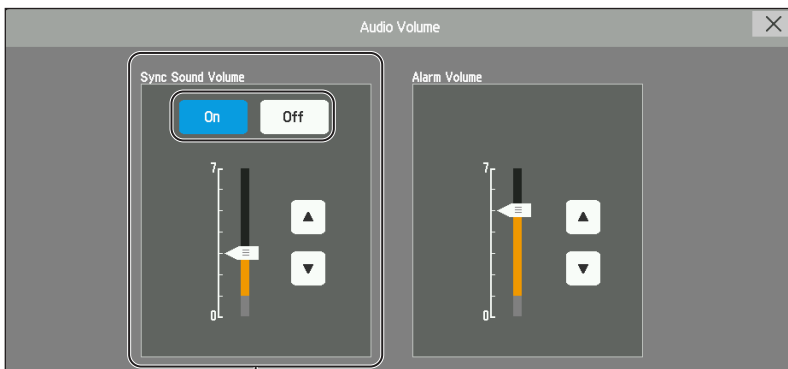
## Volume Setting Items

| Item              | Setting Details                                     |                            |
|-------------------|---|----------------------------|
| Sync Sound Volume | Set the pulse sync sound volume and on/off setting. | On/Off<br>1 to 7 (7 steps) |
| Alarm Volume      | Set the alarm sound volume.                         | 1 to 7 (7 steps)           |

## Setting the Pulse Sync Sound

Set the pulse sync sound on or off and volume.

- 1 Select the [Menu] operation key to display the Menu window.
- 2 Select [Volume] in “Setup” to display the Audio Volume window.
- 3 Select [On] or [Off] for the pulse sync sound.



Pulse sync sound

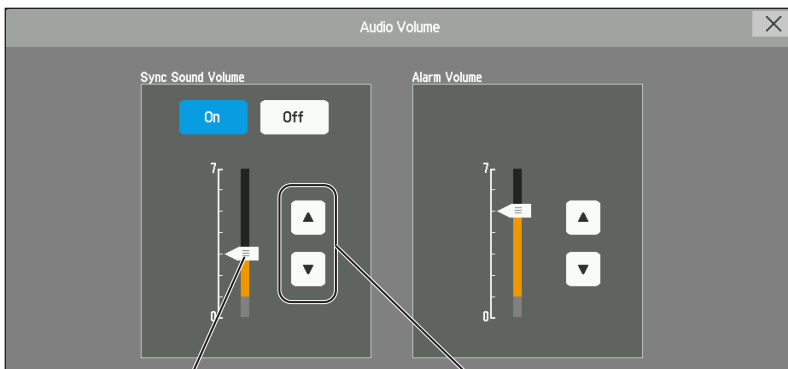
The selected item is displayed in light blue.

If set to [On], set the pulse sync sound volume in Step 4.



When the pulse sync sound is set to [Off], the volume cannot be set.

- 4 Set the volume of the pulse sync sound.



Slider

Touch above or below the slider, or slide the bar up or down to set the volume.

Select [▲] or [▼] to increase or decrease the setting by one unit at a time. If you keep touching the key, the setting changes continuously.

- 5 Select [×] to close the Audio Volume window.

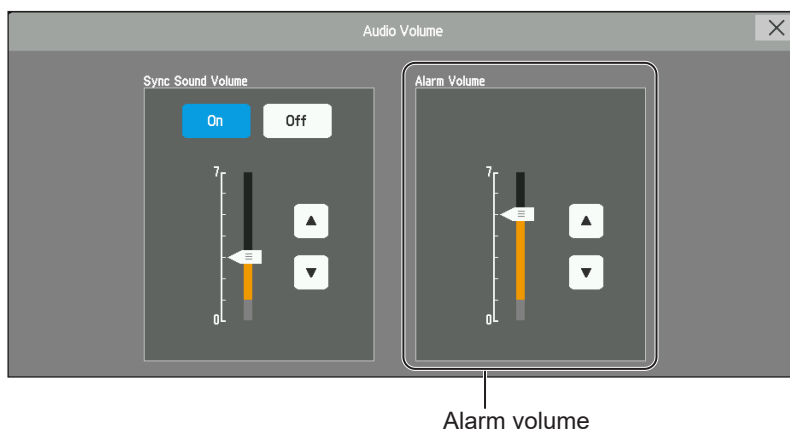
## Setting the Alarm Sound

Set the alarm sound volume.

The setting method is the same as the for the pulse sync sound volume.

Set an appropriate volume for the environment where the ventilator is used.

- 1 Select the [Menu] operation key to display the Menu window.
- 2 Select [Audio Volume] in “Setup” to display the Audio Volume window.
- 3 Set the alarm sound volume.



- 4 Select [×] to close the Audio Volume window.

### Operation at the minimum volume

On alarm occurrence, the alarm sounds at the lowest volume (1).



The lowest alarm volume is set on [System] tab in System Setup window ► the [Audio Volume] tab ► “Alarm Minimum Volume”.

Refer to the following.

Administrator’s Guide:

“[Volume] Page” in Section 3



# Cabinet Settings

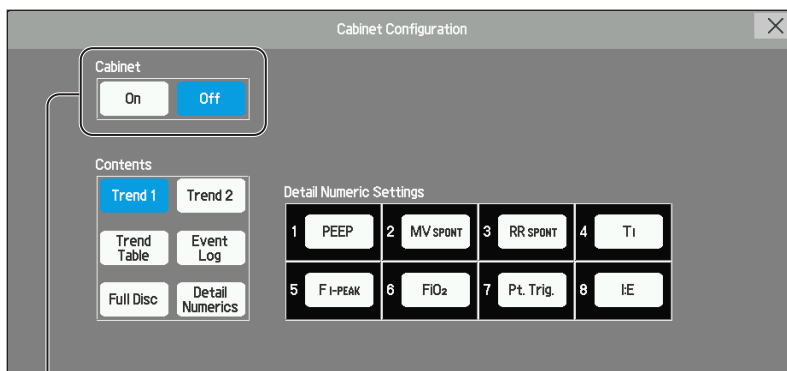
Set the content to be displayed in the cabinet area. The cabinet is an area at the bottom of the Main screen that displays numbers and a review window.

## Display Setting Items

| Item                    | Setting Details   |
|-------------------------|---|
| Cabinet                 | Set whether to display the cabinet on the Main screen.                        |
| Contents                | Set the type of cabinet to be displayed.                                      |
| Detail Numeric Settings | Set the display parameters when the cabinet type is set to [Detail Numerics]. |

## Setting Cabinet Display On/Off

- 1 Select the [Menu] operation key to display the Menu window.
- 2 Select [Cabinet] in “Setup” to display the Cabinet Configuration window.
- 3 Set “Cabinet” to [On] or [Off].

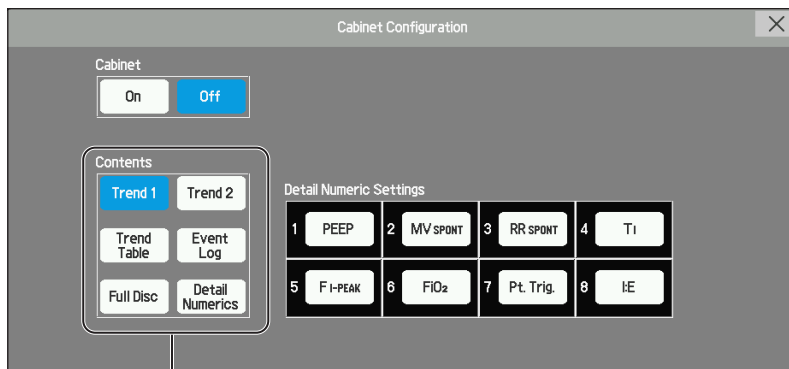


The selected item is displayed in light blue.

## Setting the Cabinet Type

Set the items to display in the cabinet.

The cabinet type can be set regardless of whether the cabinet display is turned on or off. Select the item to be displayed in the cabinet from “Detail Numeric Settings”.

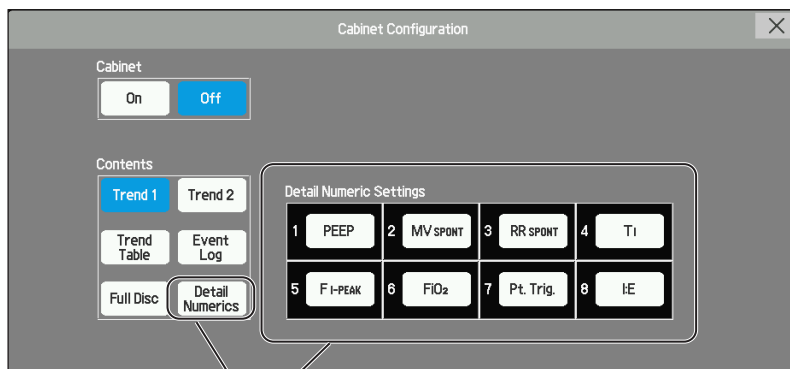


The selected item is displayed in light blue.

## When [Detail Numerics] is set in “Contents”

When “Detail Numerics” is selected, set the parameters to be displayed.

- 1 Select [Detail Numerics] in “Contents”.

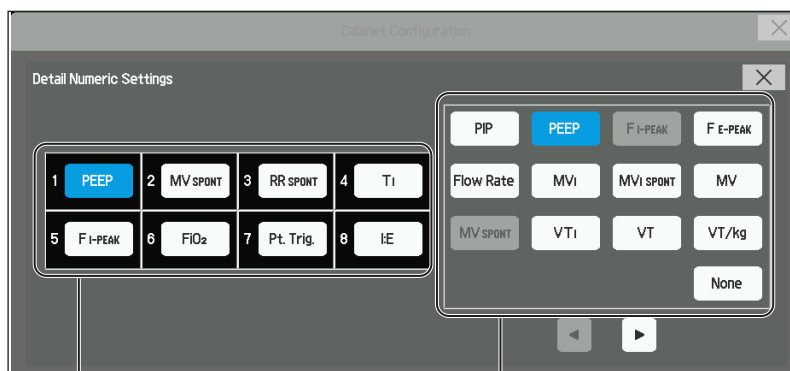


The selected item is displayed in light blue.

- 2 Set the parameters to display.

- 1) Select the parameter display position from the left.
- 2) Select a parameter from the list.

If the parameter to be set is not in the list, select [◀] or [▶] to change the list display.



Parameter display position

The selected item is displayed in light blue.

Display parameter list

The selected item is displayed in light blue. Parameters that have already been set are displayed in gray.

- 3) Repeat Steps 1 and 2 to set the remaining numeric display items.
  - 4) Select [×] to close the parameter setting window.
- 3 Select [×] to close the Cabinet Configuration window.



# Parameter Display and Waveform Settings

Set the parameters and waveforms to display on the Main screen.



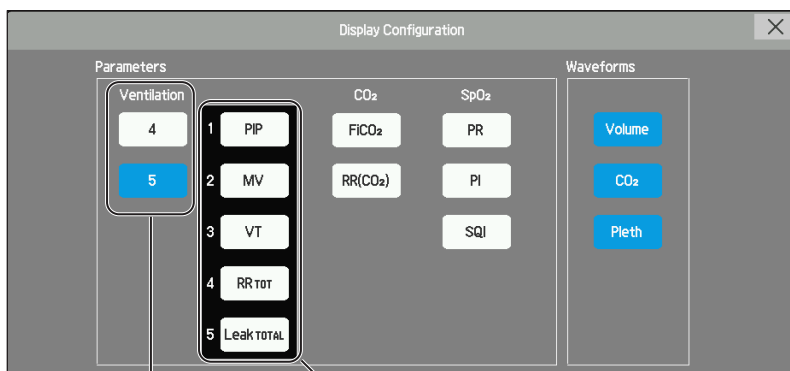
The parameters displayed on the Main screen and the waveform settings are initialized to the preset master values when [New Patient (Adult)] or [New Patient (Pediatric)] is selected on the Patient Selection window after startup.

Refer to the following.

Administrator's Guide:

“Setting Masters” in Section 3

- 1 Select the [Menu] operation key to display the Menu window.
- 2 Select [Display] in “Setup” to display the Display Configuration window.
- 3 Set the parameter display.
  - 1) Select the number of parameters to display from [4] or [5].
  - 2) Select the display position of the parameter from [1] to [5].



Number of parameters

Parameter display position

The selected item is displayed in light blue.

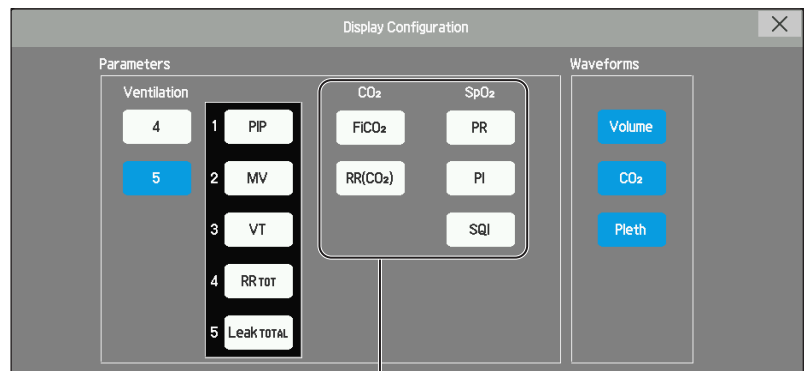
- 3) Select the ventilation parameters to display from the list.



Ventilation parameter list

- 4) Select [X] to close the Vent Parameters window.

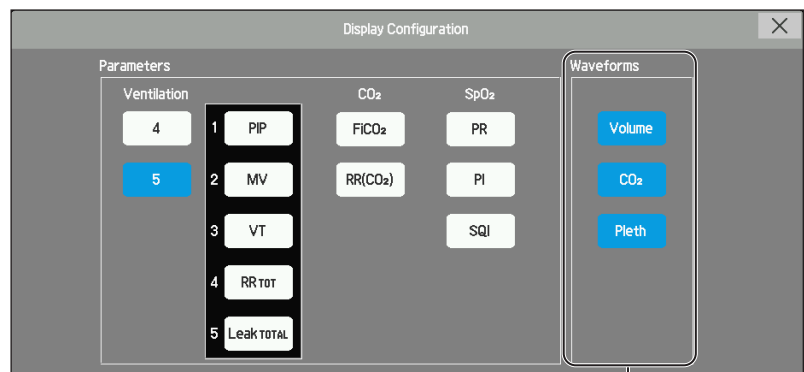
5) Select the CO<sub>2</sub> and SpO<sub>2</sub> parameters to display.



CO<sub>2</sub>, SpO<sub>2</sub>

The selected item is displayed in light blue.

4 Select the waveforms to display.



Waveforms

The selected item is displayed in light blue.

5 Select [×] to close the display window.



## Clock Accuracy

The accuracy of the ventilator clock is as follows.

- When using at normal temperature (5°C to 40°C (41°F to 104°F)):

Time error up to about  $\pm 5$  seconds a month

- Storage temperature range (-20°C to +65°C (-4°F to +149°F)):

Time error up to about  $\pm 10$  seconds a month

If the time displayed in the upper right of the Main screen is not correct, select the time display on the upper right of the screen, and reset the time on the Date/Time window.

**NOTE:** When powering on or selecting a new patient, make sure that the time displayed on the upper right of the screen is correct. Note that if you change the date and time settings during monitoring, the date and time of all stored data is also changed.



Refer to "Date and Time Settings" (p. 12-3).



# 13

## Troubleshooting

|                         |       |
|-------------------------|-------|
| Screen Messages.....    | 13-2  |
| Ventilation.....        | 13-3  |
| CO <sub>2</sub> .....   | 13-12 |
| SpO <sub>2</sub> .....  | 13-15 |
| Ventilator.....         | 13-18 |
| Troubleshooting.....    | 13-24 |
| During Measurement..... | 13-24 |
| Ventilation.....        | 13-25 |
| CO <sub>2</sub> .....   | 13-28 |
| SpO <sub>2</sub> .....  | 13-29 |



# Screen Messages

This section lists all messages that may appear on the screen while using the ventilator.


Each error message is followed by the corresponding cause and countermeasure. After taking the recommended action, make sure that the error message disappears and that the ventilator operates normally. After that, you can use the ventilator again.

**NOTE:** If the message does not disappear after taking the recommended actions, attach an “Out of Order” or “Do Not Use” or similar notice to the ventilator and contact your Nihon Kohden representative.

The alarm priorities and operations during pausing in the tables on the following pages are described below.

## Alarm priority

The priority of upper and lower limit alarms and technical alarms on the ventilator can be changed. There is also an alarm escalation function that can raise the priority of an alarm depending on its duration or parameter value.

| Priority | Meaning  |
|----------|--|
| ●        | Default priority   |
| ○        | Priority can be changed<br> Changing the alarm priority<br>Refer to the following.<br>Administrator's Guide:<br>“Setting the Alarm Priority” in Section 3 |
| ●↑, ○↑   | Priority that can be set by the alarm escalation function  |
| —        | No alarm priority setting  |

## Pausing Alarms

If you select the [Audio Paused] key for a generated alarm, the ventilator operates as follows.

| Ventilator Operations during Pausing | Description of Operation   |
|--------------------------------------|--|
| Re-alarm                             | If the [Audio Paused] key is selected, the alarm sound is temporarily paused.<br>While the alarm condition continues, the alarm indicator blinks or lights, and messages and numeric values on the screen continue to be highlighted.<br>If the alarm condition continues for longer than the alarm silence time, the alarm sound returns. |
| Silence                              | If the [Audio Paused] key is selected, the alarm sound is paused indefinitely.<br>While the alarm condition continues, the alarm indicator blinks or lights, and messages and numeric values on the screen continue to be highlighted.   |
| Termination                          | If the [Audio Paused] key is selected, the alarm sound is paused, the alarm indicator turns off, and highlighting of the measurement values is canceled.   |
| —                                    | This is a message other than an alarm.   |



Refer to “Operation After Audio Pause” in Section 9.

## Ventilation

| Message  | Priority |         |          |         | Possible Cause   | Action  | Audio Paused Operation |
|----------|----------|---------|----------|---------|--|---|------------------------|
|          | Crisis   | Warning | Advisory | Message |  |   |                        |
| High PIP | ●↑       | ○       | —        | —       | <p>The peak inspiratory pressure (PIP) measurement value is equal to or greater than the upper limit alarm.</p> <p>(If this alarm continues for a certain period of time, the ventilator forcibly ends the inspiration phase and releases the pressure to PEEP level or atmospheric pressure level.)</p> | <ul style="list-style-type: none"> <li>• Check the patient.</li> <li>• Check the control settings and alarm settings.</li> <li>• Check that there is no clogging from water droplets or other substance, or kinking or blockage in the patient interface, breathing circuit, exhalation port, pressure sensor line, and flow sensor line.</li> <li>• Calibrate the breathing circuit (Perform a circuit check).</li> <li>• If the problem is not resolved, immediately connect the patient to an alternative ventilation method and contact your Nihon Kohden representative.</li> </ul>  | Re-alarm               |
| Low PIP  | ●↑       | ○       | —        | —       | <p>The peak inspiratory pressure (PIP) measurement value is equal to or less than the lower limit alarm.</p>   | <ul style="list-style-type: none"> <li>• Check the patient.</li> <li>• Check the control settings and alarm settings.</li> <li>• Check that there is not a large leak from the patient interface.</li> <li>• Check that there are no leaks from the breathing circuit, pressure sensor line, and flow sensor line.</li> <li>• Check that there is no clogging from water droplets or other substance, kinking, or blockage in the pressure sensor line and flow sensor line.</li> <li>• Calibrate the breathing circuit (Perform a circuit check).</li> <li>• If the problem is not resolved, immediately connect the patient to an alternative ventilation method and contact your Nihon Kohden representative.</li> </ul> | Re-alarm               |



| Message   | Priority |         |          |         | Possible Cause   | Action   | Audio Paused Operation |
|-----------|----------|---------|----------|---------|--|--|------------------------|
|           | Crisis   | Warning | Advisory | Message |  |  |                        |
| High PEEP | ●↑       | ○       | —        | —       | The PEEP measurement value is greater than the EPAP/CPAP setting value by 5 hPa or more.   | <ul style="list-style-type: none"> <li>• Check the patient.</li> <li>• Check the control settings.</li> <li>• Check that there is no clogging from water droplets or other substance, or kinking or blockage in the patient interface, breathing circuit, exhalation port, pressure sensor line, and flow sensor line.</li> <li>• Calibrate the breathing circuit (Perform a circuit check).</li> <li>• If the problem is not resolved, immediately connect the patient to an alternative ventilation method and contact your Nihon Kohden representative.</li> </ul>  | Re-alarm               |
| Low PEEP  | ●↑       | ○       | —        | —       | <p>EPAP/CPAP setting = 4 to 5 hPa and the PEEP measurement value is less than the EPAP/CPAP setting by 3 hPa or less.</p> <p>Or, EPAP/CPAP setting = 6 to 11 hPa and the PEEP measurement value is less than the EPAP/CPAP setting by 4 hPa or less.</p> <p>Or, EPAP/CPAP setting = 12 hPa or more and the PEEP measurement value is less than the EPAP/CPAP setting by 5 hPa or less.</p> | <ul style="list-style-type: none"> <li>• Check the patient.</li> <li>• Check the control settings.</li> <li>• Check that there is not a large leak from the patient interface.</li> <li>• Check that there are no leaks from the breathing circuit, pressure sensor line, and flow sensor line.</li> <li>• Check that there is no clogging from water droplets or other substance, or kinking or blockage in the pressure sensor line and flow sensor line.</li> <li>• Calibrate the breathing circuit (Perform a circuit check).</li> <li>• If the problem is not resolved, immediately connect the patient to an alternative ventilation method and contact your Nihon Kohden representative.</li> </ul> | Re-alarm               |
| High MV   | ○↑       | ●       | —        | —       | The minute volume (MV) measurement value is equal to or greater than the upper limit alarm.  | <ul style="list-style-type: none"> <li>• Check the patient.</li> <li>• Check the control settings and alarm settings.</li> <li>• Check that there is not a large leak from the patient interface.</li> <li>• Check that there are no leaks from the breathing circuit, pressure sensor line, and flow sensor line.</li> <li>• When using a flow sensor, check that there is no clogging from water droplets or other substance, or kink or blockage in the flow sensor line. If necessary, replace and recalibrate the flow sensor.</li> </ul>   | Re-alarm               |

| Message    | Priority |         |          |         | Possible Cause  | Action   | Audio Paused Operation |
|------------|----------|---------|----------|---------|---|--|------------------------|
|            | Crisis   | Warning | Advisory | Message |   |  |                        |
| Low MV     | ○↑       | ●       | —        | —       | The minute volume (MV) measurement value is equal to or less than the lower limit alarm.                | <ul style="list-style-type: none"> <li>• Check the patient.</li> <li>• Check the control settings and alarm settings.</li> <li>• Check that there is not a large leak from the patient interface.</li> <li>• Check that there are no leaks from the breathing circuit, pressure sensor line, and flow sensor line.</li> <li>• When using a flow sensor, check that there is no clogging from water droplets or other substance, or kink or blockage in the flow sensor line. If necessary, replace and recalibrate the flow sensor.</li> </ul> | Re-alarm               |
| High VT    | —        | ●       | ○        | —       | The expiratory tidal volume (VT) measurement value is equal to or greater than the upper limit alarm.   | <ul style="list-style-type: none"> <li>• Check the patient.</li> <li>• Check the control settings and alarm settings.</li> <li>• Check that there is not a large leak from the patient interface.</li> <li>• Check that there are no leaks from the breathing circuit, pressure sensor line, and flow sensor line.</li> <li>• When using a flow sensor, check that there is no clogging from water droplets or other substance, or kink or blockage in the flow sensor line. If necessary, replace and recalibrate the flow sensor.</li> </ul> | Re-alarm               |
| Low VT     | —        | ●       | ○        | —       | The expiratory tidal volume (VT) measurement value is equal to or less than the lower limit alarm.      | <ul style="list-style-type: none"> <li>• Check the patient.</li> <li>• Check the control settings and alarm settings.</li> <li>• Check that there is not a large leak from the patient interface.</li> <li>• Check that there are no leaks from the breathing circuit, pressure sensor line, and flow sensor line.</li> <li>• When using a flow sensor, check that there is no clogging from water droplets or other substance, or kink or blockage in the flow sensor line. If necessary, replace and recalibrate the flow sensor.</li> </ul> | Re-alarm               |
| High RRTOT | ○↑       | ●↑      | ○        | —       | The total respiratory rate (RRTOT) measurement value is equal to or greater than the upper limit alarm. | <ul style="list-style-type: none"> <li>• Check the patient.</li> <li>• Check the control settings and alarm settings.</li> </ul>   | Re-alarm               |

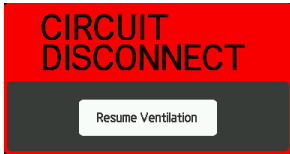


| Message                            | Priority |         |          |         | Possible Cause  | Action   | Audio Paused Operation |
|------------------------------------|----------|---------|----------|---------|---|--|------------------------|
|                                    | Crisis   | Warning | Advisory | Message |   |  |                        |
| Low RRTOT                          | ○↑       | ●↑      | ○        | —       | The total respiratory rate (RRTOT) measurement value is equal to or less than the lower limit alarm.  | <ul style="list-style-type: none"> <li>• Check the patient.</li> <li>• Check the control settings and alarm settings.</li> <li>• Check that there is not a large leak from the patient interface.</li> <li>• Check that there are no leaks from the breathing circuit, pressure sensor line, and flow sensor line.</li> <li>• When using a flow sensor, check that there is no clogging from water droplets or other substance, or kink or blockage in the flow sensor line. If necessary, replace and recalibrate the flow sensor.</li> </ul> | Re-alarm               |
| High FiO <sub>2</sub> <sup>1</sup> | ○↑       | ●       | —        | —       | <ul style="list-style-type: none"> <li>• The FiO<sub>2</sub> measurement value is at least 7% higher than the FiO<sub>2</sub> setting value (when “O<sub>2</sub> Source” is set to “HPO” in “Setup” on the Menu window).</li> <li>• The FiO<sub>2</sub> measurement value is equal to or greater than the upper limit alarm value (when “O<sub>2</sub> Source” is set to “LPO” in “Setup” on the Menu window).</li> </ul> <p>This alarm is active only when [System] in System Setup window<br/>▶ [Vent] ▶ “O<sub>2</sub> Sensor Enable” is selected.</p> | <ul style="list-style-type: none"> <li>• Check the patient.</li> <li>• Check the oxygen supply.</li> <li>• Recalibrate the O<sub>2</sub> sensor.</li> <li>• When using a galvanic oxygen sensor, replace and recalibrate the O<sub>2</sub> sensor.</li> <li>• If the problem is not resolved, immediately connect the patient to an alternative ventilation method and contact your Nihon Kohden representative.</li> </ul>  | Re-alarm               |

| Message  | Priority |         |          |         | Possible Cause  | Action   | Audio Paused Operation |
|--|----------|---------|----------|---------|---|--|------------------------|
|  | Crisis   | Warning | Advisory | Message |   |  |                        |
| Low FiO <sub>2</sub> <sup>1</sup>                          | ●        | —       | —        | —       | <ul style="list-style-type: none"> <li>The FiO<sub>2</sub> measurement value is at least 7% lower than the FiO<sub>2</sub> setting value or the FiO<sub>2</sub> measurement value is equal to or less than 18% (when “O<sub>2</sub> Source” is set to “HPO” in “Setup” on the Menu window).</li> <li>The FiO<sub>2</sub> measurement value is equal to or less than the lower limit alarm (when “O<sub>2</sub> Source” is set to “LPO” in “Setup” on the Menu window).</li> </ul> <p>This alarm is active only when [System] in System Setup window ► [Vent] ► “O<sub>2</sub> Sensor Enable” is selected.</p> | <ul style="list-style-type: none"> <li>Check the patient.</li> <li>Check the oxygen supply.</li> <li>Check the oxygen supply setting.</li> <li>Recalibrate the oxygen sensor.</li> <li>When using a galvanic oxygen sensor, replace and recalibrate the O<sub>2</sub> sensor.</li> <li>If the problem is not resolved, immediately connect the patient to an alternative ventilation method and contact your Nihon Kohden representative.</li> </ul> | Re-alarm               |
| Apnea<br>(Except for O <sub>2</sub> Therapy mode)          | ●↑       | ○       | —        | —       | <p>The apnea time is equal to or greater than the upper limit alarm.</p> <p>This alarm is active only when “Apnea Ventilation” is set to [Off] on the [Apnea Ventilation] tab of the Control Settings window in SPONT-PS or PPV mode.</p>   | <ul style="list-style-type: none"> <li>Check the patient.</li> <li>Check the control settings and alarm settings.</li> <li>Check that the patient interface and breathing circuit are not disconnected from the patient.</li> <li>Check that there is not a large leak from the patient interface.</li> <li>Set “Apnea Ventilation” to [On] on the [Apnea Ventilation] tab of the Control Settings window as necessary.</li> </ul>                   | Re-alarm               |
| Apnea Ventilation Active<br>(Only in SPONT-PS or PPV mode) | —        | —       | ●        | —       | <p>The apnea time reached or exceeded the upper limit alarm and apnea ventilation started.</p> <p>This alarm is only active when “Apnea Ventilation” on the [Apnea Ventilation] tab of the Control Settings window is set to [On].</p>  | <ul style="list-style-type: none"> <li>Check the patient.</li> <li>Check the control settings and alarm settings.</li> <li>Check that the patient interface and breathing circuit are not disconnected from the patient.</li> <li>Check that there is not a large leak from the patient interface.</li> </ul>  | Silence                |
| O <sub>2</sub> Check Sensor                                | ●        | —       | —        | —       | <ul style="list-style-type: none"> <li>Abnormality in the O<sub>2</sub> sensor.</li> <li>Incorrect setting for the O<sub>2</sub> sensor.</li> </ul> <p>This alarm is active only when [System] in System Setup window ► [Vent] ► “O<sub>2</sub> Sensor Enable” is selected.</p>   | <ul style="list-style-type: none"> <li>Check the patient.</li> <li>Check the O<sub>2</sub> sensor settings.</li> <li>Recalibrate the O<sub>2</sub> sensor.</li> <li>When using a galvanic oxygen sensor, replace and recalibrate the O<sub>2</sub> sensor.</li> <li>If the problem is not resolved, immediately connect the patient to an alternative ventilation method and contact your Nihon Kohden representative.</li> </ul>                    | Re-alarm               |



| Message                            | Priority |         |          |         | Possible Cause  | Action   | Audio Paused Operation |
|------------------------------------|----------|---------|----------|---------|---|--|------------------------|
|                                    | Crisis   | Warning | Advisory | Message |   |  |                        |
| High O <sub>2</sub> Inlet Pressure | —        | ●       | —        | —       | <p>The supply pressure to the high or low pressure oxygen input port exceeds 80 kPa.</p> <p>(Even during an alarm, gas containing oxygen is sent to the patient.)</p> <p>This alarm is effective only during ventilation operation when “O<sub>2</sub> Source” is set to “LPO” in “Setup” on the Menu window</p>  | <ul style="list-style-type: none"> <li>• Check the patient.</li> <li>• Check the oxygen supply.</li> <li>• Check the oxygen supply and FiO<sub>2</sub> settings.</li> <li>• If the problem is not resolved, immediately connect the patient to an alternative ventilation method and contact your Nihon Kohden representative.</li> </ul>  | Re-alarm               |
| O <sub>2</sub> Supply Low          | —        | ●       | —        | —       | <p>The supply pressure the high or low pressure oxygen input port is less than 250 kPa.</p> <p>(Even during an alarm, gas containing oxygen is sent to the patient but the set FiO<sub>2</sub> cannot be guaranteed.)</p> <p>This alarm is effective only during ventilation operation when the “O<sub>2</sub> Source” is set to “HPO” in “Setup” on the Menu window and the FiO<sub>2</sub> setting is set to 22% or more.</p> | <ul style="list-style-type: none"> <li>• Check the patient.</li> <li>• Check the oxygen supply.</li> <li>• Check that the high pressure oxygen hose is securely connected.</li> <li>• Check the oxygen supply and FiO<sub>2</sub> settings.</li> <li>• If the problem is not resolved, immediately connect the patient to an alternative ventilation method and contact your Nihon Kohden representative.</li> </ul> | Re-alarm               |
| O <sub>2</sub> Supply Loss         | ●        | —       | —        | —       | <p>The supply pressure to the high or low pressure oxygen input port is less than 150 kPa.</p> <p>(During an alarm, gas containing oxygen is not sent to the patient but air is sent to the patient.)</p> <p>This alarm is effective only during ventilation operation when the “O<sub>2</sub> Source” is set to “HPO” in “Setup” on the Menu window and the FiO<sub>2</sub> setting is set to 22% or more.</p>                 | <ul style="list-style-type: none"> <li>• Check the patient.</li> <li>• Check the oxygen supply.</li> <li>• Check that the high pressure oxygen hose is securely connected.</li> <li>• Check the oxygen supply and FiO<sub>2</sub> settings.</li> <li>• If the problem is not resolved, immediately connect the patient to an alternative ventilation method and contact your Nihon Kohden representative.</li> </ul> | Re-alarm               |

| Message  | Priority |         |          |         | Possible Cause   | Action  | Audio Paused Operation |
|--|----------|---------|----------|---------|--|---|------------------------|
|  | Crisis   | Warning | Advisory | Message |  |   |                        |
| Circuit Disconnect<br>(Except for O <sub>2</sub> Therapy mode) | ●        | —       | —        | —       | <ul style="list-style-type: none"> <li>Breathing circuit is disconnected from the ventilator.</li> <li>Large leak in the breathing circuit.</li> </ul> | <ul style="list-style-type: none"> <li>Check the patient.</li> <li>Check that the breathing circuit is securely connected to the patient and the ventilator.</li> <li>Check that there is not a large leak from the patient interface and breathing circuit.</li> <li>When ventilation does not restart automatically after reconnecting the breathing circuit and the patient interface, select [Resume Ventilation] on the CIRCUIT DISCONNECT popup window that appears.</li> </ul>   | Re-alarm               |
| Circuit Obstruction  | ●        | —       | —        | —       | Except for O <sub>2</sub> Therapy mode<br>Breathing circuit or exhalation port is blocked.   | <ul style="list-style-type: none"> <li>Check the patient.</li> <li>Check that there is no kink or obstruction in the patient interface, breathing circuit, and exhalation port.</li> <li>Calibrate the breathing circuit (Perform a circuit check).</li> <li>If the problem is not resolved, immediately connect the patient to an alternative ventilation method and contact your Nihon Kohden representative.</li> </ul>  | Re-alarm               |
|  |          |         |          |         | During O <sub>2</sub> Therapy mode<br>Breathing circuit or nasal cannula is blocked.   |   |                        |
| High Gas Temperature   | ●        | —       | —        | —       | High gas output temperature  | <ul style="list-style-type: none"> <li>Check the patient.</li> <li>Immediately connect the patient to an alternative ventilation method and check the following points.               <ul style="list-style-type: none"> <li>Ventilator is being used within the operating temperature range (not installed in a place which is exposed to direct sunlight).</li> <li>Not taking in hot air at the gas suction port.</li> <li>Fan ventilation opening is not blocked and the fan filter is not dirty.</li> </ul> </li> <li>If the problem is not resolved, contact your Nihon Kohden representative.</li> </ul> | Re-alarm               |



| Message                                       | Priority |         |          |         | Possible Cause   | Action   | Audio Paused Operation |
|---|----------|---------|----------|---------|--|--|------------------------|
|   | Crisis   | Warning | Advisory | Message |  |  |                        |
| Volume Target Not Met<br>(Only in PRVC mode)  | —        | —       | —        | ●       | IPAP is limited by the MaxP setting and the ventilation volume supplied to the patient did not reach the VT setting. | <ul style="list-style-type: none"> <li>• Check the patient.</li> <li>• Check the control settings.</li> <li>• Check that there is no clogging from water droplets or other substance, or kinking or blockage in the patient interface, breathing circuit, exhalation port, pressure sensor line, and flow sensor line.</li> <li>• Calibrate the breathing circuit (Perform a circuit check).</li> <li>• When using a flow sensor, check that there is no clogging from water droplets or other substance, or kink or blockage in the flow sensor line. If necessary, replace and recalibrate the flow sensor.</li> </ul> | —                      |
| Volume Target Exceeded<br>(Only in PRVC mode) | —        | —       | —        | ●       | IPAP is limited by the MinP setting and the ventilation volume supplied to the patient exceeded the VT setting.      | <ul style="list-style-type: none"> <li>• Check the patient.</li> <li>• Check the control settings.</li> <li>• Check that there is not a large leak from the patient interface.</li> <li>• Check that there are no leaks from the breathing circuit, pressure sensor line, and flow sensor line.</li> <li>• Calibrate the breathing circuit (Perform a circuit check).</li> <li>• When using a flow sensor, check that there is no clogging from water droplets or other substance, or kink or blockage in the flow sensor line. If necessary, replace and recalibrate the flow sensor.</li> </ul>                        | —                      |
| Max P Reached<br>(Only in PPV mode)           | —        | —       | —        | ●       | IPAP is limited by the MaxP setting.   | <ul style="list-style-type: none"> <li>• Check the patient.</li> <li>• Check the control settings.</li> <li>• Check that there is not a large leak from the patient interface.</li> <li>• Check that there are no leaks in the breathing circuit, pressure sensor line, and flow sensor line.</li> </ul>   | —                      |

| Message   | Priority |         |          |         | Possible Cause  | Action  | Audio Paused Operation |
|---|----------|---------|----------|---------|---|---|------------------------|
|   | Crisis   | Warning | Advisory | Message |   |   |                        |
| Max VT Reached (Only in PPV mode)                                     | —        | —       | —        | ●       | Depending on the MaxVT setting, the inspiration phase is interrupted and the pressure is released to the PEEP level.  | <ul style="list-style-type: none"> <li>• Check the patient.</li> <li>• Check the control settings.</li> <li>• Check that there is not a large leak from the patient interface.</li> <li>• Check that there are no leaks from the breathing circuit, pressure sensor line, and flow sensor line.</li> <li>• When using a flow sensor, check that there is no clogging from water droplets or other substance, or kink or blockage in the flow sensor line. If necessary, replace and recalibrate the flow sensor.</li> </ul> | —                      |
| Check Prox. Flow Sensor Line (Except for O <sub>2</sub> Therapy mode) | ●        | —       | —        | —       | <ul style="list-style-type: none"> <li>• Flow sensor line is disconnected.</li> <li>• Flow sensor line is blocked.</li> <li>• Incorrect Proximal Sensor setting in the patient circuit settings.</li> </ul> <p>This alarm is only active when the Proximal Sensor setting on the patient circuit setting window is set to “Flow Sensor”.</p> <p>During an alarm, the flow sensor inside the ventilator is used.</p> | <ul style="list-style-type: none"> <li>• Check the patient.</li> <li>• Check that there is no clogging from water droplets or other substance, or kinking or blockage in the flow sensor line.</li> <li>• Check the orientation of the flow sensor connection.</li> <li>• Check that the flow sensor line is not disconnected.</li> <li>• Check the Proximal Sensor setting in the patient circuit sensor settings.</li> </ul>  | Re-alarm               |
| Check Prox. Pressure Line (Except for O <sub>2</sub> Therapy mode)    | ●        | —       | —        | —       | <ul style="list-style-type: none"> <li>• Pressure sensor line is disconnected.</li> <li>• Pressure sensor line is blocked.</li> </ul> <p>This alarm is only active when the Proximal Sensor setting on the patient circuit setting window is set to “Pressure Sensor”.</p>  | <ul style="list-style-type: none"> <li>• Check the patient.</li> <li>• Check that there is no clogging from water droplets or other substance, or kinking or blockage in the pressure sensor line.</li> <li>• Check that the pressure sensor line is not disconnected.</li> </ul>   | Re-alarm               |
| Insp. Pressure Limited by High PIP Setting                            | —        | —       | —        | ●       | Inspiratory pressure is limited by the High PIP alarm setting.  | <ul style="list-style-type: none"> <li>• Check the patient.</li> <li>• Check the ventilator settings (EPAP/CPAP, PS, IPAP, Max P) and alarm settings (High PIP alarm).</li> </ul>   | —                      |

<sup>1</sup> When Elevated O<sub>2</sub> is operating, High/Low FiO<sub>2</sub> alarms are generated according to the criteria for Target FiO<sub>2</sub> set on the Elevated O<sub>2</sub> window.



## CO<sub>2</sub>

| Message                    | Priority |         |          |         | Possible Cause   | Action  | Alarm Pause Operation |
|----------------------------|----------|---------|----------|---------|--|---|-----------------------|
|                            | Crisis   | Warning | Advisory | Message |  |   |                       |
| High EtCO <sub>2</sub>     | ○        | ●       | —        | —       | The EtCO <sub>2</sub> measurement value is equal to or greater than the upper limit alarm.     | <ul style="list-style-type: none"> <li>• Check the patient.</li> <li>• Check the control settings and alarm settings.</li> <li>• Check that the exhalation port in the breathing circuit is securely connected.</li> <li>• Check that there is no blockage in the breathing circuit and exhalation port.</li> <li>• Replace the NPPV cap-ONE mask and airway adapter as necessary and recalibrate the CO<sub>2</sub> sensor.</li> </ul> | Re-alarm              |
| Low EtCO <sub>2</sub>      | ○        | ●       | —        | —       | The EtCO <sub>2</sub> measurement value is equal to or less than the lower limit alarm.        | <ul style="list-style-type: none"> <li>• Check the patient.</li> <li>• Check the control settings and alarm settings.</li> <li>• Check that there is not a large leak from the patient interface.</li> <li>• Replace the NPPV cap-ONE mask and airway adapter as necessary and recalibrate the CO<sub>2</sub> sensor.</li> </ul>  | Re-alarm              |
| High FiCO <sub>2</sub>     | ○        | ●       | —        | —       | The FiCO <sub>2</sub> measurement value is equal to or greater than the upper limit alarm.     | <ul style="list-style-type: none"> <li>• Check the patient.</li> <li>• Check the control settings and alarm settings.</li> <li>• Check that the exhalation port in the breathing circuit is securely connected.</li> <li>• Check that there is no blockage in the breathing circuit and exhalation port.</li> <li>• Replace the NPPV cap-ONE mask and airway adapter as necessary and recalibrate the CO<sub>2</sub> sensor.</li> </ul> | Re-alarm              |
| High RR (CO <sub>2</sub> ) | ○        | ●       | ○        | —       | The RR (CO <sub>2</sub> ) measurement value is equal to or greater than the upper limit alarm. | <ul style="list-style-type: none"> <li>• Check the patient.</li> <li>• Check the control settings and alarm settings.</li> <li>• Replace the NPPV cap-ONE mask and airway adapter as necessary and recalibrate the CO<sub>2</sub> sensor.</li> </ul>  | Re-alarm              |
| Low RR (CO <sub>2</sub> )  | ○        | ●       | ○        | —       | The RR (CO <sub>2</sub> ) measurement value is equal to or less than the lower limit alarm.    | <ul style="list-style-type: none"> <li>• Check the patient.</li> <li>• Check the control settings and alarm settings.</li> <li>• Check that there is not a large leak from the patient interface.</li> <li>• Check that there is no leak in the breathing circuit.</li> <li>• Replace the NPPV cap-ONE mask and airway adapter as necessary and recalibrate the CO<sub>2</sub> sensor.</li> </ul>                                       | Re-alarm              |

| Message  | Priority |                 |          |         | Possible Cause   | Action  | Alarm Pause Operation            |
|--|----------|-----------------|----------|---------|--|---|----------------------------------|
|  | Crisis   | Warning         | Advisory | Message |  |   |                                  |
| Apnea (CO <sub>2</sub> )   | ○↑       | ●↑              | ○        | —       | <p>The apnea time (measured by the CO<sub>2</sub> sensor) is equal to or greater than the upper limit alarm.</p> <p>This alarm occurs when the upper limit alarm is equal to or greater than the upper alarm limit regardless of the setting of “Apnea Ventilation” on the [Apnea Ventilation] tab on the Control Settings window.</p> | <ul style="list-style-type: none"> <li>Check the patient.</li> <li>Check the control settings and alarm settings.</li> <li>Check that the patient interface and breathing circuit are not disconnected from the patient.</li> <li>Check that there is not a large leak from the patient interface.</li> <li>Replace the NPPV cap-ONE mask and airway adapter as necessary and recalibrate the CO<sub>2</sub> sensor.</li> </ul> | Re-alarm                         |
| Parameter Not Available  | —        | —               | ●        | —       | An item other than a CO <sub>2</sub> sensor or SpO <sub>2</sub> probe is connected to the MULTI socket.  | Only use a CO <sub>2</sub> sensor or SpO <sub>2</sub> probe which is compatible with this ventilator. Refer to “CO <sub>2</sub> Sensors” in Section 16 for sensors that can be used with this ventilator.   | Silence                          |
| CO <sub>2</sub> Disconnect   | —        | —               | ●        | —       | CO <sub>2</sub> sensor kit is removed from the MULTI socket.   | Select the [Audio Paused] key to cancel the message.  | Termination                      |
|  |          |                 |          |         | CO <sub>2</sub> sensor kit is removed from the MULTI socket.   | Securely connect the CO <sub>2</sub> sensor kit to the MULTI socket.  |                                  |
|  |          |                 |          |         | CO <sub>2</sub> sensor kit is deteriorated.  | Replace the CO <sub>2</sub> sensor kit.   |                                  |
| CO <sub>2</sub> Duplicated Parameter   | —        | —               | ●        | —       | CO <sub>2</sub> sensor kit is connected to 2 channels.   | Connect the CO <sub>2</sub> sensor kit to only one channel.   | Silence                          |
| CO <sub>2</sub> Check CO <sub>2</sub> Cell <sup>1</sup> (When using TG-980P) | —        | ○↑ <sup>2</sup> | ●        | —       | <p>Water accumulation in breathing circuit.</p> <p>Airway adapter is dirty and measurement is not possible.</p>  | <ul style="list-style-type: none"> <li>Remove the accumulated water from the breathing circuit and reattach the airway adapter in the correct orientation in the breathing circuit.</li> <li>If necessary, replace the airway adapter.</li> </ul>   | Silence<br>Re-alarm <sup>3</sup> |
| CO <sub>2</sub> Adapter Fault  | —        | —               | ●        | —       | Damage or deterioration in the CO <sub>2</sub> adapter or break in the cord.   | Replace it with a new CO <sub>2</sub> adapter.  | Silence                          |
| CO <sub>2</sub> Sensor Fault   | —        | —               | ●        | —       | Damage or deterioration in the CO <sub>2</sub> sensor or break in the cord.  | Replace it with a new CO <sub>2</sub> sensor.   | Silence                          |
| CO <sub>2</sub> Check Sensor   | —        | —               | ●        | —       | Insufficient light intensity   | Refer to the manual for the CO <sub>2</sub> sensor kit.   | Silence                          |
| CO <sub>2</sub> Cell Disconnect <sup>1</sup> (When using TG-980P)            | —        | —               | ●        | —       | Airway adapter is disconnected.  | Connect the airway adapter to the CO <sub>2</sub> sensor kit.   | Silence                          |
| CO <sub>2</sub> Barometric Sensor Fault                                      | —        | —               | ●        | —       | <ul style="list-style-type: none"> <li>Cannot communicate with pressure sensor</li> <li>Abnormal pressure value (499 hPa or less, 1061 hPa or more)</li> </ul>   | Contact your Nihon Kohden representative.   | Re-alarm                         |



| Message   | Priority |         |          |         | Possible Cause   | Action | Alarm Pause Operation |
|---|----------|---------|----------|---------|--|--------|-----------------------|
|   | Crisis   | Warning | Advisory | Message |  |        |                       |
| CO <sub>2</sub> Out of Range <sup>1</sup><br>(When using TG-980P)         | —        | —       | —        | ●       | CO <sub>2</sub> measurement value exceeds the upper limit alarm.   | —      | —                     |
| CO <sub>2</sub> Unspecified Accuracy <sup>1</sup><br>(When using TG-980P) | —        | —       | —        | ●       | Measurement is done at a temperature or atmospheric pressure which is outside the specified operation environment. | —      | —                     |
| CO <sub>2</sub> Calibrating<br>(when using TG-900P or TG-920P)            | —        | —       | —        | ●       | Measuring the amount of reference light.   | —      | —                     |

<sup>1</sup> This message is displayed when “Available Alarm Types” is set to “All” on the Display/Sound window on the Alarm page in System Setup window.



Refer to the following.  
Administrator's Guide:  
“Alarm Settings - [Display/Sound] Page” in Section 3

<sup>2</sup> When a normal level alarm continues for a certain period of time it changes to the alarm escalation priority. The alarm escalation duration and priority cannot be set.



Refer to the following.  
Administrator's Guide:  
“[Vital Alarm Priority] Page - Setting the Alarm Escalation Conditions” in Section 3

<sup>3</sup> The operation depends on the alarm priority (Warning or Advisory). (Warning: Recovery, Caution: Silence).

## SpO<sub>2</sub>

| Message                               | Priority |         |          |         | Possible Cause  | Action   | Alarm Pause Operation |
|---------------------------------------|----------|---------|----------|---------|---|--|-----------------------|
|                                       | Crisis   | Warning | Advisory | Message |   |  |                       |
| High SpO <sub>2</sub>                 | ○        | ●       | —        | —       | The SpO <sub>2</sub> measurement value is equal to or greater than the upper limit alarm.               | <ul style="list-style-type: none"> <li>Check the patient.</li> <li>Check the control settings and alarm settings.</li> </ul>   | Re-alarm              |
| Low SpO <sub>2</sub>                  | ○↑       | ●       | —        | —       | The SpO <sub>2</sub> measurement value is equal to or less than the lower limit alarm.                  | <ul style="list-style-type: none"> <li>Check the patient.</li> <li>Check the control settings and alarm settings.</li> </ul>   | Re-alarm              |
| High PR                               | ○        | ●       | —        | —       | The PR measurement value is equal to or greater than the upper limit alarm.                             | <ul style="list-style-type: none"> <li>Check the patient.</li> <li>Check the control settings and alarm settings.</li> </ul>   | Re-alarm              |
| Low PR                                | ○        | ●       | —        | —       | The PR measurement value is equal to or less than the lower limit alarm.                                | <ul style="list-style-type: none"> <li>Check the patient.</li> <li>Check the control settings and alarm settings.</li> </ul>   | Re-alarm              |
| SpO <sub>2</sub> Sensor Fault         | —        | ●       | —        | —       | Probe is deteriorated.  | Replace the probe with a new one.  | Termination           |
|                                       |          |         |          |         | Short-circuit in probe  | Replace the probe with a new one.  |                       |
|                                       |          |         |          |         | SpO <sub>2</sub> adapter is deteriorated.   | Replace the SpO <sub>2</sub> adapter.  |                       |
|                                       |          |         |          |         | Probe failure   | Replace the probe. If the problem still occurs, replace the SpO <sub>2</sub> adapter.  |                       |
| SpO <sub>2</sub> Disconnect           | —        | —       | ●        | —       | SpO <sub>2</sub> adapter is disconnected from the MULTI socket.   | Select the [Audio Paused] key to cancel the message.   | Termination           |
|                                       |          |         |          |         | SpO <sub>2</sub> adapter is disconnected from the MULTI socket.   | Securely connect the SpO <sub>2</sub> adapter to the MULTI socket.   |                       |
|                                       |          |         |          |         | SpO <sub>2</sub> adapter is deteriorated.   | Replace the SpO <sub>2</sub> adapter.  |                       |
| Parameter Not Available               | —        | —       | ●        | —       | An item other than a CO <sub>2</sub> sensor or SpO <sub>2</sub> probe is connected to the MULTI socket. | <p>Only use a CO<sub>2</sub> sensor or SpO<sub>2</sub> probe which is compatible with this ventilator.</p> <p>Refer to “SpO<sub>2</sub> Probes” in Section 16 for probes and adapters that can be used with this ventilator.</p> | Silence               |
| SpO <sub>2</sub> Duplicated Parameter | —        | —       | ●        | —       | SpO <sub>2</sub> adapter is connected to 2 channels.  | Connect the SpO <sub>2</sub> adapter to only one channel.  | Silence               |



| Message                              | Priority        |                 |          |         | Possible Cause  | Action   | Alarm Pause Operation |   |
|--------------------------------------|-----------------|-----------------|----------|---------|---|--|-----------------------|---|
|                                      | Crisis          | Warning         | Advisory | Message |   |  |                       |   |
| SpO <sub>2</sub> Check Probe         | ○↑              | ○↑              | ●        | —       | Probe is detached.  | Check the probe attachment and attach the probe to the patient properly.   | Silence               |   |
|                                      |                 |                 |          |         | Displayed waves are flat.   | Poor connector contact   |                       | Securely connect the probe to the SpO <sub>2</sub> adapter.   |
|                                      |                 |                 |          |         |   | The probe has a broken wire or short-circuit.  |                       | Replace the probe with a new one.                             |
|                                      |                 |                 |          |         | Plethysmogram is displayed.   | The probe is not attached at the appropriate site.   |                       | Reattach the probe to the site specified in the probe manual. |
|                                      |                 |                 |          |         |   | Probe is deteriorated.   |                       | Replace the probe with a new one.                             |
| SpO <sub>2</sub> Cannot Detect Pulse | ○↑ <sup>1</sup> | ○↑ <sup>1</sup> | ●        | —       | The peripheral circulation is not sufficient for measuring the SpO <sub>2</sub> value.  | Check the patient condition and loosen the probe or change the probe attachment site to remove the problem.  | Silence               |   |
|                                      |                 |                 |          |         | The probe is attached too tightly and is obstructing the blood circulation.   | Reattach the probe.  |                       |   |
|                                      |                 |                 |          |         | Probe is detached from the patient.   | Check the probe attachment and attach the probe to the patient properly.   |                       |   |
|                                      |                 |                 |          |         | One of the following messages appeared for 30 seconds <ul style="list-style-type: none"> <li>SpO<sub>2</sub> Light Interference</li> <li>SpO<sub>2</sub> Check Probe Site</li> <li>SpO<sub>2</sub> Detecting Pulse</li> </ul> | Refer to the corresponding screen message section and remove the cause of the alarm or message.  |                       |   |
| SpO <sub>2</sub> No Probe            | —               | —               | ●        | —       | SpO <sub>2</sub> probe is disconnected from the SpO <sub>2</sub> adapter.   | Connect the probe to the SpO <sub>2</sub> adapter.   | Termination           |   |
| SpO <sub>2</sub> Light Interference  | —               | —               | ●        | —       | The measurement site is affected by light such as a surgical light, bilirubin light or fluorescent light.   | Cover the attachment site with a blanket to block the surrounding light and prevent noise from interfering with the plethysmogram.   | Silence               |   |
| SpO <sub>2</sub> Check Probe Site    | —               | —               | ●        | —       | The probe is not attached at the appropriate site.  | Reattach the probe to the site specified in the probe manual.  | Silence               |   |
|                                      |                 |                 |          |         | Probe is deteriorated.  | Replace the probe with a new one.  |                       |   |
| SpO <sub>2</sub> Low Quality Signal  | —               | —               | ●        | —       | Low signal quality <ul style="list-style-type: none"> <li>Body movement</li> <li>Small plethysmogram</li> <li>Respiration fluctuates</li> <li>Probe not attached properly</li> </ul>  | If this status continues, check the condition of the patient and probe and, if necessary, change the probe attachment site.<br>If the problem continues, measuring blood oxygen saturation from a blood sample is recommended. | Silence               |   |

| Message                          | Priority |         |          |         | Possible Cause  | Action  | Alarm Pause Operation |
|----------------------------------|----------|---------|----------|---------|---|---|-----------------------|
|                                  | Crisis   | Warning | Advisory | Message |   |   |                       |
| SpO <sub>2</sub> Detecting Pulse | —        | —       | —        | ●       | Searching for the correct plethysmogram                                     | Wait until the plethysmogram is detected.   | —                     |
|                                  |          |         |          |         | The SpO <sub>2</sub> value cannot be obtained because the wave is unstable. | Check the probe attachment and reattach the probe to the patient properly.        |                       |
|                                  |          |         |          |         | Probe is detached.  | Check the probe attachment and reattach the probe to the patient properly.        |                       |
| SpO <sub>2</sub> Weak Pulse      | —        | —       | —        | ●       | Poor peripheral circulation   | Check the patient condition and change the attachment site to remove the problem. | —                     |
|                                  |          |         |          |         | The probe is attached too tightly and is obstructing the blood circulation. | Check the probe attachment condition.   |                       |

<sup>1</sup> The “SpO<sub>2</sub> Check Probe” priority and alarm escalation setting are synchronized.



## Ventilator

| Message                             | Priority |         |          |         | Possible Cause  | Action   | Alarm Pause Operation |
|-------------------------------------|----------|---------|----------|---------|---|--|-----------------------|
|                                     | Crisis   | Warning | Advisory | Message |   |  |                       |
| AC Power Loss/Main Battery In Use   | —        | —       | ●        | —       | AC power is lost and the ventilator is operated on the main battery power.                                      | <ul style="list-style-type: none"> <li>Use the main battery while checking its remaining power.</li> <li>If there is a fully charged spare main battery, prepare to replace the battery if necessary.</li> </ul>   | Silence               |
| Main Battery Low                    | —        | ●       | —        | —       | AC power is lost and main battery charge is 30% or less.  | <ul style="list-style-type: none"> <li>If there is a fully charged spare main battery, replace the battery as soon as possible.</li> <li>If there is no fully charged spare main battery, connect the ventilator to AC power as soon as possible.</li> </ul>   | Re-alarm              |
| Main Battery Empty                  | ●        | —       | —        | —       | AC power is lost and main battery charge is 10% or less.  | <ul style="list-style-type: none"> <li>If there is a fully charged spare main battery, replace the battery as soon as possible.</li> <li>If there is no fully charged spare main battery, immediately connect the ventilator to AC power.</li> </ul>   | Re-alarm              |
| AC Power Loss/Backup Battery In Use | ●        | —       | —        | —       | AC power and main battery power is lost and the ventilator is operated on the backup battery power.             | <ul style="list-style-type: none"> <li>Connect the ventilator to AC power as soon as possible.</li> <li>If there is a fully charged spare main battery, immediately replace the battery.</li> </ul>  | Re-alarm              |
| Battery Empty                       | —        | —       | —        | ●       | When connected to AC power, the main battery charge is 10% or less or the backup battery charge is 30% or less. | <ul style="list-style-type: none"> <li>Charge the main battery and backup battery.</li> <li>When replacing the main battery, be sure to connect the ventilator to AC power.</li> </ul>   | —                     |
| Main Battery Temp Out Of Range      | —        | —       | —        | ●       | Charging stopped when the temperature of the main battery was detected as being outside the chargeable range.   | <ul style="list-style-type: none"> <li>Check that the ventilator is being used in a place which is within the operating temperature range (not installed in a place which is exposed to direct sunlight).</li> <li>Check that the fan ventilation opening is not blocked and that the fan filter is not dirty.</li> <li>This message may be displayed when the power is turned on immediately after the ventilator was stored in a cold environment. Leave the ventilator in a place within the operating temperature range for a while before using it.</li> <li>If the problem is not resolved, contact your Nihon Kohden representative.</li> </ul> | —                     |

| Message                          | Priority |         |          |         | Possible Cause  | Action   | Alarm Pause Operation |
|----------------------------------|----------|---------|----------|---------|---|--|-----------------------|
|                                  | Crisis   | Warning | Advisory | Message |   |  |                       |
| Backup Battery Temp Out Of Range | —        | —       | —        | ●       | Charging of the backup battery stopped because the temperature of the backup battery is outside the chargeable temperature range. | <ul style="list-style-type: none"> <li>Check that the ventilator is being used in a place which is within the operating temperature range (not installed in a place which is exposed to direct sunlight).</li> <li>Check that the fan ventilation opening is not blocked and that the fan filter is not dirty.</li> <li>This message may be displayed when the power is turned on immediately after the ventilator was stored in a cold environment. Leave the ventilator in a place within the operating temperature range for a while before using it.</li> <li>If the problem is not resolved, contact your Nihon Kohden representative.</li> </ul> | —                     |
| Main Battery Fault               | ●        | —       | —        | —       | Abnormality in the main battery   | <ul style="list-style-type: none"> <li>Immediately connect the ventilator to AC power as soon as possible and replace the main battery.</li> <li>If the problem is not resolved, contact your Nihon Kohden representative.</li> </ul>  | Re-alarm              |
| Backup Battery Fault             | ●        | —       | —        | —       | Abnormality in the backup battery   | Immediately connect the ventilator to AC power and contact your Nihon Kohden representative.   | Re-alarm              |
| Do Not Hot-Swap Main Battery     | ●        | —       | —        | —       | When operating on the main battery, the backup battery charge is 30% or less.   | <ul style="list-style-type: none"> <li>Immediately connect the ventilator to AC power.</li> <li>Do not replace the main battery while the ventilator is not connected to AC power.</li> </ul>  | Silence               |
| Main Battery Disconnect          | —        | —       | ●        | —       | Main battery is not inserted.   | <ul style="list-style-type: none"> <li>Insert the main battery.</li> <li>If the problem is not resolved, replace the main battery.</li> </ul>  | Silence               |
| Main Battery Expired             | —        | —       | —        | ●       | 5 years have passed since the manufacture of the main battery and the operating lifetime of the battery has expired.              | Connect the ventilator to AC power as soon as possible and replace the main battery.   | —                     |
| Backup Battery Expired           | —        | —       | —        | ●       | 3.5 years have passed since the manufacture of the backup battery and the operating lifetime of the battery has expired.          | The backup battery needs to be replaced. Connect the ventilator to AC power as soon as possible and contact your Nihon Kohden representative.  | —                     |



| Message                        | Priority |         |          |         | Possible Cause   | Action  | Alarm Pause Operation |
|--------------------------------|----------|---------|----------|---------|--|---|-----------------------|
|                                | Crisis   | Warning | Advisory | Message |  |   |                       |
| Internal Case Temp High        | ●        | —       | —        | —       | High ventilator internal temperature   | <ul style="list-style-type: none"> <li>Check that the ventilator is being used in a place which is within the operating temperature range (not installed in a place which is exposed to direct sunlight).</li> <li>Check that the fan ventilation opening is not blocked and that the fan filter is not dirty.</li> <li>If the problem is not resolved, contact your Nihon Kohden representative.</li> </ul>  | Re-alarm              |
| Blower Temp High               | —        | ●       | —        | —       | High blower temperature<br>(When this alarm occurs during O <sub>2</sub> Therapy mode, the flow rate is restricted to prevent overheating.)  | <ul style="list-style-type: none"> <li>Immediately connect the patient to an alternative ventilation method and check the following points. <ul style="list-style-type: none"> <li>Check that the temperature of the location where the ventilator is being used is within the specified range (the ventilator was not installed in a place where it is exposed to direct sunlight).</li> <li>Hot air is not being taken in through the gas intake port.</li> <li>Fan ventilation opening is not blocked and the fan filter is not dirty</li> </ul> </li> </ul> | Silence               |
| Pressure Sensor Zeroing Unable | —        | —       | —        | ●       | Pressure sensor calibration could not be completed because the fan was operating during calibration of the breather circuit (during the circuit check).  | Contact your Nihon Kohden representative.   | —                     |
| Cooling Fan Fault              | —        | ●       | —        | —       | Fan rotation is slowing down or stopped.   | <ul style="list-style-type: none"> <li>Immediately connect the patient to an alternative ventilation method and turn off the ventilator power.</li> <li>Contact your Nihon Kohden representative.</li> </ul>  | Re-alarm              |
| Check HEPA Filter              | —        | —       | ●        | —       | HEPA filter is not inserted.   | <ul style="list-style-type: none"> <li>Insert a HEPA filter.</li> <li>If the problem is not resolved, replace the HEPA filter.</li> </ul>   | Silence               |
| Cal??                          | —        | —       | —        | ●       | One or more of the breathing circuit, flow sensor, O <sub>2</sub> sensor, CO <sub>2</sub> sensor has not properly calibrated.<br>During O <sub>2</sub> Therapy mode, the breathing circuit and flow sensor cannot be calibrated. | Calibrate all uncalibrated items.   | —                     |
| SpO <sub>2</sub> Module Fault  | —        | —       | ●        | —       | SpO <sub>2</sub> adapter abnormality   | <ul style="list-style-type: none"> <li>Replace the SpO<sub>2</sub> adapter.</li> <li>If the problem is not resolved, contact your Nihon Kohden representative.</li> </ul>   | Silence               |



| Message   | Priority |         |          |         | Possible Cause   | Action   | Alarm Pause Operation |
|---|----------|---------|----------|---------|--|--|-----------------------|
|   | Crisis   | Warning | Advisory | Message |  |  |                       |
| MPU Module Fault                                | —        | —       | ●        | —       | Multi parameter unit module abnormality  | Contact your Nihon Kohden representative.  | Silence               |
| O <sub>2</sub> Sensor Disabled                  | —        | —       | —        | ●       | “O <sub>2</sub> Sensor Enable” is not selected on the [System] window ► [Vent] window in System Setup window.  | Select “O <sub>2</sub> Sensor Enable” on the [System] window ► [Vent] window in System Setup window.   | —                     |
| Waveform Freeze                                 | —        | —       | —        | ●       | [Waveform Freeze] is selected and the waveforms are frozen. Waveform freeze is automatically canceled 3 minutes after [Waveform Freeze] is selected.   | Touch [Waveform Freeze] again.   | —                     |
| Maintenance Required                            | —        | —       | ●        | —       | The operation hours of the blower have exceeded the recommended maintenance time (30,000 hours).   | Contact your Nihon Kohden representative.  | Silence               |
| Technical Fault xxxxx (xxxxx is the error code) | ●        | —       | —        | —       | Ventilator malfunction   | <ul style="list-style-type: none"> <li>• Check the patient.</li> <li>• Immediately connect the patient to an alternative ventilation method and contact your Nihon Kohden representative.</li> </ul> (Inform the Nihon Kohden representative of the error code (number) displayed in the message.)   | Re-alarm              |
| Vent Inop. xxxxx (xxxxx is the error code)      | ●        | —       | —        | —       | An abnormality was detected and ventilation operation was stopped. While ventilation operation is stopped, the patient can spontaneously breathe through the air intake and exhalation port. | <ul style="list-style-type: none"> <li>• Check the patient.</li> <li>• Immediately connect the patient to an alternative ventilation method and contact your Nihon Kohden representative.</li> <li>• When a message recommending restarting ventilation is displayed at the same time as the Vent Inop. alarm, immediately restart ventilation.</li> </ul> (Inform the Nihon Kohden representative of the error code (number) displayed in the message.) | Re-alarm              |
| CPU Rebooted                                    | ●        | —       | —        | —       | Restart of main CPU occurred.  | Contact your Nihon Kohden representative.  | Termination           |
| SD Card1 Fault                                  | —        | —       | —        | ●       | Error occurred in SD card 1 (write, read, not inserted, etc.).   | <ul style="list-style-type: none"> <li>• Check that SD card 1 is not write-protected.</li> <li>• Insert an appropriate Nihon Kohden specified SD card.</li> </ul>  | —                     |
| SD Card1 Full                                   | —        | —       | —        | ●       | The volume of data save on the SD card 1 has reached the capacity of the card.   | Insert a new Nihon Kohden specified SD card.   | —                     |



| Message   | Priority |         |          |         | Possible Cause  | Action  | Alarm Pause Operation |
|---|----------|---------|----------|---------|---|---|-----------------------|
|   | Crisis   | Warning | Advisory | Message |   |   |                       |
| SD Card2 Fault  | —        | —       | —        | ●       | Error occurred in SD card 2 (write, read, not inserted, etc.).  | <ul style="list-style-type: none"> <li>Check that SD card 2 is not write-protected.</li> <li>Insert an appropriate Nihon Kohden specified SD card.</li> </ul>   | —                     |
| SD Card2 Full   | —        | —       | —        | ●       | The volume of data save on the SD card 2 has reached the capacity of the card.  | Insert a new Nihon Kohden specified SD card.  | —                     |
| Check External Device (when communication cable is connected) | —        | —       | —        | ●       | An error has occurred in communication with the external device.  | <ul style="list-style-type: none"> <li>Check that the external device communication cable is connected correctly.</li> <li>Contact your Nihon Kohden representative.</li> </ul>   | —                     |
| Check External Device (when ZS-600P is connected)             | —        | —       | ●        | —       | System Setup window<br>▶ [System] tab ▶<br>[Communication] tab<br>▶ [Communication Type] is set to “ZS-600P”.                                     | <ul style="list-style-type: none"> <li>The ZS-600P setting cannot be used. Set System Setup window ▶ [System] tab ▶ [Communication] tab ▶ [Communication Type] to an appropriate setting. Refer to the Administrator’s Guide “[Communication] Page” in Section 3.</li> <li>Contact your Nihon Kohden representative.</li> </ul>   | Termination           |
| Audio Paused  | —        | —       | —        | ●       | When the ventilator is turned on, it starts in the audio paused condition. Refer to “Alarm Sound Suppression at Startup” in Section 9.            | <p>The audio pause ends and the error message disappears when any of the following conditions are met.</p> <ul style="list-style-type: none"> <li>The [Audio Paused] key is selected again while the alarms are paused.</li> <li>The alarm auto-recovery conditions are met. Refer to “Alarm Sound Suppression at Startup” in Section 9.</li> <li>A Vent Inop. alarm occurs.</li> </ul> | —                     |
| Audio Paused mm: ss   | —        | —       | —        | ●       | Audio is paused. The remaining audio pause time is displayed underneath the message. Refer to “Temporarily Pausing the Alarm Sound” in Section 9. | <p>The audio pause ends when any of the following conditions are met.</p> <ul style="list-style-type: none"> <li>The set pause time (1 or 2 minutes) has passed.</li> <li>The [Audio Paused] key is selected again while the alarms are paused.</li> <li>A Vent Inop. alarm occurs. Refer to “Ending the Audio Pause” in Section 9.</li> </ul>  | —                     |

| Message                          | Priority |         |          |         | Possible Cause  | Action  | Alarm Pause Operation |
|----------------------------------|----------|---------|----------|---------|---|---|-----------------------|
|                                  | Crisis   | Warning | Advisory | Message |   |   |                       |
| Ramp Up Time Remaining (min): mm | —        | —       | —        | ●       | The Ramp Up Time function is activated. The messages shows the time remaining until the set pressure is reached. Refer to “Ramp Up Time” in Section 16. | Ramp Up Time ends and the error message disappears when one of the following occurs. <ul style="list-style-type: none"> <li>• The Set Ramp Up Time is over.</li> <li>• The ventilator is in standby.</li> <li>• The ventilation mode is changed.</li> <li>• Ramp Up Time is ended on the Control Settings window.</li> <li>• The set pressure is lower than the current pressure for all relevant settings. Refer to “Ramp Up Time” in Section 16.</li> </ul> | —                     |



## Troubleshooting

If trouble occurs, refer to this list of causes and recommended actions.

After taking the recommended action, check that the trouble disappears and that the ventilator operates normally. After that, start using the ventilator again.

NOTE: If the trouble does not disappear after taking the recommended actions, attach an “Out of Order” or “Do Not Use” or similar notice to the ventilator and contact your Nihon Kohden representative.

### During Measurement

| Trouble   | Possible Cause   | Action   |
|---|--|--|
| Power does not turn on  | Neither AC power nor main battery are connected.   | Connect AC power or the main battery.  |
|   | Ventilator malfunction   | Contact your Nihon Kohden representative.  |
|   | Main battery power is discharged.  | Charge the main battery.   |
| The diagnostic window (Diagnostic Check window) is displayed even when the power is turned on | Ventilator malfunction   | Contact your Nihon Kohden representative.  |
| Screen is dark  | Brightness is turned down.   | On the [Brightness] in Screen, change the setting if necessary.<br>Refer to “Brightness Settings” in Section 12.                       |
|   | Backlight malfunction  | Contact your Nihon Kohden representative.  |
| Measurement does not start even when the sensor or probe is connected to the MULTI socket     | If the problem exists with both the left side and right side MULTI sockets: Sensor or probe malfunction, or malfunction in the ventilator input. | Replace the sensor or probe.<br>If replacing the sensor or probe does not solve the problem, contact your Nihon Kohden representative. |
| No pulse sync sound   | Pulse sync sound is set to Off.  | Set this on the [Audio Volume] window in Setup window.<br>Refer to “Audio Volume Settings” in Section 12.                              |
|   | Sound volume is turned down.   |  |
| Date and time display is incorrect  | Date and time setting is not correct.  | Change the setting on the Date/Time window.<br>Refer to “Date and Time Settings” in Section 12.  |
| Ventilator is abnormally hot  | Fan ventilation opening is obstructed.   | Check the condition of the fan ventilation opening.  |
| The touched position on the touchscreen does not correspond with the touchscreen operation    | The touch screen key positions are out of alignment.   | Calibrate the touchscreen.<br>Refer to the Administrator’s Guide “4. Calibrating the Touch Screen” in Section 4-3.                     |
| Continuous beeping sound and the ventilator restarted   | Ventilator malfunction   | Contact your Nihon Kohden representative.  |
| Buzzer sound  | Ventilator malfunction   | Contact your Nihon Kohden representative.  |
|   | Main battery operation time is short   | Replace the main battery.  |
|   | Main battery exceeded its operating lifetime.  | Replace the main battery.  |
| Main battery operation time is short  | Main battery exceeded its operating lifetime.  | Replace the main battery.  |
|   | Main battery is not calibrated.  | Calibrate the main battery.<br>Refer to the Administrator’s Guide “Calibrating the Batteries” in Section 4-3.                          |
|   | Main battery malfunction   | Replace the main battery.  |
| Backup battery operation time is short  | Backup battery exceeded its operating lifetime.  | Contact your Nihon Kohden representative.  |
|   | Backup battery is not calibrated.  | Calibrate the backup battery.<br>Refer to the Administrator’s Guide “Calibrating the Batteries” in Section 4-3.                        |
|   | Backup battery malfunction   | Contact your Nihon Kohden representative.  |

## Ventilation

| Trouble                                   | Possible Cause  | Action  |
|---|---|---|
| Cannot start calibration                  | Ventilation is in progress.   | Perform calibration in ventilation standby mode.  |
|   | Patient circuit settings are not appropriate.   | The flow sensor can only be calibrated when the flow sensor is selected in the Proximal Sensor setting on the patient circuit setting window.   |
|   | It is set to not use the O <sub>2</sub> sensor.   | The O <sub>2</sub> sensor can only be calibrated when “O <sub>2</sub> Sensor Enable” is selected in [System] window ► [Vent] page in System Setup window.   |
| Breathing circuit calibration failure     | Calibration procedure was not done correctly.   | Check the procedure which is shown on the breathing circuit check window.<br>Refer to “Calibrating the Breathing Circuit” in Section 5.   |
|   | <ul style="list-style-type: none"> <li>Breathing circuit is not connected properly.</li> <li>Pressure sensor line and flow sensor line are disconnected or kinked.</li> <li>Pressure/flow sensor port is not connected properly.</li> </ul> | Check the connection of the breathing circuit, exhalation port, pressure sensor line, and flow sensor line.<br>After checking the connections, start calibration again.<br>Refer to “Calibrating the Breathing Circuit” in Section 5. |
|   | Exhalation port is blocked.   | Check that the exhalation port is not blocked.<br>After checking the connections, start calibration again.<br>Refer to “Calibrating the Breathing Circuit” in Section 5.  |
|   | The fan does not stop.  | Contact your Nihon Kohden representative.   |
| Flow sensor calibration failure           | Flow sensor calibration procedure was not done correctly.   | Check the procedure which is displayed on the flow sensor calibration screen.<br>Refer to “Calibrating the Flow Sensor” in Section 5.   |
|   | <ul style="list-style-type: none"> <li>Flow sensor line is disconnected or kinked.</li> <li>Pressure/flow sensor port is not connected properly.</li> </ul>   | Check the flow sensor line connection.<br>After checking the connections, start calibration again.<br>Refer to “Calibrating the Breathing Circuit” in Section 5.  |
| O <sub>2</sub> sensor calibration failure | Correct procedure was not followed.   | Check the procedure which is displayed on the O <sub>2</sub> sensor calibration window.<br>Refer to “Calibrating the O <sub>2</sub> Sensor” in Section 5.   |
|   | <ul style="list-style-type: none"> <li>Low pressure oxygen supply is connected.</li> <li>High pressure oxygen supply is not connected.</li> </ul>   | Connect a high pressure oxygen supply.<br>After checking the connections, start calibration again.<br>Refer to “Calibrating the Breathing Circuit” in Section 5.  |
|   | O <sub>2</sub> sensor is used up.   | When using a galvanic oxygen sensor, replace and recalibrate the O <sub>2</sub> sensor.   |
|   | O <sub>2</sub> sensor is not connected properly.  | Check that the O <sub>2</sub> sensor is connected properly.<br>After checking the connections, start calibration again.<br>Refer to “Calibrating the Breathing Circuit” in Section 5.   |



| Trouble   | Possible Cause  | Action  |
|---|---|---|
| Rise time of the inspiration pressure waveform is abnormally long and airway pressure does not reach the target level | Inspiration rise settings are inappropriate.                                      | Check the Slope settings in the Control Settings.   |
|   | Breathing circuit is not calibrated.  | Change to ventilation standby mode and check the circuit.<br>Refer to “Calibrating the Breathing Circuit” in Section 5.   |
|   | Leak occurred   | <ul style="list-style-type: none"> <li>• Check that there is not a large leak from the patient interface.</li> <li>• Check that there are no leaks from the breathing circuit, pressure sensor line, and flow sensor line.</li> </ul> |
|   | Clog in internal filter or breathing circuit filter.                              | Check that there is no dirt or clogging in the internal filter and breathing circuit filter.  |
| Inspiration pressure waveform overshoots  | Slope settings are inappropriate.   | Check the Slope settings in the Control Settings.   |
|   | Breathing circuit is not calibrated.  | Change to ventilation standby mode and check the circuit.<br>Refer to “Calibrating the Breathing Circuit” in Section 5.   |
|   | Patient is fighting the ventilator.   | <ul style="list-style-type: none"> <li>• Check the respiration of the patient.</li> <li>• Check that the patient interface fit is appropriate.</li> </ul>   |
| Fall time of the inspiration pressure waveform is abnormally long and pressure does not fall to PEEP level            | ET% settings are inappropriate.   | Check the exhalation trigger settings in the Control Settings.  |
|   | Exhalation port is blocked.   | Check that the exhalation port is not blocked.  |
|   | Synchronicity with patient is bad.  | <ul style="list-style-type: none"> <li>• Check the respiration of the patient.</li> <li>• Check that the patient interface fit is appropriate.</li> </ul>   |
| Peak pressure measurement value diverges from the IPAP setting  | IPAP is limited by the peak pressure upper alarm limit.                           | Check the peak inspiratory pressure upper alarm limit settings.   |
|   | Leak occurred   | <ul style="list-style-type: none"> <li>• Check that there is not a large leak from the patient interface.</li> <li>• Check that there are no leaks from the breathing circuit, pressure sensor line, and flow sensor line.</li> </ul> |
|   | Clogging, kinking, or blockage  | Check that there is no clogging from water droplets or other substance, or kinking or blockage in the patient interface, breathing circuit, exhalation port, pressure sensor line, and flow sensor line.                              |
| PEEP measurement value diverges from the EPAP/CPAP setting  | Leak occurred   | <ul style="list-style-type: none"> <li>• Check that there is not a large leak from the patient interface.</li> <li>• Check that there are no leaks from the breathing circuit, pressure sensor line, and flow sensor line.</li> </ul> |
|   | Clogging, kinking, or blockage  | Check that there is no clogging from water droplets or other substance, or kinking or blockage in the patient interface, breathing circuit, exhalation port, pressure sensor line, and flow sensor line.                              |
| No triggering   | Inappropriate settings for Trig. Type, Trig. Sens. (Advanced), Trig. Sens. (Flow) | Check the Trig. Type, Trig. Sens. (Advanced), Trig. Sens.(Flow) settings in the Control Settings.   |
|   | Flow sensor not calibrated.   | When using a flow sensor, change to ventilation standby mode, and calibrate the flow sensor.<br>Refer to “Calibrating the Flow Sensor” in Section 5.  |
|   | Exhalation port is blocked.   | Check that the exhalation port is not blocked.  |

| Trouble  | Possible Cause  | Action  |
|--|---|---|
| Auto triggering  | Inappropriate settings for Trig. Type, Trig. Sens. (Advanced), Trig. Sens. (Flow)                                     | Check the Trig. Type, Trig. Sens. (Advanced), Trig. Sens. (Flow) settings in the Control Settings.  |
|  | Flow sensor not calibrated.   | When using a flow sensor, change to ventilation standby mode, and calibrate the flow sensor. Refer to “Calibrating the Flow Sensor” in Section 5.   |
|  | Condensation  | Check that there is not excessive condensation in the patient interface, breathing circuit, exhalation port, pressure sensor line, and flow sensor line.  |
| Inspiratory time measurement value is too short/long                                       | Inspiration time is restricted by inappropriate Ti Max or Ti Min settings.  | Check the Ti Max and Ti Min settings in the Control Settings.   |
| Flow waveform does not return to baseline  | Leak compensation value is being calculated.  | It takes 3 breaths to calculate the leak compensation of the ventilator.<br>Check that the flow waveform returns to the baseline after 3 breaths.   |
|  | Flow sensor not calibrated.   | When using a flow sensor, change to ventilation standby mode, and calibrate the flow sensor. Refer to “Calibrating the Flow Sensor” in Section 5.   |
| Volume waveform is distorted   | Leak compensation value is being calculated.  | It takes 3 breaths to calculate the leak compensation of the ventilator.<br>Check that the flow waveform returns to the baseline after 3 breaths.   |
|  | Leak occurred   | <ul style="list-style-type: none"> <li>Check that there is not a large leak from the patient interface.</li> <li>Check that there is no leak from the breathing circuit, pressure sensor line, and flow sensor line.</li> </ul>                                       |
| Inaccurate measurement of ventilation volume (VT, VT/kg, VTi, MV, MVi, MV SPONT, MVISPONT) | Leak occurred   | <ul style="list-style-type: none"> <li>Check that there is not a large leak from the patient interface.</li> <li>Check that there are no leaks from the breathing circuit, pressure sensor line, and flow sensor line.</li> </ul>                                     |
|  | Flow sensor not calibrated.   | When using a flow sensor, change to ventilation standby mode, and calibrate the flow sensor. Refer to “Calibrating the Flow Sensor” in Section 5.   |
|  | Patient information (patient type, height, gender) was not validly entered, or the predicted body weight was invalid. | Check the entered patient information (patient type, height, gender). Refer to “Displaying the Patient Info Window” in Section 8.   |
| FiO <sub>2</sub> measurement value is not stable   | O <sub>2</sub> sensor not calibrated.   | Change to ventilation standby mode and calibrate the O <sub>2</sub> sensor. Refer to “Calibrating the O <sub>2</sub> Sensor” in Section 5.  |
|  | O <sub>2</sub> sensor is used up.   | When using a galvanic oxygen sensor, replace and recalibrate the O <sub>2</sub> sensor.   |
| Sync sound synchronizes with ventilation   | Gas suction port is blocked.  | Check that the gas suction port is not blocked by a curtain or anything else.   |
|  | Condensation  | Check that there is not excessive condensation in the patient interface, breathing circuit, exhalation port, pressure sensor line, and flow sensor line.  |
|  | Foreign object is in the breathing circuit.   | Check that there is no foreign object in the breathing circuit.   |
| Ventilation automatically starts during ventilation standby mode                           | The ventilator detected spontaneous breathing and ended ventilation standby mode.                                     | When 30 seconds pass after entering ventilation standby mode, if the ventilator detects spontaneous breathing, it ends ventilation standby mode and restarts ventilation.<br>To continue ventilation standby mode, disconnect the patient from the patient interface. |



| Trouble  | Possible Cause                     | Action   |
|--|------------------------------------|--|
| Volume waveform is distorted                             | Waveform display settings are Off. | Set the volume waveform display to On. Refer to “Parameter Display and Waveform Settings” in Section 12.   |
| Cannot resume ventilation after CIRCUIT DISCONNECT alarm | Patient is not detected.           | When a CIRCUIT DISCONNECT alarm occurs, the ventilator stops ventilation and restores normal airflow. When the cause of the alarm is removed, the ventilator detects the breathing circuit connection from the increase in air pressure in the circuit and restarts ventilation. Depending on the condition of the breathing circuit and the patient interface, the breathing circuit connection might not be detected in some cases. In those cases, select [Resume Ventilation] in the CIRCUIT DISCONNECT popup window and manually restart ventilation. |

## CO<sub>2</sub>

| Trouble   | Possible Cause  | Action   |
|---|---|--|
| Measurement value is low                                | Airway adapter is dirty.  | Replace the airway adapter with a new one.   |
|   | CO <sub>2</sub> is mixed in with the inspiration. (TG-900P and TG-920P only)                                | Check the measurement accuracy. Refer to “Inspection of Measuring Accuracy” in Section 10.                                 |
|   | Zero calibration is not performed. (TG-980P only)   | Perform zero calibration. Refer to “Performing Zero Calibration Using a TG-980P CO <sub>2</sub> Sensor Kit” in Section 10. |
|   | Leak occurred   | Check that there is not a large leak from the patient interface.   |
| Measurement value is not accurate.                      | Oscillation   | Check the ventilator and other areas to remove the cause.  |
|   | Very high or irregular respiration rate of the patient  | Correct measurement is not possible.   |
|   | Suction into the airway adapter through the suction catheter (TG-900P and TG-920P only)                     | Do not use the suction catheter for suction into the airway adapter.   |
|   | Jackson-Rees, Mapleson D or other breathing circuit is connected to the patient. (TG-900P and TG-920P only) | Correct measurement is not possible.   |
| No CO <sub>2</sub> waveform                             | Oscillation   | Correct measurement is not possible.   |
|   | Airway adapter is disconnected.   | Check the breathing circuit and attach it correctly.   |
|   | Waveform display settings are Off.  | Set the CO <sub>2</sub> waveform display to On. Refer to “Parameter Display and Waveform Settings” in Section 12.          |
|   | Large leak from the patient interface   | Adjust the fit of the patient interface.   |
| CO <sub>2</sub> adapter LED is blinking red             | Damaged CO <sub>2</sub> sensor or CO <sub>2</sub> adapter (TG-900P and TG-920P only)                        | Replace the CO <sub>2</sub> sensor or CO <sub>2</sub> adapter with a new one.  |
|   | Apnea continues for more than 20 seconds (TG-900P and TG-920P only)   | Regardless of the alarm setting, the LED blinks red if apnea continues for more than 20 seconds.                           |
| FiCO <sub>2</sub> is not displayed (when using TG-980P) | Numeric display setting is Off.   | Set the FiCO <sub>2</sub> display to On. Refer to “Parameter Display and Waveform Settings” in Section 12.                 |
| RR (CO <sub>2</sub> ) is not displayed                  | Numeric display setting is Off.   | Set the RR (CO <sub>2</sub> ) display to On. Refer to “Parameter Display and Waveform Settings” in Section 12.             |

**SpO<sub>2</sub>**

| <b>Trouble</b>   | <b>Possible Cause</b>   | <b>Action</b>   |
|--|---|---|
| Measurement value is unstable                            | Inappropriate probe size  | Use a probe size appropriate for the patient.   |
|  | The probe is attached to a limb (hand or foot) which has an NIBP cuff or measurement catheter inserted. | Attach the probe to the opposite hand or foot.<br>Avoid measuring at a site where there are large fluctuations in the blood flow. |
|  | An ESU is used.   | Keep the ESU away from the probe cable and SpO <sub>2</sub> connection cord, and wait until the plethysmogram stabilizes.         |
|  | Measurement is performed on a site with venous pulse.   | Correct measurement is not possible.  |
| SpO <sub>2</sub> value does not match blood sample value | Probe is not attached properly. (Probe emitter and detector are not facing each other, etc.)            | Correctly attach the probe.   |
|  | Probe attachment site is not appropriate.   | Reattach the probe to a site specified in the probe manual.   |
|  | The measurement site is not clean.  | If necessary, remove nail polish and clean the measuring site   |
|  | Too much abnormal hemoglobin. (COHb, MetHb, etc.)   | Correct measurement is not possible.  |
|  | Dye is injected in the blood. (methylene blue or indocyanine green)                                     | Correct measurement is not possible.  |
|  | Measurement is performed during CPR.  | Correct measurement is not possible.  |
| Probe is damaged or deformed                             | Probe was disinfected with an unspecified disinfectant.   | Replace the probe with a new one.<br>Disinfect the probe by a method which is described in the probe manual.                      |
|  | Probe is repeatedly used.   | Replace the probe with a new one when it passes the probe expiration date.  |
| Sine wave noise on the plethysmogram                     | Light interference  | Cover the probe attachment site and block the surrounding light.  |
| Plethysmogram waveform is not displayed                  | Waveform display setting is Off.  | Set the plethysmogram waveform display to On.<br>Refer to “Parameter Display and Waveform Settings” in Section 12.                |
| Pulse rate (PR) is not displayed                         | Numeric display setting is Off.   | Set the PR display to On.<br>Refer to “Parameter Display and Waveform Settings” in Section 12.                                    |
| Pulse amplitude index (PI) is not displayed              | Numeric display setting is Off.   | Set the PI display to On.<br>Refer to “Parameter Display and Waveform Settings” in Section 12.                                    |
| SQI is not displayed                                     | Numeric display setting is Off.   | Set the SQI display to On.<br>Refer to “Parameter Display and Waveform Settings” in Section 12.                                   |



# 14

## Maintenance

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# Preoperational, Operational and Postoperational Checks

The ventilator contains parts which gradually deteriorate with use. Original performance might not be delivered if any part of the ventilator is deteriorated. Perform preoperational, operational and postoperational checks to assure continued safe operation.

Record the results of the checks in the “Maintenance Check Sheet”. Make sure to carefully store the “Maintenance Check Sheet” for future reference.

Use the “Maintenance Check Sheet” by making copies of it. The item numbers on the maintenance check sheet correspond to the item numbers of the procedures in the following table.

If there is an abnormality, take appropriate measures by referring to Section 13 “Troubleshooting” and the Administrator’s Guide.

If the ventilator is suspected to be faulty, attach a “Do Not Use” or “Under Repairs” sign to it and contact your Nihon Kohden representative.

Furthermore, make sure to order the specified accessories and consumables when stock is running low.

In addition to the preoperational, operational and postoperational checks, perform periodic inspections every 6 months (twice a year, in principle) and replace consumable parts to ensure that the ventilator is operating normally.

For details on the six-month inspection, refer to the Administrator’s Guide.



Refer to the following.  
Administrator’s Guide:  
Section 4-3 “6-month Inspection”

## Preoperational Checks

For preoperational check items and ventilator configuration and conditions for the preoperational check, refer to Section 5 “Preparation for Ventilation, Calibration and Preoperational Check”.



Refer to “Performing Preoperational Checks” in Section 5.

## Operational Checks

| Item |                 | Description   |
|------|-----------------|---|
| 1    | Basic operation | The screen display is normal (There is no abnormal brightness, distortion or color problems). |
|      |                 | The touch screen is operating normally.   |
|      |                 | The operation knob is operating normally.   |
|      |                 | There are no error messages or abnormalities during operation.                                |
| 2    | Setup           | The control settings are appropriate for the patient.   |
|      |                 | The alarm settings are appropriate for the patient and control settings.                      |





| Item |                   | Description   |
|------|-------------------|---|
| 3    | Heated humidifier | The settings for the heated humidifier are appropriate.                     |
|      |                   | The water level for the humidifier chamber is correct.                      |
| 4    | Breathing circuit | There is no looseness in the breathing circuit connections looseness.       |
|      |                   | There are no obstructions in the breathing circuit hose.                    |
|      |                   | No water has accumulated in the breathing circuit hose.                     |
|      |                   | The water that accumulates in the water trap is emptied correctly.          |
|      |                   | Water is not accumulating in the pressure sensor tube and flow sensor tube. |
|      |                   | The exhalation port is not blocked.   |

## Postoperational Checks

Always perform the following postoperational checks after using the ventilator.

The checks ensure that the ventilator can be used normally and smoothly the next time it is used.

Make sure to order the specified accessories and consumables when stock is running low.

| Item   |                            | Description   |
|--|----------------------------|---|
| 1  | Checking for abnormalities | No abnormalities occurred during use.   |
|  |                            | No dirt, scratches or damage occurred on the outside of the ventilator.   |
| 2  | Organization and storage   | The power of the ventilator and heated humidifier is turned off.  |
|  |                            | The breathing circuit and humidifier chamber are disconnected from the ventilator.  |
|  |                            | Used breathing circuits and humidifier chambers have been sterilized or disposed of correctly.  |
|  |                            |  Refer to the Breathing Circuit and Heated Humidifier Operator's Manual. |
|  |                            | The ventilator, sensors and cables have been properly cleaned and disinfected.  |
|  |                            |  Refer to "Cleaning, Disinfection and Storage" (p. 14-10).               |
|  |                            | The ventilator, sensors and cables are properly stored.   |
|  |                            |  Refer to "Cleaning, Disinfection and Storage" (p. 14-10).               |
|  |                            | Substances such as chemicals and liquids are not left in the surrounding area.  |
|  |                            | The Operator's Manual is easily accessible.   |
| Accessories are stored properly.   |                            |   |
| There is no shortage of consumables.   |                            |   |
| The battery labels and inspection dates have been confirmed on the [Info] page of the System Setup window.   |                            |   |
|  Refer to the following.<br>Administrator's Guide:<br>"Checking the Information" in Section 3 |                            |   |



# Expiration Date, Replacement and Disposal

## Ventilator

### Periodic Replacement Parts

The following parts of the ventilator need to be replaced regularly according to the following table in order to maintain the function and performance of the ventilator.

If replacement must be done by a service representative, contact your Nihon Kohden representative.

| Periodic Part Replacement                | Usage Period                        | Person Doing Replacement       | Remarks   |
|--|-------------------------------------|--------------------------------|---|
| Ventilator                               |                                     |                                |   |
| Breath delivery unit                     | Approx. 30,000 hours                | Nihon Kohden service personnel | Contact your Nihon Kohden representative.   |
| Accessories                              |                                     |                                |   |
| Main battery <sup>1</sup><br>(SB-831V)   | Approx. 2 years                     | Nihon Kohden service personnel | Contact your Nihon Kohden representative.   |
| Backup battery <sup>1</sup><br>(SB-330Z) |                                     |                                |   |
| YS-119P7 air intake HEPA filter          | Approx. 1 year                      | Nihon Kohden service personnel | Contact your Nihon Kohden representative.   |
| YS-119P6 internal filter                 |                                     |                                |   |
| YS-119P8 air intake dust filter          | Approx. 1 month                     | Ventilator user                | Refer to “YS-119P8 Air Intake Dust Filter” (p. 14-6).                                 |
| YS-119P9 fan filter                      | Irregular (approx. 1 month maximum) |                                | Refer to “YS-119P9 Fan Filter” (p. 14-8).   |
| YS-119P4 galvanic oxygen sensor          | Irregular (approx. 1 year maximum)  | Ventilator administrator       | Refer to the following. Administrator’s Guide: Section 4 “Maintenance and Inspection” |

<sup>1</sup> The main and backup batteries require battery calibration once every 6 months.



Refer to the following.  
Administrator’s Guide:  
“Calibrating the Batteries” in Section 4-3

## Disposal

### ⚠ WARNING

Dispose of Nihon Kohden products according to your local laws and your facility’s guidelines for waste disposal. Otherwise, it may affect the environment. If there is a possibility that the product may have been contaminated with infection, dispose of it as medical waste according to your local laws and your facility’s guidelines for medical waste. Otherwise, it may cause infection.

NOTE: Remove the batteries before disposing of the ventilator.

## Main Battery (SB-831V)

### Expiration Date

Replace the main battery every 2 years.

### Replacement Method

For the replacement method, refer to “Inserting the Main Battery” in Section 4.



Refer to “Inserting the Main Battery” in Section 4.

- NOTE
- Always use an SB-831V lithium ion battery as the main battery.
  - Replace the main battery every 2 years with a new one and check that it is always ready for emergency use at any time.
  - The main battery cannot be inserted when this device is mounted on the cart.
  - Replacement should be done by a Nihon Kohden representative or specialized technician.

### Disposal

The main battery is a lithium ion secondary battery.

It is recommended to recycle the used main battery for environmental protection.

#### CAUTION

Dispose of Nihon Kohden products according to your local laws and your facility's guidelines for waste disposal. Otherwise, it may affect the environment. If there is a possibility that the product may have been contaminated with infection, dispose of it as medical waste according to your local laws and your facility's guidelines for medical waste. Otherwise, it may cause infection.

## Backup Battery (SB-330Z)

### Expiration Date

Replace the backup battery every 2 years.

### Replacement Method

When the backup battery needs to be replaced, contact your Nihon Kohden sales representative.

#### CAUTION

The backup battery must be replaced by qualified service personnel.



## Disposal

The backup battery is a nickel metal hydride secondary battery.

It is recommended to recycle used backup batteries for environmental protection.

### ⚠ CAUTION

Dispose of Nihon Kohden products according to your local laws and your facility's guidelines for waste disposal. Otherwise, it may affect the environment. If there is a possibility that the product may have been contaminated with infection, dispose of it as medical waste according to your local laws and your facility's guidelines for medical waste. Otherwise, it may cause infection.

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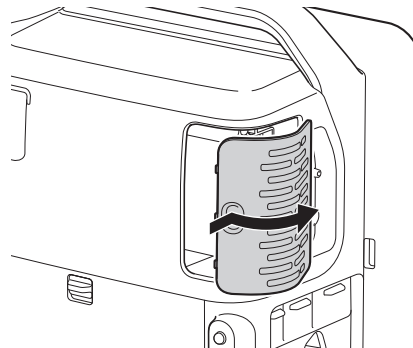
## YS-119P8 Air Intake Dust Filter

### Expiration Date

Replace the YS-119P8 air intake dust filter on the gas inlet port **every month**.

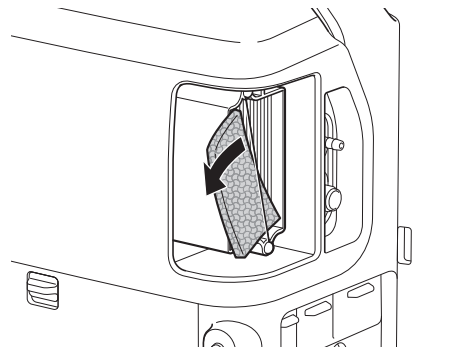
### Replacement Method

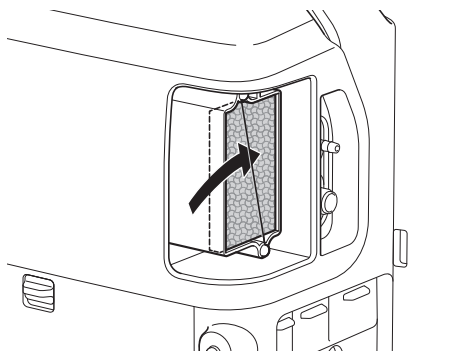
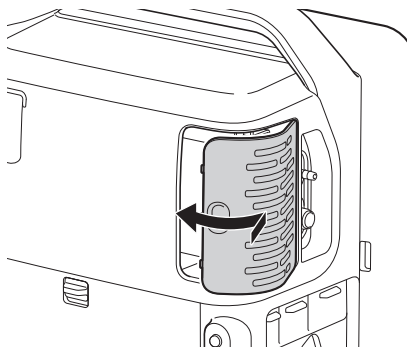
- 1 Remove the cover from the **gas inlet port** on the left side panel of the ventilator.



Put your finger on the recessed part of the cover and remove it in the direction of the arrow.

- 2 Remove the old dust filter.



**3** Install a new dust filter.**4** Attach the cover that was removed in Step 1 to the **gas inlet port**.

## Disposal

**⚠ WARNING**

Dispose of Nihon Kohden products according to your local laws and your facility's guidelines for waste disposal. Otherwise, it may affect the environment. If there is a possibility that the product may have been contaminated with infection, dispose of it as medical waste according to your local laws and your facility's guidelines for medical waste. Otherwise, it may cause infection.



## YS-119P9 Fan Filter

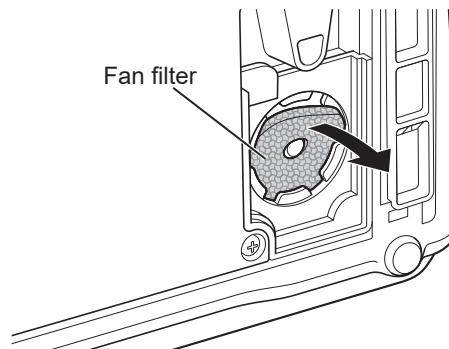
### Expiration Date

Replace the YS-119P9 fan filter on the bottom panel of the ventilator **every month**.

NOTE: When damage, dirt or dust can be seen on the fan filter, replace it as soon as possible.

### Replacement Method

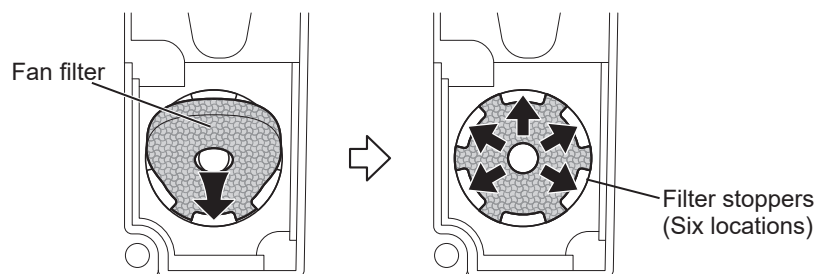
- 1 Pinch the old fan filter with your fingers and remove it.



- 2 Install a new fan filter.

Fit the center hole on the fan filter into the raised area in the center of the ventilation outlet, and fit the outer edge of the fan filter behind the filter stoppers.

NOTE: Make sure the fan filter does not stick out beyond the filter stoppers.



### Disposal

#### ⚠ WARNING

Dispose of Nihon Kohden products according to your local laws and your facility's guidelines for waste disposal. Otherwise, it may affect the environment. If there is a possibility that the product may have been contaminated with infection, dispose of it as medical waste according to your local laws and your facility's guidelines for medical waste. Otherwise, it may cause infection.

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## YS-119P4 Oxygen Sensor

### Disposal

Dispose of used YS-119P4 galvanic oxygen sensors as follows.

**⚠ WARNING**

Dispose of Nihon Kohden products according to your local laws and your facility's guidelines for waste disposal. Otherwise, it may affect the environment. If there is a possibility that the product may have been contaminated with infection, dispose of it as medical waste according to your local laws and your facility's guidelines for medical waste. Otherwise, it may cause infection.

---

## Breathing Circuit and Heated Humidifier

Refer to the operator's manual of the breathing circuit and heated humidifier for instructions on how to dispose of them.



Refer to the Breathing Circuit and Heated Humidifier Operator's Manual.

---

## CO<sub>2</sub> Sensor Kit

Refer to the CO<sub>2</sub> sensor kit for instructions on how to dispose of it.



Refer to the CO<sub>2</sub> Sensor Kit Operator's Manual.

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## SpO<sub>2</sub> Probe and SpO<sub>2</sub> Adapter

Refer to the operator's manual of the SpO<sub>2</sub> probe and SpO<sub>2</sub> adapter for instructions on how to dispose of them.



Refer to the SpO<sub>2</sub> Probe and SpO<sub>2</sub> Adapter Operator's Manual.



## Cleaning, Disinfection and Storage

### CAUTION

Before maintenance, cleaning or disinfection, turn the ventilator power off and disconnect the power cord from the AC socket. Failure to follow this instruction may result in electrical shock and ventilator malfunction.

NOTE: When using a flammable solvent such as ethanol, use it in a location that is sufficiently ventilated, avoiding enclosed areas.

## Ventilator

### CAUTION

If fluids are accidentally spilled into the ventilator, take the ventilator out of service and contact your Nihon Kohden representative. The ventilator must be disassembled, cleaned, dried and tested for safety, function and performance.

- NOTE
- The ventilator is not waterproof. Make sure water does not enter the inside of the unit.
  - After cleaning and disinfecting, wipe off any moisture with a dry cloth and only use it after the ventilator is fully dried.
  - Do not sterilize the ventilator. This may cause surface deterioration, cracks, discoloration and malfunction.

## Cleaning Exterior Surfaces

After using the ventilator, wipe the exterior surface with a soft cloth moistened with disinfecting ethanol 76.9 to 81.4 vol% at 15°C (59°F), neutral detergent diluted with water, or isopropyl alcohol 70 vol%. Dry the exterior surface thoroughly after cleaning.

NOTE: Do not use organic solvents such as thinner, benzene or industrial alcohol since they can cause the plastic surface to melt or crack.

### Fan Filter Dust

Dust may accumulate in the fan filter on the bottom of the ventilator. Check filter periodically to find if dust has accumulated. Replace the fan filter if dust has accumulated.



Refer to “YS-119P9 Fan Filter” (p. 14-8).

## Disinfecting the Exterior Surface

Wipe it with a soft cloth containing any of the following disinfectants.

- Alkyldiaminoethylglycine hydrochloride: 0.5%
- Benzalkonium chloride: 0.2%
- Benzethonium chloride solution: 0.2%
- Chlorhexidine gluconate solution: 0.5%
- Phtharal: 0.55%
- Phenol: 1.8 to 2.3w/v%
- Isopropyl alcohol: 70 vol%

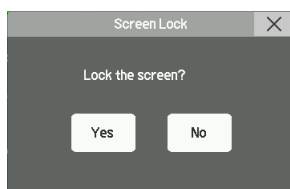
NOTE • Use disinfectants at their proper concentrations.

- Do not use organic solvents such as thinner or benzine since they can cause the plastic surface to melt or crack.
- When disinfecting with a spray, do not let the spray remain on the surface. Wipe it off with a cloth.
- Do not disinfect with sodium hypochlorite.
- Do not sterilize or disinfect using UV irradiation or ozone.

## Display

### Cleaning the Display

When cleaning the display while using the ventilator, first lock the screen so that it is not activated by accidentally touching the touch keys or operation knob. Then, wipe off any dust from the display.



**1** Select the [Menu] operation key to display the Menu window.

**2** Select [Screen Lock] in “Screen” to display the Screen Lock window.

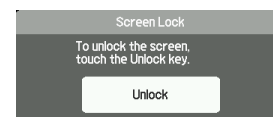
Selecting [Screen Lock] from the function keys also displays the Screen Lock window. (Only when the function is assigned to a function key)

**3** Select [Yes].

This turns off the touch screen and operation knob.



- Select [No] to cancel the screen lock and return to the Main screen.
- The following message appears when touching the touch screen or operation knob while the screen is locked.



**4** Wipe off dirt from the display using a dry and soft cloth, a cloth moistened with a neutral detergent, or a soft cloth moistened with ethanol and thoroughly wrung out.

NOTE • Do not use rough cloth.

- Do not use organic solvents, acids or alkaline detergents.



- 5 Operate the touch screen or operation knob to unlock the screen. When a confirmation message appears, touch [Unlock] on the message. The screen is unlocked.

---

Pressing the **power switch** on the ventilator also unlocks the screen.

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## Main Battery (SB-831V)

### Cleaning

#### Cleaning period: Once every 6 months

The main battery can be cleaned in the same way as the exterior of the ventilator.



Refer to “Ventilator” (p. 14-10).

### Storage

- Always make sure to store batteries mounted to the ventilator with the AC power connected.
- When not using the ventilator for an extended period of time (approximately 6 months or longer), remove the batteries from the ventilator and store them in a dry location at a temperature between  $-20$  and  $+35^{\circ}\text{C}$  ( $-4$  and  $95^{\circ}\text{F}$ ) to prevent rust from forming on them.
- Make sure to recharge the batteries before use after storing them for 1 month or longer. Furthermore, note that the battery power for the main battery may degrade due to self-discharge even when storing them for a short period of time fully charged.
- Replace the main battery every 2 years from the usage start date to ensure full functionality for the ventilator.
- Charge the batteries once every 6 months when not using them for an extended period of time.

---

## Backup Battery (SB-330Z)

### Storage

- Always make sure to store batteries mounted to the ventilator with the AC power connected.
- When not using the ventilator for an extended period of time (approximately 6 months or longer), remove the batteries from the ventilator and store them in a dry location at a temperature between  $-20$  and  $+35^{\circ}\text{C}$  ( $-4$  and  $95^{\circ}\text{F}$ ) to prevent rust from forming on them.
- Make sure to recharge the batteries before use after storing them for 1 month or longer. Furthermore, note that the battery power for the backup battery may degrade due to self-discharge even when storing them short term fully charged.
- Replace the backup battery every 2 years from the usage start date to ensure full functionality for the ventilator.
- Charge the batteries once every 6 months when not using them for an extended period of time.

---

## Breathing Circuit and Heated Humidifier

Refer to the operator's manual of the breathing circuit and heated humidifier for instructions.



Refer to the Breathing Circuit and Heated Humidifier Manual.

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## CO<sub>2</sub> Sensor Kit

Refer to the operators manual of the CO<sub>2</sub> sensor kit documentation for instructions.



Refer to the CO<sub>2</sub> Sensor Kit Operator's Manual.

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## SpO<sub>2</sub> Probe and SpO<sub>2</sub> Adapter

Refer to the operators manual of the SpO<sub>2</sub> probe and SpO<sub>2</sub> adapter for instructions.



Refer to the SpO<sub>2</sub> Probe and SpO<sub>2</sub> Adapter Operator's Manual.

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## Cables

Clean and disinfect the YJ-332Z connection cable 2.5 m, YJ-333Z connection cable 5.0 m and YJ-334Z connection cable 10.0 m in the same way as the ventilator. Refer to the instructions for cleaning and disinfecting the ventilator.



Refer to the "Ventilator" (p. 14-10).



## Maintenance and Inspection

The ventilator provides assisted breathing for spontaneously breathing patients. To ensure that functionality and performance are not degraded or impacted, perform the “Preoperational, Operational and Postoperational Checks” and the periodic “Six-Month Inspection” and also replace the consumable parts and periodic replacement parts. A periodic inspection by a Nihon Kohden service personnel is required at least once a year. When periodic inspections are needed, contact your Nihon Kohden representative.

If abnormalities are found as a result of the inspection and the ventilator is suspected to be faulty, attach an “Do Not Use” or “Under Repairs” label to the ventilator and contact your Nihon Kohden representative.

For details on the “Six Month Inspection” for ensuring proper ventilator operation, refer to the Administrator’s Guide: Section 4 “Maintenance and Inspection”.



Refer to the following.  
Administrator’s Guide:  
Section 4-3 “6-month Inspection”



# 15

## Factory Default Settings

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# Settings, Details and List of Default Settings

The setting contents and default values of the Menu window setting items are shown in the table below.

## Description of symbols in the backup column

| Symbol | Description   |
|--------|---|
| OK     | Included in backup and system initialization.   |
| △      | Included in system initialization.  |
| —      | Not included in backup and system initialization. When the power is turned off, the settings are not saved. |
| Master | Returns to the master value when a new patient is admitted.   |



### About Backup

These settings can be exported on the System Setup window ► [Info] tab ► [Maintenance] tab ► [Load/Save Settings] window.

## Patient

| Setting      |                        | Description                           | Default Setting    |                    | Backup |
|--------------|------------------------|---------------------------------------|--------------------|--------------------|--------|
|              |                        |                                       | Adult              | Pediatric          |        |
| Patient Type |                        | Adult, Pediatric                      | Adult              |                    | △      |
| Height       | cm (inch) <sup>1</sup> | 50 to 250 cm (1 ft 8 in to 8 ft 2 in) | 174<br>(5 ft 9 in) | 130<br>(4 ft 3 in) |        |
| Gender       |                        | Male, Female                          | Male               |                    |        |

<sup>1</sup> The unit can be set on the [Units] window in the System Configuration window.



Refer to the following.

Administrator's Guide:

"Unit Settings" in Section 2

## Circuit Configuration

| Setting               |                   | Description   | Default Setting |           | Backup |
|-----------------------|-------------------|---|-----------------|-----------|--------|
|                       |                   |   | Adult           | Pediatric |        |
| Circuit Configuration | Exhalation Port   | NK, None, Others  | NK              |           | OK     |
|                       | Proximal Sensor   | Pressure Sensor, Flow Sensor  | Flow Sensor     |           |        |
|                       | Patient Interface | Mask (NK), Mask (without Exhalation Port), Mask (with Exhalation Port), ETT/Trach | Mask (NK)       |           |        |



## Control Settings

| Setting             | Unit                             | Description  | Step           | Default Setting |           | Backup   |              |
|---------------------|----------------------------------|--|----------------|-----------------|-----------|----------|--------------|
|                     |                                  |  |                | Adult           | Pediatric |          |              |
| Ventilation Mode    |                                  | SPONT-PS, S/T, PCV <sup>1</sup> ,<br>PRVC <sup>1</sup> , PPV <sup>1</sup> , O <sub>2</sub><br>Therapy <sup>1</sup> |                | SPONT-PS        | SPONT-PS  | OK       |              |
| <b>SPONT-PS</b>     |                                  |  |                |                 |           |          |              |
| Basic Settings      | EPAP/CPAP                        | hPa<br>(cmH <sub>2</sub> O,<br>mbar) <sup>2</sup>  | 4 to 25        | 1               | 4         | 4        | OK<br>Master |
|                     | PS (ΔP)                          | hPa<br>(cmH <sub>2</sub> O,<br>mbar) <sup>2</sup>  | 0 to 36        | 1               | 4         | 4        |              |
|                     | Slope                            | —  | 1 to 6         | 1               | 2         | 2        |              |
|                     | FiO <sub>2</sub> <sup>3, 4</sup> | %  | 21 to 100      | 1               | 21        | 21       |              |
|                     | Trig. Type                       | —  | Advanced, Flow | —               | Advanced  | Advanced |              |
|                     | Trig. Sens.<br>(Advanced)        | —  | Auto, 1 to 7   | 1               | Auto      | Auto     |              |
|                     | Trig. Sens.<br>(Flow)            | L/min  | 0.1 to 10.0    | 0.1             | 3.0       | 3.0      |              |
| Additional Settings | ET%                              | %  | 5 to 80        | 1               | 25        | 25       | —            |
|                     | Ti Max                           | s  | 0.30 to 7.50   | 0.05            | 3.00      | 3.00     |              |
|                     | Ti Min                           | s  | 0.30 to 7.50   | 0.05            | 0.30      | 0.30     |              |
|                     | Press. Release                   | —  | Off, 1 to 3    | 1               | Off       | Off      |              |
| Ramp Up Time        | min                              | Off, 5 to 45   | 5              | Off             | Off       | —        |              |
| Apnea Ventilation   | Apnea                            | s  | 5 to 60        | 1               | 20        | 20       | OK<br>Master |
|                     | Apnea Ventilation                | —  | On, Off        | —               | On        | On       |              |
|                     | IPAP                             | hPa<br>(cmH <sub>2</sub> O,<br>mbar) <sup>2</sup>  | 5 to 40        | 1               | 8         | 8        |              |
|                     | EPAP                             | hPa<br>(cmH <sub>2</sub> O,<br>mbar) <sup>2</sup>  | 4 to 25        | 1               | 4         | 4        |              |
|                     | Slope                            | —  | 1 to 6         | 1               | 2         | 2        |              |
|                     | RR                               | /min   | 4 to 60        | 1               | 15        | 15       |              |
|                     | Ti <sup>5</sup>                  | s  | 0.30 to 7.50   | 0.05            | 1.00      | 1.00     |              |
| I:E <sup>5</sup>    | —                                | 1.0 to 20.0  | 0.1            | 3.0             | 3.0       |          |              |



| Setting               | Unit                            | Description                                       | Step           | Default Setting |           | Backup   |              |
|-----------------------|---------------------------------|---|----------------|-----------------|-----------|----------|--------------|
|                       |                                 |   |                | Adult           | Pediatric |          |              |
| <b>S/T</b>            |                                 |   |                |                 |           |          |              |
| Basic Settings        | IPAP                            | hPa<br>(cmH <sub>2</sub> O,<br>mbar) <sup>2</sup> | 5 to 40        | 1               | 8         | 8        | OK<br>Master |
|                       | EPAP                            | hPa<br>(cmH <sub>2</sub> O,<br>mbar) <sup>2</sup> | 4 to 25        | 1               | 4         | 4        |              |
|                       | Slope                           | —   | 1 to 6         | 1               | 2         | 2        |              |
|                       | FiO <sub>2</sub> <sup>3,4</sup> | %   | 21 to 100      | 1               | 21        | 21       |              |
|                       | RR                              | /min  | 4 to 60        | 1               | 4         | 4        |              |
|                       | Ti <sup>5</sup>                 | s   | 0.30 to 7.50   | 0.05            | 1.00      | 1.00     |              |
|                       | I:E <sup>5</sup>                | —   | 1.0 to 20.0    | 0.1             | 14.0      | 14.0     |              |
|                       | Trig. Type                      | —   | Advanced, Flow | —               | Advanced  | Advanced |              |
|                       | Trig. Sens.<br>(Advanced)       | —   | Auto, 1 to 7   | 1               | Auto      | Auto     |              |
|                       | Trig. Sens.<br>(Flow)           | L/min   | 0.1 to 10.0    | 0.1             | 3.0       | 3.0      |              |
| Additional Settings   | ET%                             | %   | 5 to 80        | 1               | 25        | 25       | —            |
|                       | Ti Max                          | s   | 0.30 to 7.50   | 0.05            | 3.00      | 3.00     |              |
|                       | Ti Min                          | s   | 0.30 to 7.50   | 0.05            | 0.30      | 0.30     |              |
| Ramp Up Time          | min                             | Off, 5 to 45                                      | 5              | Off             | Off       | —        |              |
| <b>PCV</b>            |                                 |   |                |                 |           |          |              |
| Basic Settings        | IPAP                            | hPa<br>(cmH <sub>2</sub> O,<br>mbar) <sup>2</sup> | 5 to 40        | 1               | 8         | 8        | OK<br>Master |
|                       | EPAP                            | hPa<br>(cmH <sub>2</sub> O,<br>mbar) <sup>2</sup> | 4 to 25        | 1               | 4         | 4        |              |
|                       | Slope                           | —   | 1 to 6         | 1               | 2         | 2        |              |
|                       | FiO <sub>2</sub> <sup>3,4</sup> | %   | 21 to 100      | 1               | 21        | 21       |              |
|                       | RR                              | /min  | 4 to 60        | 1               | 15        | 15       |              |
|                       | Ti <sup>5</sup>                 | s   | 0.30 to 7.50   | 0.05            | 1.00      | 1.00     |              |
|                       | I:E <sup>5</sup>                | —   | 1.0 to 20.0    | 0.1             | 3.0       | 3.0      |              |
|                       | Trig. Type                      | —   | Advanced, Flow | —               | Advanced  | Advanced |              |
|                       | Trig. Sens.<br>(Advanced)       | —   | Auto, 1 to 7   | 1               | Auto      | Auto     |              |
| Trig. Sens.<br>(Flow) | L/min                           | 0.1 to 10.0                                       | 0.1            | 3.0             | 3.0       |          |              |
| Additional Settings   | Ramp Up Time                    | min   | Off, 5 to 45   | 5               | Off       | Off      | —            |



| Setting             | Unit  | Description                                       | Step           | Default Setting |           | Backup   |              |
|---------------------|---|---|----------------|-----------------|-----------|----------|--------------|
|                     |   |   |                | Adult           | Pediatric |          |              |
| <b>PRVC</b>         |   |   |                |                 |           |          |              |
| Basic Settings      | VT  | mL  | 100 to 2000    | 5               | 500       | 150      | OK<br>Master |
|                     | EPAP  | hPa<br>(cmH <sub>2</sub> O,<br>mbar) <sup>2</sup> | 4 to 25        | 1               | 4         | 4        |              |
|                     | Slope   | —   | 1 to 6         | 1               | 2         | 2        |              |
|                     | FiO <sub>2</sub> <sup>3, 4</sup>                  | %   | 21 to 100      | 1               | 21        | 21       |              |
|                     | RR  | /min  | 4 to 60        | 1               | 4         | 4        |              |
|                     | Ti <sup>5</sup>                                   | s   | 0.30 to 7.50   | 0.05            | 1.00      | 1.00     |              |
|                     | I:E <sup>5</sup>                                  | —   | 1.0 to 20.0    | 0.1             | 14.0      | 14.0     |              |
|                     | Trig. Type  | —   | Advanced, Flow | —               | Advanced  | Advanced |              |
|                     | Trig. Sens.<br>(Advanced)                         | —   | Auto, 1 to 7   | 1               | Auto      | Auto     |              |
|                     | Trig. Sens.<br>(Flow)                             | L/min   | 0.1 to 10.0    | 0.1             | 3.0       | 3.0      |              |
| Additional Settings | ET%   | %   | 5 to 80        | 1               | 25        | 25       |              |
|                     | Ti Max  | s   | 0.30 to 7.50   | 0.05            | 3.00      | 3.00     |              |
|                     | Ti Min  | s   | 0.30 to 7.50   | 0.05            | 0.30      | 0.30     |              |
|                     | Max P   | hPa<br>(cmH <sub>2</sub> O,<br>mbar) <sup>2</sup> | 6 to 40        | 1               | 25        | 25       |              |
| Min P               | hPa<br>(cmH <sub>2</sub> O,<br>mbar) <sup>2</sup> | 5 to 39   | 1              | 6               | 6         |          |              |



| Setting                      | Unit                             | Description   | Step           | Default Setting |           | Backup   |           |
|------------------------------|----------------------------------|---|----------------|-----------------|-----------|----------|-----------|
|                              |                                  |   |                | Adult           | Pediatric |          |           |
| <b>PPV<sup>1</sup></b>       |                                  |   |                |                 |           |          |           |
| Basic Settings               | PPV%                             | %   | 0 to 100       | 1               | 30        | 30       | OK Master |
|                              | EPAP/CPAP                        | hPa<br>(cmH <sub>2</sub> O,<br>mbar) <sup>2</sup>                 | 4 to 25        | 1               | 4         | 4        |           |
|                              | FiO <sub>2</sub> <sup>3, 4</sup> | %   | 21 to 100      | 1               | 21        | 21       |           |
|                              | Max E                            | hPa/L<br>(cmH <sub>2</sub> O/L,<br>mbar/L) <sup>2</sup>           | 0 to 100       | 1               | 15        | 15       |           |
|                              | Max R                            | hPa/L/s<br>(cmH <sub>2</sub> O/<br>L/s,<br>mbar/L/s) <sup>2</sup> | 0 to 50        | 1               | 4         | 4        |           |
|                              | Trig. Type                       | —   | Advanced, Flow | —               | Advanced  | Advanced |           |
|                              | Trig. Sens.<br>(Advanced)        | —   | Auto, 1 to 7   | 1               | Auto      | Auto     |           |
|                              | Trig. Sens.<br>(Flow)            | L/min   | 0.1 to 10.0    | 0.1             | 3.0       | 3.0      |           |
|                              | ET%                              | %   | 5 to 80        | 1               | 5         | 5        |           |
| Additional Settings          | Ti Max                           | s   | 0.30 to 7.50   | 0.05            | 3.00      | 3.00     | OK Master |
|                              | Ti Min                           | s   | 0.30 to 7.50   | 0.05            | 0.30      | 0.30     |           |
|                              | Max P                            | hPa<br>(cmH <sub>2</sub> O,<br>mbar) <sup>2</sup>                 | 6 to 40        | 1               | 20        | 20       |           |
|                              | Max VT                           | mL  | 100 to 2000    | 5               | 1000      | 1000     |           |
| Apnea Ventilation            | Apnea                            | s   | 5 to 60        | 1               | 20        | 20       | OK Master |
|                              | Apnea Ventilation                | —   | On, Off        | —               | On        | On       |           |
|                              | IPAP                             | hPa<br>(cmH <sub>2</sub> O,<br>mbar) <sup>2</sup>                 | 5 to 40        | 1               | 8         | 8        |           |
|                              | EPAP                             | hPa<br>(cmH <sub>2</sub> O,<br>mbar) <sup>2</sup>                 | 4 to 25        | 1               | 4         | 4        |           |
|                              | Slope                            | —   | 1 to 6         | 1               | 2         | 2        |           |
|                              | RR                               | /min  | 4 to 60        | 1               | 15        | 15       |           |
|                              | Ti <sup>5</sup>                  | s   | 0.30 to 7.50   | 0.05            | 1.00      | 1.00     |           |
|                              | I:E <sup>5</sup>                 | —   | 1.0 to 20.0    | 0.1             | 3.0       | 3.0      |           |
| <b>O<sub>2</sub> Therapy</b> |                                  |   |                |                 |           |          |           |
| Basic Settings               | Flow Rate                        | L/min   | 1 to 60        | 1               | 15        | 15       | OK Master |
|                              | FiO <sub>2</sub> <sup>3, 4</sup> | %   | 21 to 100      | 1               | 50        | 50       |           |

<sup>1</sup> This can only be set when “PPV” is set to “On” on the [Vent] window in the System Configuration window.



Refer to the following.  
Administrator's Guide:  
“Ventilation Settings” in Section 2

<sup>2</sup> The unit can be change on the [Units] window in the System Configuration window.



Refer to the following.  
Administrator's Guide:  
“Unit Settings” in Section 2

<sup>3</sup> This can be changed only when “O<sub>2</sub> Source” is set to [HPO] on the [O<sub>2</sub> Source] window.



Refer to “O<sub>2</sub> Source Settings” in Section 12.

<sup>4</sup> The same oxygen concentration setting applies to all ventilation modes. Changing the oxygen concentration in one mode changes the setting for the other modes.



- <sup>5</sup> Displayed on the Control Settings Master window with the contents which are set in “Inspiration Setting” on the System Setup ► [Parameters] tab ► [Vent] window.



Refer to the following.  
Administrator's Guide:  
“[Vent] Page” in Section 3

## Elevated O<sub>2</sub>

| Setting                      | Description   |      | Default Setting |           | Backup |
|------------------------------|---------------|------|-----------------|-----------|--------|
|                              | Setting Range | Step | Adult           | Pediatric |        |
| Operating Time               | 30 s to 5 min | 10 s | 2 min           |           | △      |
| Increase FiO <sub>2</sub> by | 1% to 79%     | 1%   | 79%             |           |        |

## Scale

| Setting | Description  | Default Setting |           | Backup |
|---------|--|-----------------|-----------|--------|
|         |  | Adult           | Pediatric |        |
| Paw     | 0 to 10, 0 to 20, 0 to 30, 0 to 50, 0 to 100                   | 0 to 50         |           | OK     |
| Flow    | -10 to +10, -20 to +20, -50 to +50, -100 to +100, -200 to +200 | -100 to +100    |           |        |
| Volume  | 0 to 150, 0 to 300, 0 to 500, 0 to 1000, 0 to 3500             | 0 to 500        |           |        |
| Time    | 10 s, 12 s, 15 s, 20 s, 30 s                                   | 12 s            |           |        |

## Monitoring

### CO<sub>2</sub>

| Setting                                 |                         | Description   | Default Setting      |           | Backup |
|---|-------------------------|---|----------------------|-----------|--------|
|   |                         |   | Adult                | Pediatric |        |
| EtCO <sub>2</sub> Max Hold <sup>1</sup> |                         | 10 s, 20 s, Off   | 10 s                 |           | OK     |
| Scale                                   | mmHg (kPa) <sup>2</sup> | 0 to 40, 0 to 60, 0 to 80, 0 to 120, 0 to 150 (0.0 to 5.5, 0.0 to 8.0, 0.0 to 10.5, 0.0 to 16.0, 0.0 to 20.0) | 0 to 40 (0.0 to 5.5) |           |        |

<sup>1</sup> Available only when a TG-980P CO<sub>2</sub> sensor kit is used.

<sup>2</sup> The unit can be set on the [Units] window in the System Configuration window.



Refer to the following.  
Administrator's Guide:  
“Unit Settings” in Section 2

### SpO<sub>2</sub>

| Setting                           | Description                            | Default Setting  |           | Backup |
|-----------------------------------|--|------------------|-----------|--------|
|                                   |  | Adult            | Pediatric |        |
| Sensitivity                       | ×1/8, ×1/4, ×1/2, ×1, ×2, ×4, ×8, Auto | Auto             |           | OK     |
| Sync Pitch                        | Fixed, SpO <sub>2</sub>                | SpO <sub>2</sub> |           |        |
| Response                          | Fast, Normal, Slow                     | Normal           |           |        |
| SpO <sub>2</sub> Sensitivity Mode | Max, Normal                            | Normal           |           |        |



# Alarm Settings

| Parameters                     |             | Unit  | Description                     |         | Default Setting |           | Backup       |
|--------------------------------|-------------|---|---------------------------------|---------|-----------------|-----------|--------------|
|                                |             |   | Settings                        | Step    | Adult           | Pediatric |              |
| PIP                            | Upper limit | hPa (cmH <sub>2</sub> O, mbar) <sup>1</sup> | 6.0 to 50.0                     | 1       | 50.0            | 50.0      | OK<br>Master |
|                                | Lower limit | hPa (cmH <sub>2</sub> O, mbar) <sup>1</sup> | Off, 4.0 to 39.0                | 1       | Off             | Off       |              |
| MV                             | Upper limit | L/min                                       | Off, 0.2 to 30.0                | 0.1     | 15.0            | 5.0       |              |
|                                | Lower limit | L/min                                       | Off, 0.1 to 29.9                | 0.1     | 2.0             | 1.0       |              |
| VT                             | Upper limit | mL  | Off, 10 to 3500                 | 5       | 2500            | 500       |              |
|                                | Lower limit | mL  | Off, 5 to 3495                  | 5       | Off             | Off       |              |
| RR <sub>TOT</sub>              | Upper limit | /min  | Off, 2 to 150                   | 1       | 30              | 30        |              |
|                                | Lower limit | /min  | Off, 0 to 149                   | 1       | 6               | 6         |              |
| Apnea                          | Upper limit | s   | 5 to 60                         | 1       | 20              | 20        |              |
| FiO <sub>2</sub> <sup>1</sup>  | Upper limit | %   | Off, 22 to 100                  | 1       | 50              | 50        |              |
|                                | Lower limit | %   | 18 to 99                        | 1       | 18              | 18        |              |
| EtCO <sub>2</sub>              | Upper limit | mmHg (kPa) <sup>1</sup>                     | Off, 2 to 99 (Off, 0.2 to 13.0) | 1 (0.1) | Off             | Off       |              |
|                                | Lower limit | mmHg (kPa) <sup>1</sup>                     | Off, 1 to 98 (Off, 0.1 to 12.9) | 1 (0.1) | Off             | Off       |              |
| FiCO <sub>2</sub> <sup>3</sup> | Upper limit | mmHg (kPa) <sup>1</sup>                     | Off, 1 to 99 (Off, 0.1 to 13.0) | 1 (0.1) | Off             | Off       |              |
| RR (CO <sub>2</sub> )          | Upper limit | /min  | Off, 2 to 150                   | 1       | Off             | Off       |              |
|                                | Lower limit | /min  | Off, 0 to 149                   | 1       | Off             | Off       |              |
| Apnea (CO <sub>2</sub> )       | Upper limit | s   | Off, 5 to 40                    | 5       | 20              | 20        |              |
| SpO <sub>2</sub>               | Upper limit | %   | Off, 51 to 100                  | 1       | Off             | Off       |              |
|                                | Lower limit | %   | Off, 50 to 99                   | 1       | 90              | 90        |              |
| PR                             | Upper limit | /min  | Off, 31 to 300                  | 1       | 140             | 170       |              |
|                                | Lower limit | /min  | Off, 30 to 299                  | 1       | 50              | 75        |              |

<sup>1</sup> The unit can be change on the [Units] window in the System Configuration window.



Refer to the following.  
Administrator's Guide:  
"Unit Settings" in Section 2

<sup>2</sup> This can be changed only when "O<sub>2</sub> Source" is set to [LPO] on the [O<sub>2</sub> Source] window. When set to [HPO], the upper and lower limit alarms change depending on the ventilation parameter setting.



Refer to the following.  
"O<sub>2</sub> Source Settings" in Section 12.  
"Alarms" in Section 16.

<sup>3</sup> Available only when a TG-980P CO<sub>2</sub> sensor kit is used.



## Review

### Trend

For details on parameters and scales, refer to Trend Graphs and Scales.

| Setting |                |        |       | Description                      | Default Setting                |           | Backup |  |
|---------|----------------|--------|-------|----------------------------------|--------------------------------|-----------|--------|--|
|         |                |        |       |                                  | Adult                          | Pediatric |        |  |
| Trend 1 | Top            | Left1  | Setup | Refer to Trend Graphs and Scales | MV                             |           | OK     |  |
|         |                |        | Scale |                                  | 0.0 to 20.0                    |           |        |  |
|         |                | Right1 | Setup |                                  | None                           |           |        |  |
|         |                |        | Scale |                                  | —                              |           |        |  |
|         | Bottom         | Left2  | Setup |                                  | None                           |           |        |  |
|         |                |        | Scale |                                  | —                              |           |        |  |
|         |                | Right2 | Setup |                                  | None                           |           |        |  |
|         |                |        | Scale |                                  | —                              |           |        |  |
|         | Time Scale     |        |       |                                  | 1 h, 2 h, 4 h, 8 h, 24 h, 72 h | 4 h       |        |  |
|         | Display Format |        |       |                                  | Max-Min, Average               | Average   |        |  |
| Trend 2 | Top            | Left1  | Setup | Refer to Trend Graphs and Scales | RRTOR                          |           | OK     |  |
|         |                |        | Scale |                                  | 0 to 50                        |           |        |  |
|         |                | Right1 | Setup |                                  | None                           |           |        |  |
|         |                |        | Scale |                                  | —                              |           |        |  |
|         | Bottom         | Left2  | Setup |                                  | None                           |           |        |  |
|         |                |        | Scale |                                  | —                              |           |        |  |
|         |                | Right2 | Setup |                                  | None                           |           |        |  |
|         |                |        | Scale |                                  | —                              |           |        |  |
|         | Time Scale     |        |       |                                  | 1 h, 2 h, 4 h, 8 h, 24 h, 72 h | 4 h       |        |  |
|         | Display Format |        |       |                                  | Max-Min, Average               | Average   |        |  |



## Trend Graphs and Scales

| Item                     | Description                           | Unit  | Scale                  | Default Setting      |           |
|--------------------------|---------------------------------------|---|------------------------|----------------------|-----------|
|                          |                                       |   |                        | Adult                | Pediatric |
| PIP                      | Peak inspiratory pressure             | hPa (cmH <sub>2</sub> O, mbar) <sup>1</sup> | 0.0 to 100.0           | 0.0 to 50.0          |           |
| PEEP                     | Positive end expiratory pressure      | hPa (cmH <sub>2</sub> O, mbar) <sup>1</sup> | 0.0 to 100.0           | 0.0 to 30.0          |           |
| FI-PEAK                  | Peak inspiratory flow                 | L/min                                       | 0 to 200               | 0 to 50              |           |
| FE-PEAK                  | Peak expiratory flow                  | L/min                                       | -200.0 to 0.0          | -50.0 to 0.0         |           |
| Flow Rate                | Flow rate                             | L/min                                       | 0.0 to 100.0           | 0.0 to 50.0          |           |
| MVI                      | Total inspiratory minute volume       | L/min                                       | 0.0 to 100.0           | 0.0 to 20.0          |           |
| MVISPONT                 | Spontaneous inspiratory minute volume | L/min                                       | 0.0 to 100.0           | 0.0 to 20.0          |           |
| MV                       | Total expiratory minute volume        | L/min                                       | 0.0 to 100.0           | 0.0 to 20.0          |           |
| MVSPONT                  | Spontaneous expiratory minute volume  | L/min                                       | 0.0 to 100.0           | 0.0 to 20.0          |           |
| VTi                      | Inspiratory tidal volume              | mL  | 0 to 3500              | 0 to 1000            |           |
| VT                       | Expiratory tidal volume               | mL  | 0 to 3500              | 0 to 1000            |           |
| VT/kg                    | Expiratory tidal volume /kg           | mL/kg                                       | 0.0 to 50.0            | 0.0 to 20.0          |           |
| RRTOT                    | Total respiratory rate                | /min  | 0 to 150               | 0 to 50              |           |
| RRSPONT                  | Spontaneous respiration rate          | /min  | 0 to 150               | 0 to 50              |           |
| Ti                       | Inspiratory time                      | s   | 0.00 to 100.00         | 0.00 to 10.00        |           |
| Te                       | Expiratory time                       | s   | 0.00 to 100.00         | 0.00 to 10.00        |           |
| Ti/TTOT                  | Inspiratory duty cycle                | %   | 0 to 90                | 0 to 50              |           |
| I:E                      | I:E ratio                             | —   | 0.0 to 9.0             | 0 to 5.0             |           |
| LeakTOTAL                | Total leakage flow                    | L/min                                       | 0.0 to 200.0           | 0.0 to 50.0          |           |
| LeakPATIENT              | Patient leakage flow                  | L/min                                       | 0.0 to 200.0           | 0.0 to 50.0          |           |
| Leak%                    | Leakage volume ratio                  | %   | 0 to 100               | 0 to 100             |           |
| Pt. Trig.                | Spontaneous breathing ratio           | %   | 0 to 100               | 0 to 100             |           |
| O <sub>2</sub> Gas Usage | O <sub>2</sub> gas usage              | L/min                                       | 0.0 to 100.0           | 0.0 to 50.0          |           |
| FiO <sub>2</sub>         | FiO <sub>2</sub>                      | %   | 0 to 100               | 15 to 50             |           |
| SpO <sub>2</sub>         | SpO <sub>2</sub>                      | —   | 0 to 100               | 80 to 100            |           |
| PR                       | Pulse rate                            | /min  | 0 to 300               | 0 to 100             |           |
| PI                       | Pulse-amplitude index                 | %   | 0.01 to 100.00         | 0.01 to 100.00       |           |
| EtCO <sub>2</sub>        | EtCO <sub>2</sub>                     | mmHg (kPa) <sup>1</sup>                     | 0 to 150 (0.0 to 20.0) | 0 to 40 (0.0 to 5.5) |           |
| FiCO <sub>2</sub>        | FiCO <sub>2</sub>                     | mmHg (kPa) <sup>1</sup>                     | 0 to 100 (0.0 to 15.0) | 0 to 5 (0.0 to 0.5)  |           |
| RR (CO <sub>2</sub> )    | Respiratory rate (CO <sub>2</sub> )   | /min  | 0 to 150               | 0 to 50              |           |

<sup>1</sup> The unit can be change on the [Units] window in the System Configuration window.



Refer to the following.

Administrator's Guide:

“Unit Settings” in Section 2



## Trend Table

| Setting         |    | Description  | Default Setting       |           | Backup |
|-----------------|----|--|-----------------------|-----------|--------|
|                 |    |  | Adult                 | Pediatric |        |
| Parameter Setup | 1  | PIP, PEEP, FI-PEAK, FE-PEAK, Flow Rate, MV <sub>I</sub> , MV <sub>I</sub> SPONT, MV, MV <sub>SPONT</sub> , VT <sub>I</sub> , VT, VT/kg, RR <sub>TOT</sub> , RR <sub>SPONT</sub> , T <sub>I</sub> , T <sub>E</sub> , T <sub>I</sub> /T <sub>TOT</sub> , I:E, Leak <sub>TOTAL</sub> , Leak <sub>PATIENT</sub> , Leak%, Pt.Trig., O <sub>2</sub> Gas Usage, FiO <sub>2</sub> , SpO <sub>2</sub> , PR, PI, EtCO <sub>2</sub> , FiCO <sub>2</sub> , RR (CO <sub>2</sub> ), None | PIP                   |           | OK     |
|                 | 2  |  | PEEP                  |           |        |
|                 | 3  |  | MV                    |           |        |
|                 | 4  |  | MV <sub>SPONT</sub>   |           |        |
|                 | 5  |  | VT <sub>I</sub>       |           |        |
|                 | 6  |  | VT                    |           |        |
|                 | 7  |  | RR <sub>TOT</sub>     |           |        |
|                 | 8  |  | RR <sub>SPONT</sub>   |           |        |
|                 | 9  |  | Leak <sub>TOTAL</sub> |           |        |
|                 | 10 |  | FiO <sub>2</sub>      |           |        |
| Interval Setup  |    | 1 min, 5 min, 10 min, 15 min, 30 min, 1 h  | 1 min                 |           |        |

## Event Log

| Setting             |          | Description   | Default Setting   |           | Backup |
|---------------------|----------|---|---|-----------|--------|
|                     |          |   | Adult   | Pediatric |        |
| Alarm Log           | Type     | Vent, Vital, Technical  | Vent, Vital, Technical  |           | OK     |
|                     | Priority | Crisis, Warning, Advisory, Information  | Crisis, Warning, Advisory, Information  |           |        |
| Operation Log Setup |          | Control Settings, Alarm Operation, Calibration, Other Settings, Patient Info, All | Control Settings, Alarm Operation, Calibration, Other Settings, Patient Info, All |           |        |

## Full Disclosure

| Setting         |                 | Description | Default Setting |           | Backup |
|-----------------|-----------------|-------------|-----------------|-----------|--------|
|                 |                 |             | Adult           | Pediatric |        |
| Displayed Waves | Paw             | On, Off     | On              |           | OK     |
|                 | Flow            | On, Off     | On              |           |        |
|                 | Volume          | On, Off     | On              |           |        |
|                 | CO <sub>2</sub> | On, Off     | On              |           |        |
|                 | Pleth           | On, Off     | On              |           |        |



## Setup

### O<sub>2</sub> Source

| Setting               | Description | Default Setting |           | Backup |
|-----------------------|-------------|-----------------|-----------|--------|
|                       |             | Adult           | Pediatric |        |
| O <sub>2</sub> Source | HPO, LPO    | HPO             |           | OK     |

### Audio Volume

| Setting           | Description                        | Default Setting |           | Backup |
|-------------------|------------------------------------|-----------------|-----------|--------|
|                   |                                    | Adult           | Pediatric |        |
| Sync Sound Volume | On, Off                            | On              |           | OK     |
|                   | 1 to 7 (8 levels: 0 cannot be set) | 3               |           |        |
| Alarm Volume      | 1 to 7 (8 levels: 0 cannot be set) | 5               |           |        |

### Cabinet

| Setting                 | Description  | Default Setting  |           | Backup |
|-------------------------|--|------------------|-----------|--------|
|                         |  | Adult            | Pediatric |        |
| Cabinet                 | On, Off  | Off              |           | OK     |
| Contents                | Trend 1, Trend 2, Trend Table, Event Log, Full Disc, Detail Numerics | Trend 1          |           |        |
| Detail Numeric Settings | 1  | PEEP             |           |        |
|                         | 2  | MVSPONT          |           |        |
|                         | 3  | RRSPONT          |           |        |
|                         | 4  | Ti               |           |        |
|                         | 5  | Fi-PEAK          |           |        |
|                         | 6  | FiO <sub>2</sub> |           |        |
|                         | 7  | Pt.Trig.         |           |        |
|                         | 8  | I:E              |           |        |



## Display Configuration

| Setting    |                  | Description           | Default Setting |           | Backup |  |
|------------|------------------|-----------------------|-----------------|-----------|--------|--|
|            |                  |                       | Adult           | Pediatric |        |  |
| Parameters | Ventilation      | 4, 5                  | 5               |           | OK     |  |
|            |                  | 1                     | PIP             |           |        |  |
|            |                  | 2                     | MV              |           |        |  |
|            |                  | 3                     | VT              |           |        |  |
|            |                  | 4                     | RRTOT           |           |        |  |
|            | 5                | LeakTOTAL             |                 |           |        |  |
|            | CO <sub>2</sub>  | FiCO <sub>2</sub>     | On, Off         | Off       |        |  |
|            |                  | RR (CO <sub>2</sub> ) | On, Off         | Off       |        |  |
|            | SpO <sub>2</sub> | PR                    | On, Off         | Off       |        |  |
|            |                  | PI                    | On, Off         | Off       |        |  |
| SQI        |                  | On, Off               | Off             |           |        |  |
| Waveforms  | Volume           | On, Off               | On              |           |        |  |
|            | CO <sub>2</sub>  | On, Off               | On              |           |        |  |
|            | Pleth            | On, Off               | On              |           |        |  |

## Screen

### Brightness

| Setting    | Description         | Default Setting |           | Backup |
|------------|---------------------|-----------------|-----------|--------|
|            |                     | Adult           | Pediatric |        |
| Brightness | 1 to 15 (15 levels) | 12              |           | OK     |

### Date/Time Settings

| Setting | Description  | Default Setting |           | Backup |
|---------|--------------|-----------------|-----------|--------|
|         |              | Adult           | Pediatric |        |
| Year    | 2000 to 2050 | —               | —         | —      |
| Month   | 01 to 12     |                 |           |        |
| Day     | 01 to 31     |                 |           |        |
| Hour    | 00 to 23     |                 |           |        |
| Minute  | 00 to 59     |                 |           |        |



# 16

## Technical Information

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# Specifications

## Function and Performance

### Ventilation and O<sub>2</sub> Therapy

#### Mounting Mode

| Mode   | Start of Inspiration     | Start of Expiration      | Inspiratory Pressure |
|--|--------------------------|--------------------------|----------------------|
| SPONT-PS (Spontaneous with pressure support)         | Apnea                    | Time-cycled              | IPAP                 |
|  | Patient-triggered breath | Patient-triggered breath | EPAP/CPAP+PS         |
| S/T (Spontaneous with timed backup)                  | Time                     | Time-cycled              | IPAP                 |
|  | Pat.-trig                | Patient-triggered breath | IPAP                 |
| PCV (Pressure control ventilation)                   | Time                     | Time-cycled              | IPAP                 |
|  | Patient-triggered breath | Time-cycled              | IPAP                 |
| PRVC (Pressure regulated volume control ventilation) | Time                     | Time-cycled              | Min P ≤ IPAP ≤ Max P |
|  | Patient-triggered breath | Patient-triggered breath | Min P ≤ IPAP ≤ Max P |
| PPV (Proportional pressure support ventilation)      | Apnea                    | Time-cycled              | IPAP                 |
|  | Patient-triggered breath | Patient-triggered breath | ≤ Max P              |
| O <sub>2</sub> therapy                               | —                        | —                        | —                    |

#### Control Settings

Parameters that can be set in each mode

| Parameters   | SPONT-PS | S/T | PCV | PRVC | PPV | O <sub>2</sub> Therapy |
|--|----------|-----|-----|------|-----|------------------------|
| Expiratory positive airway pressure/Continuous positive airway pressure (EPAP/CPAP) <sup>1</sup> | OK       | OK  | OK  | OK   | OK  | —                      |
| Inspiratory positive airway pressure (IPAP)  | —        | OK  | OK  | —    | —   | —                      |
| Pressure support (PS) <sup>2</sup>   | OK       | —   | —   | —    | —   | —                      |
| Inspiratory time (Ti) <sup>3</sup>   | —        | OK  | OK  | OK   | —   | —                      |
| Maximum inspiratory time (Ti Max)  | OK       | OK  | —   | OK   | OK  | —                      |
| Minimum inspiratory time (Ti Min)  | OK       | OK  | —   | OK   | OK  | —                      |
| I:E ratio (I:E) <sup>3</sup>   | —        | OK  | OK  | OK   | —   | —                      |
| Respiratory rate (RR)  | —        | OK  | OK  | OK   | —   | —                      |
| FiO <sub>2</sub> (FiO <sub>2</sub> ) <sup>5</sup>  | OK       | OK  | OK  | OK   | OK  | OK                     |
| Pressure slope (Slope)   | OK       | OK  | OK  | OK   | OK  | —                      |
| Pressure release (Press. Release)  | OK       | —   | —   | —    | —   | —                      |
| Ramp up time (Ramp Up Time)  | OK       | OK  | OK  | —    | —   | —                      |
| Maximum pressure (Max P)   | —        | —   | —   | OK   | OK  | —                      |
| Minimum pressure (Min P)   | —        | —   | —   | OK   | —   | —                      |
| Tidal volume (VT)  | —        | —   | —   | OK   | —   | —                      |
| Maximum tidal volume (Max VT)  | —        | —   | —   | —    | OK  | —                      |



| Parameters  | SPONT-PS | S/T | PCV | PRVC | PPV | O <sub>2</sub> Therapy |
|---|----------|-----|-----|------|-----|------------------------|
| PPV support % (PPV%)                                    | —        | —   | —   | —    | OK  | —                      |
| Maximum elastance (Max E)                               | —        | —   | —   | —    | OK  | —                      |
| Maximum resistance (Max R)                              | —        | —   | —   | —    | OK  | —                      |
| Flow rate (Flow Rate)                                   | —        | —   | —   | —    | —   | OK                     |
| Trigger type (Trig. Type)                               | OK       | OK  | OK  | OK   | OK  | —                      |
| Trigger sensitivity (advanced) (Trig. Sens. (Advanced)) | OK       | OK  | OK  | OK   | OK  | —                      |
| Trigger sensitivity (flow) (Trig. Sens. (Flow))         | OK       | OK  | OK  | OK   | OK  | —                      |
| Expiratory trigger % (ET%)                              | OK       | OK  | —   | OK   | OK  | —                      |
| Apnea time (Apnea)                                      | OK       | —   | —   | —    | OK  | —                      |
| Apnea ventilation (Apnea Ventilation) <sup>4</sup>      | OK       | —   | —   | —    | OK  | —                      |

<sup>1</sup> Parameter notation in SPONT-PS and PPV mode is EPAP/CPAP, parameter notation in other modes is EPAP.

<sup>2</sup> Above EPAP/CPAP

<sup>3</sup> Depending on the setting, either T<sub>I</sub> or I:E can be set.

<sup>4</sup> Available when Apnea Ventilation is set to On.

<sup>5</sup> Can be changed only when high pressure oxygen is selected for O<sub>2</sub> source.

### Settings

| Parameters   | Settings          | Resolution |
|--|-------------------|------------|
| Expiratory positive airway pressure/Continuous positive airway pressure (EPAP/CPAP) <sup>1</sup> | 4 to 25 hPa       | 1 hPa      |
| Inspiratory positive airway pressure (IPAP)  | 5 to 40 hPa       | 1 hPa      |
| Pressure support (PS) <sup>2</sup>   | 0 to 36 hPa       | 1 hPa      |
| Inspiratory time (T <sub>I</sub> ) <sup>3</sup>  | 0.3 to 7.5 s      | 0.05 s     |
| Maximum inspiratory time (T <sub>I</sub> Max)  | 0.3 to 7.5 s      | 0.05 s     |
| Minimum inspiratory time (T <sub>I</sub> Min)  | 0.3 to 7.5 s      | 0.05 s     |
| I:E ratio (I:E) <sup>3</sup>   | 1.0 to 20.0       | 0.1        |
| Respiratory rate (RR)  | 4 to 60/min       | 1/min      |
| FiO <sub>2</sub> (FiO <sub>2</sub> )   | 21 to 100%        | 1%         |
| Pressure slope (Slope)   | 1 to 6            | 1          |
| Pressure release (Press. Release)  | Off, 1 to 3       | 1          |
| Ramp up time (Ramp Up Time)  | Off, 5 to 45 min  | 5 min      |
| Maximum pressure (Max P)   | 6 to 40 hPa       | 1 hPa      |
| Minimum pressure (Min P)   | 5 to 39 hPa       | 1 hPa      |
| Tidal volume (VT)  | 100 to 2000 mL    | 5 mL       |
| Maximum tidal volume (Max VT)  | 100 to 2000 mL    | 5 mL       |
| PPV support % (PPV%)   | 0 to 100%         | 1%         |
| Maximum elastance (Max E)  | 0 to 100 hPa/L    | 1 hPa/L    |
| Maximum resistance (Max R)   | 0 to 50 hPa/L/s   | 1 hPa/L/s  |
| Flow rate (Flow Rate)  | 1 to 60 L/min     | 1 L/min    |
| Trigger type (Trig. Type)  | Advanced, Flow    | —          |
| Trigger sensitivity (advanced) (Trig. Sens. (Advanced))  | Auto, 1 to 7      | 1          |
| Trigger sensitivity (flow) (Trig. Sens. (Flow))  | 0.1 to 10.0 L/min | 0.1 L/min  |
| Expiratory trigger % (ET%)   | 5 to 80%          | 1%         |

<sup>1</sup> The PS upper limit setting is restricted so that PS + EPAP/CPAP does not exceed 40 hPa.

<sup>2</sup> This setting fixes “I” to 1 and sets “E”.

## Apnea Ventilation Settings

| Parameters               | Settings     | Resolution |
|--------------------------|--------------|------------|
| Apnea Ventilation        | Off, On      | —          |
| (Apnea) IPAP             | 5 to 40 hPa  | 1 hPa      |
| (Apnea) EPAP             | 4 to 25 hPa  | 1 hPa      |
| (Apnea) Ti               | 0.3 to 7.5 s | 0.05 s     |
| (Apnea) I:E <sup>1</sup> | 1.0 to 20.0  | 0.1        |
| (Apnea) RR               | 4 to 60/min  | 1/min      |
| (Apnea) Slope            | 1 to 6       | 1          |

<sup>1</sup> This setting fixes “I” to 1 and sets “E”.

## Other Settings

|                       |   |
|-----------------------|---|
| Patient interface:    | The type of patient interface to be used can be selected.                         |
| Types:                | Mask (NK), Mask (with Exhalation Port), Mask (without Exhalation Port), ETT/Trach |
| Exhalation port:      | The type of exhalation port to be used can be selected.                           |
| Types:                | NK, None, Other   |
| Oxygen supply source: | The oxygen supply source to be used can be selected.                              |
| Types:                | Low pressure oxygen (LPO), High pressure oxygen (HPO)                             |

## Moving to Standby

Standby mode can be activated by the user. In Ventilation Standby mode, ventilation stops and ventilation parameter display and ventilation related alarms are disabled. Standby mode can be cleared by the user. When cleared, ventilation restarts<sup>1</sup>, and ventilation parameter display and ventilation related alarms are enabled.

<sup>1</sup> Ventilation restarts even when spontaneous breathing by the patient is detected.

## Monitoring

## Waveform Data

Measurement parameters and display range

| Parameters            | Display Range     |
|-----------------------|-------------------|
| Pressure (Paw)        | -5 to 60 hPa      |
| Flow                  | -200 to 200 L/min |
| Volume                | -50 to 3500 mL    |
| Plethysmogram (Pleth) | —                 |
| CO <sub>2</sub>       | 0 to 150 mmHg     |

## Ventilation Measurement Area

Ventilation parameters, measurement range and measurement accuracy

| Parameters  | Measurement Range   | Measurement Accuracy                    |
|---|---------------------|---|
| Peak inspiratory pressure (PIP)                   | 0.0 to 99.9 hPa     | ± (2 + 4% of reading) hPa               |
| Positive end expiratory pressure (PEEP)           | 0.0 to 99.9 hPa     | ± (2 + 4% of reading) hPa               |
| Peak inspiratory flow (FI-PEAK)                   | 0.0 to 200.0 L/min  | ± (0.5 + 15% of reading) L/min          |
| Peak expiratory flow (FE-PEAK)                    | -200.0 to 0.0 L/min | ± (0.5 + 15% of reading) L/min          |
| Total inspiratory minute volume (MVi)             | 0.0 to 99.9 L/min   | Larger of ±15% of reading or ±0.4 L/min |
| Spontaneous inspiratory minute volume (MVi SPONT) | 0.0 to 99.9 L/min   | Larger of ±15% of reading or ±0.4 L/min |
| Total expiratory minute volume (MV)               | 0.0 to 99.9 L/min   | Larger of ±15% of reading or ±0.4 L/min |
| Spontaneous expiratory minute volume (MVSPONT)    | 0.0 to 99.9 L/min   | Larger of ±15% of reading or ±0.4 L/min |
| Inspiratory tidal volume (VTi)                    | 0 to 3500 mL        | ± (4 + 15% of reading) mL               |
| Expiratory tidal volume (VT)                      | 0 to 3500 mL        | ± (4 + 15% of reading) mL               |
| Expiratory tidal volume /kg (VT/kg)               | 0.0 to 50.0 mL/kg   | —                                       |



| Parameters  | Measurement Range | Measurement Accuracy |
|---|-------------------|----------------------|
| Total respiratory rate (RR <sub>TOT</sub> )         | 0 to 150 /min     | ±1/min               |
| Spontaneous respiratory rate (RR <sub>SPONT</sub> ) | 0 to 150 /min     | ±1/min               |
| Inspiratory duty cycle (Ti/T <sub>TOT</sub> )       | 0 to 90%          | —                    |
| I:E ratio <sup>1</sup> (I:E)                        | 0.0 to 99.9       | —                    |
| Inspiratory time (Ti)                               | 0.00 to 99.99 s   | ±30 ms               |
| Expiratory time (Te)                                | 0.00 to 99.99 s   | ±30 ms               |
| Total leakage flow (Leak <sub>TOTAL</sub> )         | 0 to 200 L/min    | —                    |
| Patient leakage flow (Leak <sub>PATIENT</sub> )     | 0 to 200 L/min    | —                    |
| Leakage volume ratio (Leak%)                        | 0 to 100%         | —                    |
| Spontaneous breathing ratio (Pt. Trig.)             | 0 to 100%         | —                    |
| O <sub>2</sub> gas usage (O <sub>2</sub> Gas Usage) | 0 to 99 L/min     | —                    |
| Flow rate (Flow Rate)                               | 0 to 99 L/min     | —                    |

<sup>1</sup> This measurement fixes “I” to 1 and measures “E”.

## O<sub>2</sub> Measurement

Measuring parameters, measurement range and measurement accuracy

| Parameters <sup>1</sup>              | Measurement Range | Measurement Accuracy      |
|--------------------------------------|-------------------|---------------------------|
| FiO <sub>2</sub> (FiO <sub>2</sub> ) | 15 to 100%        | ±(2.5 + 2.5% of reading)% |

<sup>1</sup> The galvanic oxygen sensor regulates accuracy 30 minutes after power on, and the paramagnetic oxygen sensor regulates accuracy 5 minutes after power on.

## SpO<sub>2</sub> Measurement

- Display refresh cycle: Every second or at alarm occurrence
- Wavelength range: 2 wavelengths within the range of 650 nm to 950 nm
- Irradiance: Maximum irradiance of 5.5 mW/sr or less
- Display range: 0 to 100% SpO<sub>2</sub>
- Nominal range: 70 to 100% SpO<sub>2</sub>
- Measurement accuracy<sup>1, 2</sup> (rms<sup>3</sup>): Depends on probe. Refer to the probe manual.
- ±3%SpO<sub>2</sub> (70%SpO<sub>2</sub> ≤ SpO<sub>2</sub> < 80%SpO<sub>2</sub>)
- ±2%SpO<sub>2</sub> (80%SpO<sub>2</sub> ≤ SpO<sub>2</sub> ≤ 100%SpO<sub>2</sub>)
- Accuracy guaranteed environmental temperature: 18 to 40°C (64 to 104°F)

<sup>1</sup> Essential performance in EMC standard

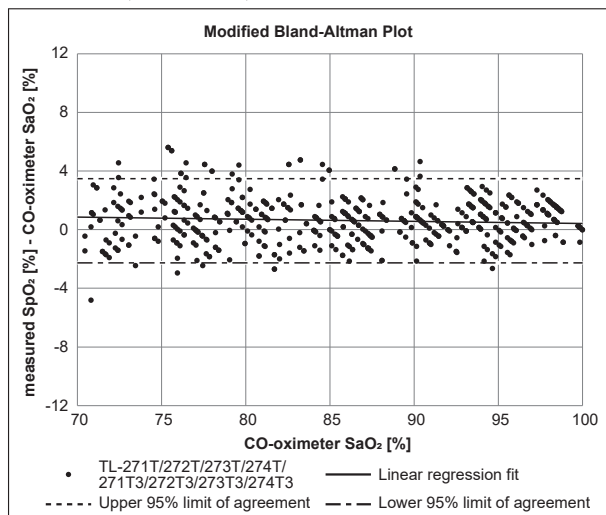
- <sup>2</sup> • The SpO<sub>2</sub> accuracy was tested using the TL-201T, TL-260T, TL-271T, TL-631T and TL-051ST SpO<sub>2</sub> probes. The testing was performed during induced hypoxia on healthy volunteers (Ethnicity: 10 Caucasians, 2 Africans, 4 Asians, 1 Haitian, 2 Hispanics, 2 Hispanics/Caucasians, 6 Indians), (Skin: 7 Very light, 14 Olive hue, 6 Dark olive), (Age: 21 to 30), (16 men and 11 women) under the condition of no motion.
- Arterial blood was sampled and measured by a CO-oximeter. The difference between SpO<sub>2</sub> measured by the SpO<sub>2</sub> probe and functional SaO<sub>2</sub> measured by a CO-oximeter was calculated using the root-mean-square (rms) according to ISO 80601-2-61: 2011 and ISO 80601-2-61: 2017. This measurement accuracy figure represents 2/3 of all test measurements.
- A pulse oximeter tester that generates simulated signals can be used to check the difference from the design specification, but it cannot be used as a replacement for human signals for testing accuracy.

<sup>3</sup> About rms:

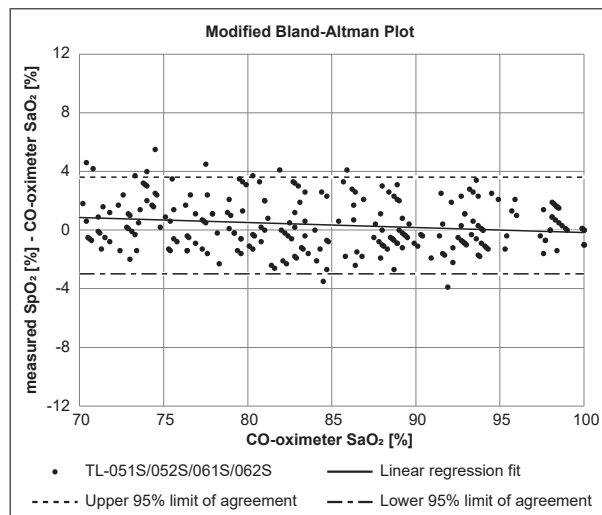
The SpO<sub>2</sub> accuracy is calculated using the root mean square of the difference between the reference value and measurement value. The SpO<sub>2</sub> accuracy figure represents 2/3 of all test measurements.

Modified Bland-Altman Plots

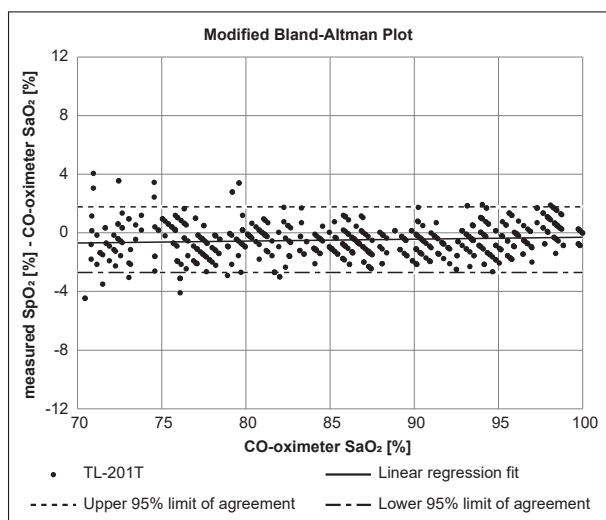
- TL-271T, TL-272T, TL-273T, TL-274T, TL-271T3, TL-272T3, TL-273T3, TL-274T3



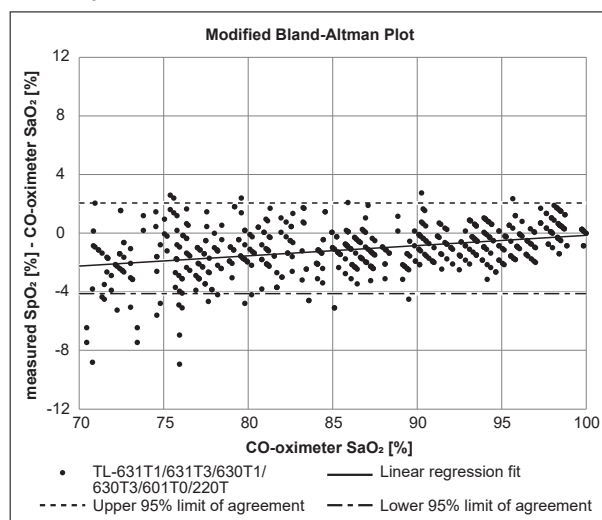
- TL-051S, TL-052S, TL-061S, TL-062S



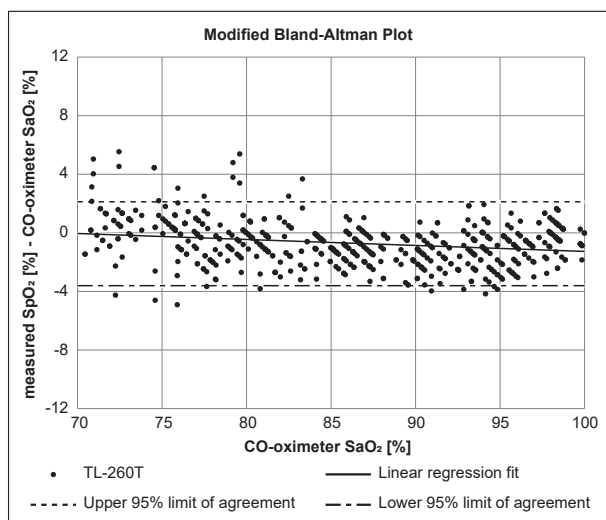
- TL-201T



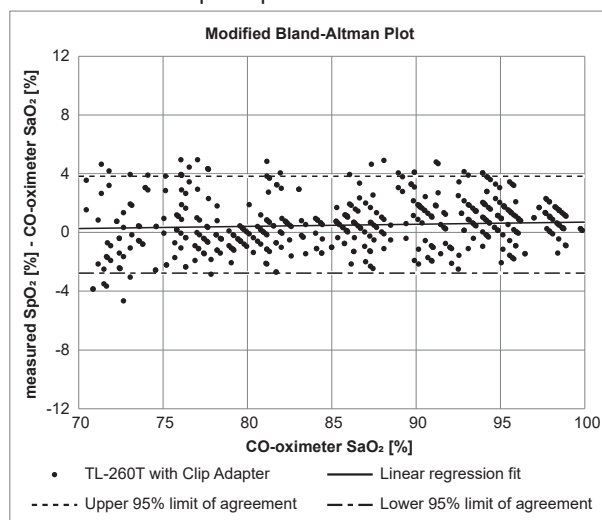
- TL-631T1, TL-631T3, TL-630T1, TL-630T3, TL-601T0, TL-220T



- TL-260T



- TL-260T with Clip Adapter





### Pulse Rate (PR)

|   |                         |
|---|-------------------------|
| Display range:                            | 30 to 300 pulses/minute |
| Nominal range:                            | 30 to 300 pulses/minute |
| Measurement accuracy (rms <sup>1</sup> ): | ±3%±1 pulses/minute     |

<sup>1</sup> About rms:

The SpO<sub>2</sub> accuracy is calculated using the root mean square of the difference between the reference value and measurement value. The SpO<sub>2</sub> accuracy figure represents 2/3 of all test measurements.

NOTE: A pulse oximeter function tester that generates pseudo test signals can be used to check for deviation from the preset design values, but it cannot be used as an alternative to accurate measurements using a human body.

### CO<sub>2</sub> Measurement

Display refresh cycle: Every second or at alarm occurrence

Measurement range:

TG-900P, TG-920P: 0 to 13.3 kPa (0 to 100 mmHg)

TG-980P: 0 to 20.0 kPa (0 to 150 mmHg)

Detectable respiration rate:

TG-900P, TG-920P: 3 to 150 bpm±10%

TG-980P: 0 to 150 bpm±1 bpm

Measurement accuracy<sup>1</sup>:

TG-900P: ±0.40 kPa (0 ≤ CO<sub>2</sub> ≤ 1.33 kPa)

(±3 mmHg (0 ≤ CO<sub>2</sub> ≤ 10 mmHg))

±0.53 kPa (1.33 ≤ CO<sub>2</sub> ≤ 5.33 kPa)

(±4 mmHg (10 < CO<sub>2</sub> ≤ 40 mmHg))

Read-value ±10% (5.33 < CO<sub>2</sub> ≤ 13.3 kPa)

(40 < CO<sub>2</sub> ≤ 100 mmHg)

When there is no atmospheric pressure, air inspiration or condensation

TG-920P: ±0.40 kPa (0 ≤ CO<sub>2</sub> ≤ 1.33 kPa)

(±3 mmHg (0 ≤ CO<sub>2</sub> ≤ 10 mmHg))

±0.53 kPa (1.33 < CO<sub>2</sub> ≤ 5.33 kPa)

(±4 mmHg (10 < CO<sub>2</sub> ≤ 40 mmHg))

Read-value ±10% (5.33 < CO<sub>2</sub> ≤ 13.3 kPa)

(40 < CO<sub>2</sub> ≤ 100 mmHg)

When there is no atmospheric pressure, air inspiration or condensation; When sensor temperature is stabilized and at least 7 minutes has elapsed

TG-980P: ±0.27 kPa (0 ≤ CO<sub>2</sub> ≤ 5.33 kPa)

(±2 mmHg (0 ≤ CO<sub>2</sub> ≤ 40 mmHg))

Read-value ±5% (5.33 < CO<sub>2</sub> ≤ 9.33 kPa)

(40 < CO<sub>2</sub> ≤ 70 mmHg)

Read-value ±7% (9.33 < CO<sub>2</sub> ≤ 13.3 kPa)

(70 < CO<sub>2</sub> ≤ 100 mmHg)

Read-value ±10% (13.3 < CO<sub>2</sub> ≤ 20.0 kPa)

(100 < CO<sub>2</sub> ≤ 150 mmHg)

When there is no condensation

<sup>1</sup> EMC essential performance

### Calibration

The ventilator has a calibration function for manually calibrating the following items.

- Flow sensor
- Pressure sensor <sup>1</sup>

- O<sub>2</sub> sensor
- Breathing circuit
- CO<sub>2</sub> sensor

<sup>1</sup> Pressure sensor calibration is done automatically at the time of breathing circuit calibration.

## Alarms

### Alarm Classification (Cause)

The ventilator alarms are classified as follows according to the cause of the alarm.

Upper/lower limit alarms: Alarm is generated when measurement reaches the specified upper or lower limit.

Technical alarms: Alarm is generated when an abnormality is detected in the ventilator or measurement environment.

### Alarm Classification (Priority)

Crisis alarms: Generated when the patient's life is in danger or when there is risk of serious injury if urgent measures are not taken.

Warning alarms: Generated when there is risk of injury to the patient or impact on the ventilator or system if prompt measures are not taken.

Advisory alarms: Generated when there is risk of minor injury, discomfort or pain to the patient if measures are not taken; or when accurate measurements are not possible.

Power supply abnormality alarms: Generated when there is a power or system failure.

### Alarms Display

Alarms are indicated by messages, measurement value highlighting, alarm indicator blinking/lighting and alarm sounds. (For details on alarm sounds, refer to “Alarm Sound (Excluding Power Supply Abnormality Alarms)” (p. 16-12) and “Power Supply Abnormality Alarms Sounds” (p. 16-12).)

| Alarm Classification (Priority) | Alarm Indicator | Numerics  | Screen Messages                            |
|---------------------------------|-----------------|---|--|
| Crisis alarm                    | Red blinking    | Highlighted in parameter color or priority color <sup>1</sup> | Red highlighting                           |
| Warning alarm                   | Yellow blinking | Highlighted in parameter color or priority color <sup>1</sup> | Yellow or orange highlighting <sup>2</sup> |
| Advisory alarm                  | Blue or yellow  | Highlighted in parameter color or priority color <sup>1</sup> | Blue or yellow highlighting <sup>2</sup>   |
| Power supply abnormality alarms | Red blinking    |   |  |

<sup>1</sup> Set by selecting [Highlight Color Type] on the [Display] page in the [System] window of the System Setup window.

<sup>2</sup> Set by selecting [Alarm Priority Color] on the [Display/Sound] page in the [Alarm] window of the System Setup window.



Refer to the following.  
Administrator's Guide:  
Section 3 “System Setup Settings”

### Temporary Audio Pause

When the [Audio Paused] key is selected, all alarms are paused for a certain period of time. The audio pause icon and the remaining pause time are displayed.

Audio paused time: 1 or 2 minutes (selectable)

### Alarm Settings

The alarms for each parameter can be set to On or Off and upper and lower limits can also be set.

Numerical settings can be set manually.

Specified alarm settings are displayed on the screen with the measurement values.

When the upper or lower limit for any alarm is set to Off, the Alarm Off icon appears beside the measurement value for that parameter.



## Alarm Settings Table

### Ventilation Measurement

| Parameters                              | Settings    |  | Step      |
|---|-------------|--|-----------|
| Peak inspiratory pressure (PIP)         | Upper limit | 6 to 50 hPa  | 1 hPa     |
|   | Lower limit | Off, 4 to 39 hPa   | 1 hPa     |
| Positive end expiratory pressure (PEEP) | Upper limit | EPAP/CPAP setting + 5 hPa (fixed)  | —         |
|   | Lower limit | EPAP/CPAP setting – 3 hPa (fixed)<br>(EPAP/CPAP setting: 5 hPa or less)<br>EPAP/CPAP setting – 4 hPa (fixed)<br>(EPAP/CPAP setting: 6 to 11 hPa)<br>EPAP/CPAP setting – 5 hPa (fixed)<br>(EPAP/CPAP setting: 12 hPa or more) | —         |
| Total expiratory minute volume (MV)     | Upper limit | 0.2 to 30.0 L/min, Off   | 0.1 L/min |
|   | Lower limit | Off, 0.1 to 29.9 L/min   | 0.1 L/min |
| Expiratory tidal volume (VT)            | Upper limit | 10 to 3,500 mL, Off  | 5 mL      |
|   | Lower limit | Off, 5 to 3495 mL  | 5 mL      |
| Respiratory rate (RR)                   | Upper limit | 2 to 150 /min, Off   | 1/min     |
|   | Lower limit | Off, 0 to 149 /min   | 1/min     |
| Apnea time (Apnea)                      | Upper limit | 5 to 60 s  | 1 s       |

### O<sub>2</sub> Measurement

| Parameters                           | Settings    |  | Step |
|--------------------------------------|-------------|--|------|
| FiO <sub>2</sub> (FiO <sub>2</sub> ) | Upper limit | At HPO: FiO <sub>2</sub> setting +7 % (fixed)  | —    |
|                                      |             | At LPO: 22 to 100%, Off                        | 1%   |
|                                      | Lower limit | At HPO: FiO <sub>2</sub> setting – 7 % (fixed) | —    |
|                                      |             | At LPO: 18 to 99%                              | 1%   |

### SpO<sub>2</sub> Measurement

| Parameters       | Settings    |                     | Step  |
|------------------|-------------|---------------------|-------|
| SpO <sub>2</sub> | Upper limit | 51 to 100%, Off     | 1%    |
|                  | Lower limit | Off, 50 to 99%      | 1%    |
| Pulse Rate (PR)  | Upper limit | 31 to 300 /min, Off | 1/min |
|                  | Lower limit | Off, 30 to 299 /min | 1/min |

### CO<sub>2</sub> Measurement

| Parameters   | Settings    |                    | Step   |
|--|-------------|--------------------|--------|
| End tidal CO <sub>2</sub> partial pressure (EtCO <sub>2</sub> )          | Upper limit | 2 to 99 mmHg, Off  | 1 mmHg |
|  | Lower limit | Off, 1 to 98 mmHg  | 1 mmHg |
| Fractional concentration of inspired carbon dioxide (FiCO <sub>2</sub> ) | Upper limit | 1 to 99 mmHg, Off  | 1 mmHg |
| Respiratory rate (CO <sub>2</sub> ) (RR (CO <sub>2</sub> ))              | Upper limit | 2 to 150 /min, Off | 1/min  |
|  | Lower limit | Off, 0 to 149 /min | 1/min  |
| Apnea time (Apnea)   | Upper limit | 5 to 40 s, Off     | 5 s    |

## Units

Height: Select from cm, feet/inch

Pressure: Select from cmH<sub>2</sub>O, hPa, mbar

Weight: kg

CO<sub>2</sub>: Select from mmHg, kPa

(Each item can be selected individually)

## Screen

### Display

|               |                               |
|---------------|-------------------------------|
| Type/size:    | 12.1 inch, TFT color LCD      |
| Resolution:   | 1024 dots (H) × 768 dots (V)  |
| Viewing area: | 245.76 mm (H) × 184.32 mm (V) |
| Pixel pitch:  | 0.240 mm (H) × 0.240 mm (V)   |

### Waveform Display

|                            |   |
|----------------------------|---|
| Display mode:              | Fixed mode  |
| Display max. trace number: | 5 traces  |
| Display parameters:        | Paw, flow, volume, plethysmogram (Pleth), CO <sub>2</sub>   |
| Waveform display time:     | Select from 10 s, 12 s, 15 s, 20 s, 30 s  |
| Waveform freeze:           | Press the Waveform Freeze key to freeze the waveform plot and display numeric values at the cursor position. The cursor can be moved by using the operation knob or touch screen.<br>(Measurement functions are available for Paw waveform, Flow waveform, Volume waveform and CO <sub>2</sub> waveform only) |
| Display color:             | Select from 12 colors   |

### Measurement Value Display

|                                   |  |
|-----------------------------------|--|
| Display parameters:               | Peak inspiratory pressure (PIP), positive end expiratory pressure (PEEP), peak inspiratory flow (FI-PEAK), peak expiratory flow (FE-PEAK), total inspiratory minute volume (MVI), spontaneous inspiratory minute volume (MVI SPONT), total expiratory minute volume (MV), spontaneous expiratory minute volume (MVSPONT), inspiratory tidal volume (VTI), expiratory tidal volume (VT), expiratory tidal volume /kg (VT/kg), total respiratory rate (RRTOT), spontaneous respiratory rate (RRSPONT), inspiratory duty cycle (Ti/TTOT), I:E ratio (I:E), inspiratory time (Ti), expiratory time (TE), total leakage flow (LeakTOTAL), patient leakage flow (LeakPATIENT), leakage volume ratio (Leak%), spontaneous breathing ratio (Pt. Trig.), O <sub>2</sub> gas usage (O <sub>2</sub> Gas Usage), flow rate (Flow Rate), FiO <sub>2</sub> , SpO <sub>2</sub> , pulse rate (PR), pulse-amplitude index (PI), EtCO <sub>2</sub> , FiCO <sub>2</sub> and CO <sub>2</sub> , respiratory rate (CO <sub>2</sub> ) (RR (CO <sub>2</sub> )) |
| Synchronization icons:            | Respiration sync mark, pulse sync mark   |
| Upper/lower limit alarm settings: | Numerics, icons  |
| Display color:                    | Select from 12 colors  |

## LED Display

### Alarm Indicator

Displayed when a patient or device related alarm occurs.

- Crisis alarm: Blinking red
- Warning alarm: Blinking yellow
- Advisory alarm: Lit blue or yellow
- Power abnormality alarm: Blinking red

The alarm indicator is also synchronized with the pulse and blinks green.

### Operation Lamp

Lit when the ventilator is operating.

### AC Power Lamp

Lit when AC power is supplied.



## Battery Charging Lamp

Displays the charging status for the main battery and backup battery.

- Charging complete: Lights
- Charging: 0.5 Hz blinking
- Abnormality: 5 Hz blinking
- Battery operation: Off

## Operation

### Touch Screen

Touch the key displayed on the screen to operate the touch screen.

### Operation Knob

Changes settings and performs various operations.

### Power Switch

The ventilator is turned on by pressing the power switch when the power is turned off.

Pressing the power switch during operation displays the Shutdown window.

Pressing the power switch also unlocks the screen when it is locked.

### Check Key

Press and hold the Check key while turning the power on to display the diagnostic window.

## Sound

### Sync Sound

Generates a sound when synchronizing with the pulse.

Sync sound pitch Fixed (high, middle, low), Variable (Pitch change according to SpO<sub>2</sub> value).

### Alarm Sound (Excluding Power Supply Abnormality Alarms)

When an alarm occurs, a sound is generated based on the type of alarm (priority).

The following alarm sounds can be selected for the ventilator alarms.

| Alarm Classification<br>(Priority) | Alarm Sound Types            |                              |                        |
|------------------------------------|------------------------------|------------------------------|------------------------|
|                                    | NK1 Sound                    | NK2 Sound                    | IEC Sound <sup>1</sup> |
| Crisis alarm                       | Continuous pip sound         | Continuous ping sound        | caf-af                 |
| Warning alarm                      | Continuous bing bong sound   | Continuous ding ding sound   | caf                    |
| Advisory alarm                     | Single beep every 20 seconds | Single beep every 20 seconds | af                     |

<sup>1</sup> Complies with the sound classifications in IEC 60601-1-8:2012 “Ventilation”

### Power Supply Abnormality Alarms Sounds

A buzzing sound is generated during a Power supply abnormality alarm.

### Operation Sounds

Generated based on touch screen, operation knob and power switch operations.

### Sound Volume Adjustment (excluding power abnormality alarm)

Sync sound: Adjustable (volume can be set to zero)

Alarm sound: Adjustable (volume cannot be set to zero)

Key click sound: Adjustable (volume can be set to zero)

### Alarm Volume (excluding power abnormality alarm)

Volume range 45 to 85 dB (A) (Only when the type of alarm sounds are set to IEC sounds)

Complies with IEC 60601-1-8:2012.

## Saving Data

### Storing Settings

The following settings are retained even after the ventilator power is turned Off.

- Patient information
- Ventilation mode, control settings
- Calibration values (circuit check, flow sensor calibration, O<sub>2</sub> sensor calibration)
- System settings (display, screen and window layout, audio volume settings, etc.)
- Alarm settings (upper and lower limits, audio paused time, sounds, priority, delay time settings, etc.)
- Default settings (upper and lower limit alarm, ventilation mode)
- Key settings
- Unit settings
- Password settings, etc.

### Saving and Reviewing Patient Data

The ventilator has the function of saving and reviewing the following data.

|                           |   |
|---------------------------|---|
| Trend graph:              | Measurement values of each parameter can be displayed on the trend graph<br>Display time 72 hours |
| Trend table:              | Measurements for each parameter can be displayed in a trend table.<br>Display time 72 hours       |
| Full disclosure waveform: | Waveforms can be displayed.<br>Display time 72 hours  |
| Event log:                | Alarm event log and operation log can be displayed.<br>Alarm log 32,768 events                    |

### Saving Long-term Data

The ventilator can save the following data for longer than 1 year.

- Numeric data (stored at 1 min. intervals)
- Event log (alarm event log, operation log, etc.) (each occurrence is saved)

## Power

The ventilator is powered by AC power supply, main battery (SB-831V lithium ion battery) and backup battery (SB-330Z battery pack).

The ventilator can be started by using either AC power or the main battery. It cannot be started with the backup battery.

### Power Supply Priority

Power is supplied to the ventilator according to the following priority order.

- 1st: AC power
- 2nd: Main battery
- 3rd: Backup battery

### Main Battery

The main battery operates when there is no AC power.

Compatible battery pack: SB-831V

Battery operation time: 2 hours<sup>1</sup>



## Backup Battery

The backup battery operates when the main battery is completely discharged and AC power is not available.

Compatible battery pack: SB-330Z

<sup>1</sup> Operating conditions are as follows.

Display brightness: Maximum

SpO<sub>2</sub>, CO<sub>2</sub> measurement: During measurement

Control settings: Refer to the table below.

| Setting Item     | Setting |
|------------------|---------|
| Ventilation Mode | S/T     |
| IPAP             | 8 hPa   |
| EPAP             | 4 hPa   |
| Ti               | 1.0 s   |
| RR               | 15/min  |
| FiO <sub>2</sub> | 21%     |
| Slope            | 1       |

Test lung conditions: Refer to the table below.

| Setting Item | Setting   |
|--------------|-----------|
| Compliance   | 50 mL/hPa |
| Resistance   | 5 hPa/L/s |

## Interface

### SD card slot 1

Insert an SD card into this slot to save monitoring data.

### SD card slot 2

Insert an SD card into this slot to save numeric data and event history, update software, and other uses.

### USB Interface

Connects to an USB device.

### External device connection socket 1

Connect the nurse call system.

### External device connection socket 2

Connect an external device

## Applicable Laws and Standards

### Applicable Standards

IEC 60601-1:2012  
 IEC 60601-1-2:2007  
 IEC 60601-1-2:2014  
 IEC 60601-1-6:2010  
 IEC 60601-1-6 Amendment 1:2013  
 IEC 62366:2007  
 IEC 62366 Amendment 1:2014  
 IEC 60601-1-8:2006  
 IEC 60601-1-8:2012<sup>1 2</sup>  
 IEC 60601-1-9:2007  
 IEC 60601-1-9 Amendment 1:2013  
 IEC 60601-2-49:2011  
 IEC 62304:2006  
 IEC 62304 Amendment 1:2015  
 ISO 80601-2-12:2011  
 ISO 80601-2-55:2011  
 ISO 80601-2-61:2011

<sup>1</sup> Excluding power supply abnormality alarms.

<sup>2</sup> Only the “IEC standard” alarm sound complies with clause 6.3.3.2.

## Classification

### Type of protection against electrical shock

Class I

Internally powered equipment

(Internally powered equipment when operating on internal power supply; Class I equipment when operating on AC power)

### Degree of protection against electrical shock

SpO<sub>2</sub> and CO<sub>2</sub> connections: Defibrillator-proof type BF applied part

Gas output: Type BF applied part

### Degree of protection provided by enclosures

IP22 (Protected against solid foreign objects of 12.5 mm ø and greater, Protected against vertically falling water drops when enclosure tilted up to 15°)

### Type according to sterilization or disinfection method specified by the manufacturer

Not applicable

### Type according to degree of safety of use in the presence of flammable anesthetic gas mixture with air, or with flammable anesthetic gas mixture with oxygen and nitrous oxide

Equipment not suitable for use in the presence of FLAMMABLE ANESTHETIC MIXTURE WITH AIR, OR WITH OXYGEN OR NITROUS OXIDE

### Mode of operation

Continuous operation

### ME equipment type

Indoor mobile type



## Environment

### Storage Environment

|                       |                             |
|-----------------------|-----------------------------|
| Ambient temperature:  | -20 to +65°C (-4 to +149°F) |
| Relative humidity:    | 10 to 95%                   |
| Atmospheric pressure: | 700 to 1060 hPa             |

### Transport Environment

|                       |                             |
|-----------------------|-----------------------------|
| Ambient temperature:  | -20 to +65°C (-4 to +149°F) |
| Relative humidity:    | 10 to 95%                   |
| Atmospheric pressure: | 700 to 1060 hPa             |

## Operating Environment and Power

### Operating Environment Conditions

|                       |                           |
|-----------------------|---------------------------|
| Ambient temperature:  | 5 to 40°C (41 to 104°F)   |
| Relative humidity:    | 15 to 95% (noncondensing) |
| Atmospheric pressure: | 700 to 1060 hPa           |

### Power

AC and DC compatible

Power voltage:

|                      |   |
|----------------------|---|
| AC:                  | Rated: 100 to 240 V<br>Operating range: 90 to 264 V |
| DC (Main battery):   | Rated: 14.4 V<br>Operating range: 12.0 to 16.0 V    |
| DC (Backup battery): | Rated: 12.0 V<br>Operating range: 11.0 to 16.0 V    |

Power input: 220 VA

Power frequency: 50 Hz/60 Hz ± 3 Hz

Power supply safety standard: IEC 60601-1:2012

### Pneumatic

High-pressure oxygen supply:

|                           |                               |
|---------------------------|-------------------------------|
| Pressure:                 | 280 to 600 kPa (41 to 87 psi) |
| Maximum flow (3 s avg.):  | 200 L/min                     |
| Maximum flow (10 s avg.): | 80 L/min                      |

Low pressure oxygen supply:

|                |                 |
|----------------|-----------------|
| Peak pressure: | 80 kPa (11 psi) |
| Maximum flow:  | 12 L/min        |

### Noise<sup>1</sup>

Sound level: 50 dB (A)

Sound output level: 63 dB (A)

<sup>1</sup> Measurement conditions comply with ISO 80601-2-12:2011

## EMC Standards

IEC 60601-1-2:2007

IEC 60601-1-2:2014

## Dimensions and Weight

### Dimensions

W 330 mm  $\pm$ 15 mm  $\times$  H 340 mm  $\pm$ 15 mm  $\times$  D 175 mm  $\pm$ 15 mm (excluding protrusions)

### Weight

7.6 kg  $\pm$ 10% (including the 2 batteries, but not including other accessories)

### Weight (when mounted on cart)

60.3 kg<sup>1</sup>

<sup>1</sup> Specification when the following units are in the configuration: KC-331Z cart, ventilator (including 2 batteries), breathing circuit set, KH-330Z support arm, dual E cylinder mount, 2 oxygen cylinders, humidifier, water bag pole, physiological saline, and cables and hoses

## Requirements from International Standards

### IEC 60601-1:2005+Amendment 1:2012

#### Operator Position during Normal Use

Position where the operator can directly touch the screen (typical reading distance is 80 cm)

#### Recovery Time after Defibrillation

10 s

### ISO 80601-2-12:2011

Particular requirements for basic safety and essential performance of critical care ventilators

#### Essential Performance<sup>1</sup>

Delivery of ventilation at the PATIENT-CONNECTION PORT within the ALARM LIMITS set by the OPERATOR or generation of an ALARM CONDITION.

- Oxygen level ALARM CONDITIONS
- AIRWAY PRESSURE
- Expired volume
- Electrical supply failure
- INTERNAL ELECTRICAL Power SOURCE nears depletion
- Gas supply failure
- Gas failure cross flow

<sup>1</sup> ISO 80601-2-12:2011 201.4.3.101

#### Ventilation Control Performance<sup>1</sup>

|   |                                |
|---|--------------------------------|
| VT control accuracy:  | $\pm$ (15% of setting) mL      |
| EPAP/CPAP control accuracy:                                     | $\pm$ (2 + 4% of setting) hPa  |
| IPAP control accuracy:  | $\pm$ (2 + 4% of setting) hPa  |
| FiO <sub>2</sub> control accuracy:                              | $\pm$ (2.5 + 2.5% of setting)% |
| FLOW RATE control precision (O <sub>2</sub> Therapy mode only): | $\pm$ (15% of setting) L/min   |

<sup>1</sup> According to the conditions specified in ISO 80601-2-12:2011 Table 201.103 and Table 201.104.



### Response of the VENTILATOR to an increase in O<sub>2</sub> concentration<sup>1</sup>

Within 30 seconds (Air supply volume 500 mL)

Within 50 seconds (Air supply volume 150 mL)

<sup>1</sup> According to the conditions specified in ISO 80601-2-12:2011 Table 201.105.

Time until oxygen concentration rises from 21% to the configured concentration of 90%

Based on an air supply volume of 150 mL or 500 mL

### Maximum Limit Pressure

60 hPa

### Maximum Operating Pressure

4 to 40 hPa (For details, refer to “Ventilation Mode Description” (p. 16-40))

### Breathing Circuit Characteristics

Resistance: < 5 hPa at 30 L/min

Compliance: < 1 mL/hPa

### Measurement Uncertainty<sup>1</sup>

Pressure: ±1% of full scale

Flow: ±2% of reading

Volume: ±2% of reading or 20 mL (whichever is larger)

Oxygen concentration: ±0.5%

<sup>1</sup> The ventilator's performance has been verified by an ASL5000 manufactured by IngMar Medical and an O2L manufactured by Oxigraf. Therefore, the information on accuracy described in this manual includes the measurement errors of these 2 measuring devices.

## ISO 80601-2-55:2011

Particular requirements for the basic safety and essential performance of respiratory gas monitors

### Automatic Air Pressure Calibration

The ventilator has a function for automatically calibrating the effect of air pressure on CO<sub>2</sub> and O<sub>2</sub> measurements.

### Measurement Accuracy Safety

Measurement accuracy for CO<sub>2</sub> and O<sub>2</sub> measurements is satisfied 6 hours after turning on the power.

### Mixed Gas Measurement Accuracy<sup>1</sup>

Mixed gas measurement accuracy conforms to the accuracy requirements for CO<sub>2</sub> and O<sub>2</sub> measurements.

<sup>1</sup> The ventilator is not intended for use in operating rooms. Therefore, it was not designed for mixed gases such as volatile anesthetic gas and N<sub>2</sub>O gas.

### Sampling Rate

CO<sub>2</sub> measurement: Based on TG-900P, TG-920P and TG-980P specifications.

O<sub>2</sub> measurement: 1 s

### Total System Response Time

CO<sub>2</sub> measurement: Within 3 s

O<sub>2</sub> measurement: Within 40 s

## ISO 80601-2-61:2011

Particular requirements for basic safety and essential performance of pulse oximeter equipment

### Calibration of Standard Compliant Products

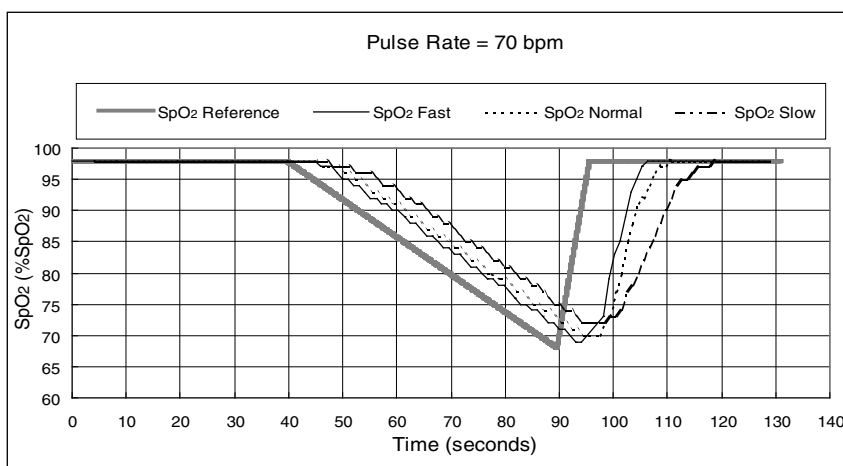
TL-201T and JL-500P2



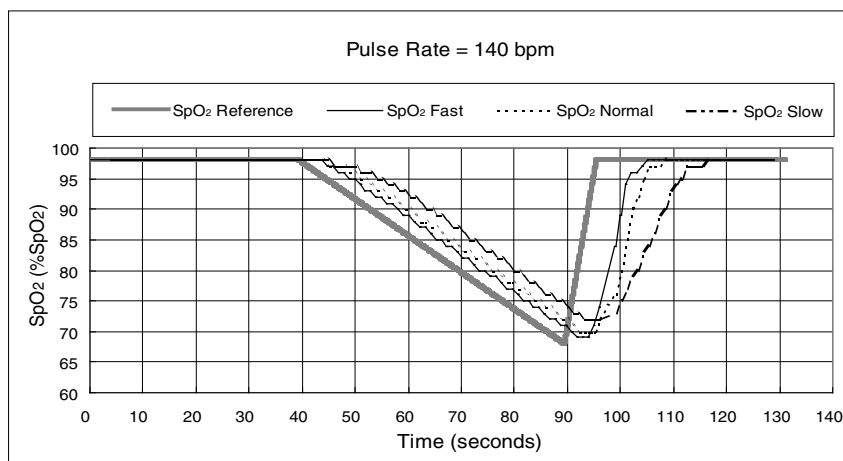
### Response time:

- Response selection: Fast, Norm, Slow
- Response time: Examples of response times corresponding to changes in the SpO<sub>2</sub> value and pulse rate (PR) are shown below.

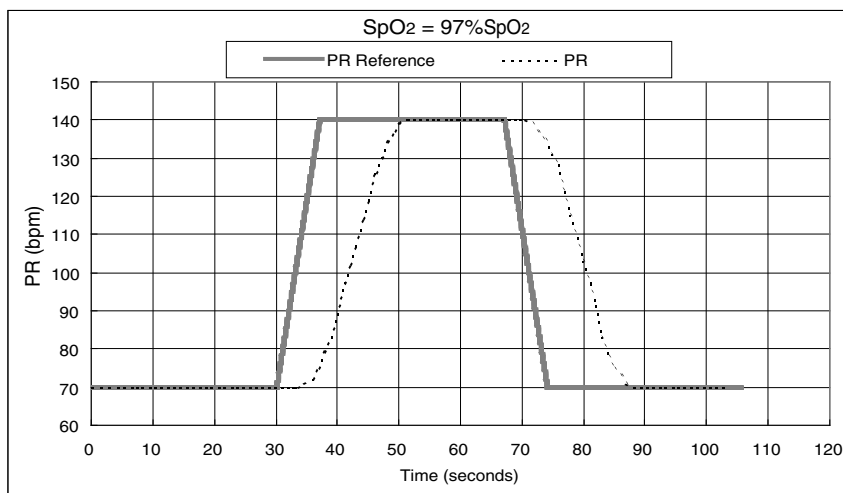
Example 1: PR = 70 bpm, and SpO<sub>2</sub> value is changed at 0.6%SpO<sub>2</sub> per second



Example 2: PR = 140 bpm, and SpO<sub>2</sub> value is changed at 0.6%SpO<sub>2</sub> per second



Example 3: SpO<sub>2</sub> value = 97%SpO<sub>2</sub>, and PR is changed at 10 beats per second





## IEC 60601-1-8:2012

General requirements, test methods and guidelines for the alarm systems of electrical medical equipment and electrical medical systems

### Alarm Delay Time

Includes time to output alarms from the LAN socket on the ventilator when connected to the network.

Upper and lower limit alarms:

Approximately 5 seconds after the measured value reaches the alarm setting range<sup>1</sup>

0 to 30 seconds

Technical alarms:

Approximately 1 second after detecting alarm status

Nurse call output delay time:

Approximately 1 second after alarm occurrence<sup>2</sup>

0 to 60 seconds

<sup>1</sup> When the alarm delay time setting is 0 s. When the alarm delay time is set, an alarm is generated if the set delay time elapses.

<sup>2</sup> When nurse call output delay setting is 0 s. When the nurse call output delay time is set, the nurse call is output after the set delay time.

## IEC 60601-1-9:2007+Amendment 1:2013

### Consumption during NORMAL USE

|                             |  |
|-----------------------------|--|
| Energy:                     | Not applicable   |
| Consumable materials/parts: | Ventilation unit, SB-831V main battery, SB-330V backup battery, YS-119P7 air intake HEPA filter, YS-119P6 internal filter, YS-119P8 air intake dust filter, YS-119P9 fan filter, YS-119P4 Galvanic oxygen sensor |
| Disposables:                | Disposable breathing circuits, etc.  |
| Water:                      | Not applicable   |
| Gasses:                     | Not applicable   |
| Chemicals/reagents:         | Not applicable   |

### Emissions during NORMAL USE

|                                       |                |
|---------------------------------------|----------------|
| WASTE water:                          | Not applicable |
| WASTE consumable materials:           | Not applicable |
| Acoustic energy:                      | Not applicable |
| Heat:                                 | Not applicable |
| Gasses:                               | Not applicable |
| Vapours:                              | Not applicable |
| Particulates:                         | Not applicable |
| HAZARDOUS SUBSTANCES and other WASTE: | Not applicable |

### HAZARDOUS SUBSTANCES, radioactive sources and induced radioactive materials

Not applicable



# Electromagnetic Emissions and Immunity

## IEC 60601-1-2:2007

### Guidance and Manufacturer's Declaration – Electromagnetic Emissions

| Guidance and manufacturer's declaration – electromagnetic emissions  |            |  |
|--|------------|--|
| This NKV-330 is intended for use in the electromagnetic environment specified below. The customer or the user of the NKV-330 should assure that it is used in such an environment. |            |  |
| Emission test  | Compliance | Electromagnetic environment - guidance   |
| RF emissions<br>CISPR 11   | Group 1    | The NKV-330 use RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.  |
| RF emissions<br>CISPR 11   | Class B    | The NKV-330 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions<br>IEC 61000-3-2  | Class A    |  |
| Voltage fluctuations/<br>flicker emissions<br>IEC 61000-3-3  | Complies   |  |


### Guidance and Manufacturer's Declaration – Electromagnetic Immunity

| Guidance and manufacturer's declaration – electromagnetic immunity   |  |  |   |
|--|--|--|---|
| This NKV-330 is intended for use in the electromagnetic environment specified below. The customer or the user of the NKV-330 should assure that it is used in such an environment. |  |  |   |
| IMMUNITY test  | IEC 60601 TEST LEVEL   | Compliance level   | Electromagnetic environment - guidance  |
| Electrostatic discharge (ESD)<br>IEC 61000-4-2   | ±6 kV contact<br>±8 kV air   | ±6 kV contact<br>±8 kV air   | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.   |
| Electrical fast transient/ burst<br>IEC 61000-4-4  | ±2 kV for power supply lines<br>±1 kV for input/output lines   | ±2 kV for power supply lines<br>±1 kV for input/output lines   | Mains power quality should be that of a typical commercial or hospital environment.   |
| Surge<br>IEC 61000-4-5   | ±1 kV differential mode<br>±2 kV common mode   | ±1 kV differential mode<br>±2 kV common mode   | Mains power quality should be that of a typical commercial or hospital environment.   |
| Voltage dips, short interruptions and voltage variations on power supply input lines<br>IEC 61000-4-11   | <5% $U_T$ (>95% dip in $U_T$ ) for 0.5 cycles<br>40% $U_T$ (60% dip in $U_T$ ) for 5 cycles<br>70% $U_T$ (30% dip in $U_T$ ) for 25 cycles<br><5% $U_T$ (>95% dip in $U_T$ ) for 5 s | <5% $U_T$ (>95% dip in $U_T$ ) for 0.5 cycles<br>40% $U_T$ (60% dip in $U_T$ ) for 5 cycles<br>70% $U_T$ (30% dip in $U_T$ ) for 25 cycles<br><5% $U_T$ (>95% dip in $U_T$ ) for 5 s | Mains power quality should be that of a typical commercial or hospital environment.<br><br>If the user of the NKV-330 requires continued operation during power mains interruptions, it is recommended that the NKV-330 be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60Hz) magnetic field<br>IEC 61000-4-8  | 3 A/m  | 3 A/m  | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.   |
| NOTE $U_T$ is the a.c. mains voltage prior to application of the test level.   |  |  |   |



**Guidance and manufacturer's declaration – electromagnetic immunity**

The NKV-330 is intended for use in the electromagnetic environment specified below. The customer or the user of the NKV-330 should assure that it is used in such an environment.

| IMMUNITY test              | IEC 60601 TEST LEVEL   | Compliance level              | Electromagnetic environment - guidance  |
|----------------------------|--|-------------------------------|---|
| Conducted RF IEC 61000-4-6 | 3 Vrms<br>150 kHz to 80 MHz<br>outside ISM bands <sup>a</sup><br><br>10 Vrms<br>150 kHz to 80 MHz<br>inside ISM bands <sup>a</sup> | 3 Vrms<br><br><br><br>10 Vrms | Portable and mobile RF communications equipment should be used no closer to any part of the NKV-330, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br><br>Recommended separation distance<br>$d = 1.2\sqrt{P}$<br><br>$d = 1.2\sqrt{P}$<br><br>where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and $d$ is the recommended separation distance in meters (m). <sup>b</sup><br><br>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey <sup>c</sup> , should be less than the compliance level in each frequency range. <sup>d</sup><br><br>Interference may occur in the vicinity of equipment marked with the following symbol:<br><br> |

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

<sup>a</sup> The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

<sup>b</sup> The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.


<sup>c</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the NKV-330 is used exceeds the applicable RF compliance level above, the NKV-330 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the NKV-330.

<sup>d</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.



### Guidance and manufacturer's declaration – electromagnetic immunity

This NKV-330 is intended for use in the electromagnetic environment specified below. The customer or the user of the NKV-330 should assure that it is used in such an environment.

| IMMUNITY test                | IEC 60601 TEST LEVEL        | Compliance level | Electromagnetic environment - guidance   |
|------------------------------|-----------------------------|------------------|--|
| Radiated RF<br>IEC 61000-4-3 | 10 V/m<br>80 MHz to 2.5 GHz | 10 V/m           | <p>Portable and mobile RF communications equipment should be used no closer to any part of the NKV-330, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1.2\sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2.3\sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <math>d</math> is the recommended separation distance in metres (m).<sup>b</sup></p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey <sup>c</sup> should be less than the compliance level in each frequency range<sup>d</sup>.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p>  |

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

<sup>a</sup> The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

<sup>b</sup> The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

<sup>c</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the NKV-330 is used exceeds the applicable RF compliance level above, the NKV-330 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the NKV-330.

<sup>d</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.



## Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the NKV-330

| Recommended separation distances between portable and mobile RF communications equipment and the NKV-330  |   |  |  |   |
|---|---|--|--|---|
| The NKV-330 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the NKV-330 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the NKV-330 as recommended below, according to the maximum output power of the communications equipment. |   |  |  |   |
| Rated maximum output power of transmitter<br>W  | Separation distance according to frequency of transmitter m |  |  |   |
|   | 150 kHz to 80 MHz other than ISM bands<br>$d = 1.2\sqrt{P}$ | 150 kHz to 80 MHz ISM bands<br>$d = 1.2\sqrt{P}$ | 80 MHz to 800 MHz<br>$d = 1.2\sqrt{P}$ | 800 MHz to 2.5 GHz<br>$d = 2.3\sqrt{P}$ |
| 0.01  | 0.12  | 0.12   | 0.12                                   | 0.23                                    |
| 0.1   | 0.38  | 0.38   | 0.38                                   | 0.73                                    |
| 1   | 1.2   | 1.2  | 1.2                                    | 2.3                                     |
| 10  | 3.8   | 3.8  | 3.8                                    | 7.3                                     |
| 100   | 12  | 12   | 12                                     | 23                                      |
| For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.   |   |  |  |   |
| NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.   |   |  |  |   |
| NOTE 2 The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.  |   |  |  |   |
| NOTE 3 An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.   |   |  |  |   |
| NOTE 4 These guidelines might not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.  |   |  |  |   |



## IEC 60601-1-2:2014

### Guidance and Manufacturer's Declaration – Electromagnetic Emissions

| Guidance and manufacturer's declaration – electromagnetic emissions  |            |  |
|--|------------|--|
| This NKV-330 is intended for use in the electromagnetic environment specified below. The customer or the user of the NKV-330 should assure that it is used in such an environment. |            |  |
| Emission test  | Compliance | Electromagnetic environment - guidance   |
| RF emissions<br>CISPR 11   | Group 1    | The NKV-330 use RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.  |
| RF emissions<br>CISPR 11   | Class B    | The NKV-330 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic emissions<br>IEC 61000-3-2  | Class A    |  |
| Voltage fluctuations/<br>flicker emissions<br>IEC 61000-3-3  | Complies   |  |


### Guidance and Manufacturer's Declaration – Electromagnetic Immunity

| Guidance and manufacturer's declaration – electromagnetic immunity   |  |  |  |
|--|--|--|--|
| This NKV-330 is intended for use in the electromagnetic environment specified below. The customer or the user of the NKV-330 should assure that it is used in such an environment. |  |  |  |
| IMMUNITY test  | IEC 60601 TEST LEVEL   | Compliance level   | Electromagnetic environment - guidance   |
| Electrostatic discharge (ESD)<br>IEC 61000-4-2   | ±8 kV contact<br>±2 kV, ±4 kV, ±8 kV,<br>±15 kV air  | ±8 kV contact<br>±2 kV, ±4 kV, ±8 kV,<br>±15 kV air  | Floors should be wood, concrete or ceramic tiles. If floors are covered with synthetic material, the relative humidity should be at least 30%.   |
| Electrical fast transient/<br>burst<br>IEC 61000-4-4   | ±2 kV for power supply lines<br>±1 kV for input/output lines   | ±2 kV for power supply lines<br>±1 kV for input/output lines   | Mains power quality should be that of a typical commercial or hospital environment.  |
| Surge<br>IEC 61000-4-5   | ±1 kV differential mode<br>±2 kV common mode   | ±1 kV differential mode<br>±2 kV common mode   | Mains power quality should be that of a typical commercial or hospital environment.  |
| Voltage dips, short interruptions and voltage variations on power supply input lines<br>IEC 61000-4-11   | 0% $U_T$ ; 0.5 cycles<br>At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<br>0% $U_T$ ; 1 cycle<br>and<br>70% $U_T$ ; 25/30 cycles<br>Single phase: at 0°<br>0% $U_T$ ; 250/300 cycles | 0% $U_T$ ; 0.5 cycles<br>At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°<br>0% $U_T$ ; 1 cycle<br>and<br>70% $U_T$ ; 25/30 cycles<br>Single phase: at 0°<br>0% $U_T$ ; 250/300 cycles | Mains power quality should be that of a typical commercial or hospital environment. If the user of the NKV-330 requires continued operation during power mains interruptions, it is recommended that the NKV-330 be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60Hz) magnetic field<br>IEC 61000-4-8  | 30 A/m   | 30 A/m   | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.  |
| NOTE $U_T$ is the a.c. mains voltage prior to application of the test level.   |  |  |  |



**Guidance and manufacturer's declaration – electromagnetic immunity**

This NKV-330 is intended for use in the electromagnetic environment specified below. The customer or the user of the NKV-330 should assure that it is used in such an environment.

| IMMUNITY test  | IEC 60601 TEST LEVEL  | Compliance level                         | Electromagnetic environment - guidance  |
|--|---|--|---|
| <p>Conducted RF<br/>IEC 61000-4-6</p> <p>Radiated RF<br/>IEC 61000-4-3</p> | <p>3 Vrms<br/>150 kHz to 80 MHz</p> <p>ISM bands<sup>a</sup></p> <p>3 V/m<br/>80 MHz to 2.7 GHz</p> | <p>3 Vrms</p> <p>6 Vrms</p> <p>3 V/m</p> | <p>Portable and mobile RF communications equipment should be used no closer to any part of the NKV-330, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> <p><math>d = 1.2\sqrt{P}</math></p> <p><math>d = 0.6\sqrt{P}</math></p> <p><math>d = 1.2\sqrt{P}</math> 80 MHz to 800 MHz</p> <p><math>d = 2.3\sqrt{P}</math> 800 MHz to 2.7 GHz</p> <p>where <math>P</math> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <math>d</math> is the recommended separation distance in metres (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey<sup>b</sup>, should be less than the compliance level in each frequency range<sup>c</sup>.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> <p style="text-align: center;"></p> |

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

<sup>a</sup> The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

<sup>b</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the NKV-330 is used exceeds the applicable RF compliance level above, the NKV-330 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the NKV-330.

<sup>c</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

## Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the NKV-330

| Recommended separation distances between portable and mobile RF communications equipment and the NKV-330  |  |  |   |
|---|--|--|---|
| The NKV-330 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the NKV-330 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the NKV-330 as recommended below, according to the maximum output power of the communications equipment. |  |  |   |
| Rated maximum output power of transmitter<br>W  | Separation distance according to frequency of transmitter<br>m |  |   |
|   | 150 kHz to 80 MHz<br>$d = 1.2\sqrt{P}$                         | 80 MHz to 800 MHz<br>$d = 1.2\sqrt{P}$ | 800 MHz to 2.7 GHz<br>$d = 2.3\sqrt{P}$ |
| 0.01  | 0.12   | 0.12                                   | 0.23                                    |
| 0.1   | 0.38   | 0.38                                   | 0.73                                    |
| 1   | 1.2  | 1.2                                    | 2.3                                     |
| 10  | 3.8  | 3.8                                    | 7.3                                     |
| 100   | 12   | 12                                     | 23                                      |
| For transmitters rated at a maximum output power not listed above, the recommended separation distance $d$ in metres (m) can be determined using the equation applicable to the frequency of the transmitter, where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.   |  |  |   |
| NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.   |  |  |   |
| NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.  |  |  |   |



## Test Specifications for ENCLOSURE PORT IMMUNITY to RF Wireless Communications Equipment

| Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment   |                 |   |  |                   |              |                           |
|---|-----------------|---|--|-------------------|--------------|---------------------------|
| Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the NKV-330, including cables specified by the manufacturer. If the distance is closer than 30 cm (12 inches), the performance of the NKV-330 may decrease. |                 |   |  |                   |              |                           |
| Test frequency (MHz)  | Band (MHz)      | Service   | Modulation                               | Maximum power (W) | Distance (m) | IMMUNITY TEST LEVEL (V/m) |
| 385   | 380 - 390       | TETRA 400   | Pulse modulation<br>18 Hz                | 1.8               | 0.3          | 27                        |
| 450   | 430 - 470       | GMRS 460,<br>FRS 460  | FM<br>± 5 kHz<br>deviation<br>1 kHz sine | 2                 | 0.3          | 28                        |
| 710   | 704 - 787       | LTE Band 13, 17   | Pulse modulation<br>217 Hz               | 0.2               | 0.3          | 9                         |
| 745   |                 |   |  |                   |              |                           |
| 780   |                 |   |  |                   |              |                           |
| 810   | 800 - 960       | GSM 800/900,<br>TETRA 800,<br>iDEN 820,<br>CDMA 850,<br>LTE Band 5          | Pulse modulation<br>18 Hz                | 2                 | 0.3          | 28                        |
| 870   |                 |   |  |                   |              |                           |
| 930   |                 |   |  |                   |              |                           |
| 1435.4  | 1427.9 - 1510.9 | LTE Band 11<br>21, UMTS   | Pulse modulation<br>217 Hz               | 2                 | 0.3          | 28                        |
| 1452.9  |                 |   |  |                   |              |                           |
| 1720  | 1700 - 1990     | GSM 1800;<br>CDMA 1900;<br>GSM 1900;<br>DECT; LTE Band 1,<br>3, 4, 25; UMTS | Pulse modulation<br>217 Hz               | 2                 | 0.3          | 28                        |
| 1845  |                 |   |  |                   |              |                           |
| 1970  |                 |   |  |                   |              |                           |
| 2450  | 2400 - 2570     | Bluetooth, WLAN,<br>802.11 b/g/n, RFID<br>2450,<br>LTE Band 7               | Pulse modulation<br>217 Hz               | 2                 | 0.3          | 28                        |
| 5240  | 5100 - 5800     | WLAN 802.11 a/n   | Pulse modulation<br>217 Hz               | 0.2               | 0.3          | 9                         |
| 5500  |                 |   |  |                   |              |                           |
| 5785  |                 |   |  |                   |              |                           |



## EMC

IEC 60601-1-2:2007

IEC 60601-1-2:2014

## Environments of Intended Use

Professional healthcare facility environment (physician offices, clinics, limited care facilities, freestanding surgical centers, multiple treatment facilities, hospitals (patient room))

## Essential Performance

The ventilator provides ventilation or ventilatory support through positive-pressure to adult or pediatric patients (patients with a VT of 100 mL or more) who require mechanical ventilation to aid spontaneous breathing.

## Use of the Ventilator Adjacent to or Stacked with Other Equipment

Use of this ventilator adjacent to or stacked with other equipment could result in improper operation. If adjacent or stacked use is necessary, observe the ventilator and the other equipment to verify that they are operating normally.

## System Configuration for EMC Test

The ventilator has been tested to comply with the following EMC standards with the following configuration.

- IEC 60601-1-2:2007
- IEC 60601-1-2:2014

If any device or cable other than those specified by Nihon Kohden is used, the ventilator might not comply with the specified EMC standards.

### IEC 60601-1-2:2007

| Tested Configuration                         | Cable Length |
|--|--------------|
| NKV-330 ventilator                           | —            |
| TG-980P CO <sub>2</sub> sensor kit           | 2.9 m        |
| JL-500P2 SpO <sub>2</sub> adapter            | 2.5 m        |
| TL-201T2 finger probe                        | 1.6 m        |
| 095611B AC power cord VM1276                 | 1.8 m        |
| 547748A AC power cord VM0306B/0304B          | 2.0 m        |
| 9000-050909 grounding lead (DIN)             | 4.0 m        |
| SB-831V lithium ion battery                  | —            |
| SB-330Z battery pack                         | —            |
| 9000-065837 paramagnetic oxygen sensor       | —            |
| 9000-066116 single limb breathing set WT-EXH | 2.4 m        |
| 9000-065835 single-use flow sensor           | 1.8 m        |
| 9000-065345 air intake HEPA filter           | —            |

| Tested Configuration                                       | Cable Length |
|--|--------------|
| 9000-065347 air intake dust filter                         | —            |
| 9000-065344 internal filter                                | —            |
| 9000-066101 fan filter                                     | —            |
| YJ-330Z nurse call connection cable                        | 0.4 m        |
| RS232C-9PM-9SM-ST1-E-2.5 RS232C cable                      | 2.5 m        |
| LD-CTS10/RS LAN cable                                      | 10.0 m       |
| KC-331Z cart L   | —            |
| 9000-066105 dual E-cylinder mount                          | —            |
| KH-330Z support arm  | —            |
| DH-330Z mount plate  | —            |
| DH-331Z rail hook  | —            |
| V460A pressure resistant oxygen hose (Kawasaki Technology) | 5.0 m        |



## IEC 60601-1-2:2014

| Tested Configuration                     | Cable Length |
|--|--------------|
| NKV-330 ventilator                       | —            |
| TG-980P CO <sub>2</sub> sensor kit       | 2.9 m        |
| JL-500P2 SpO <sub>2</sub> adapter        | 2.5 m        |
| TL-201T2 finger probe                    | 1.6 m        |
| 095611B AC power cord VM1276             | 1.8 m        |
| 547748A AC power cord VM0306B/0304B      | 2.0 m        |
| 9000-050909 grounding lead (DIN)         | 4.0 m        |
| SB-831V lithium ion battery              | —            |
| SB-330Z battery pack                     | —            |
| YS-119P5 paramagnetic oxygen sensor      | —            |
| VB-311Z single limb breathing set WT-WXH | 2.4 m        |
| TF-300Z flow sensor                      | 1.8 m        |
| YS-119P6 air intake HEPA filter          | —            |
| YS-119P7 air intake dust filter          | —            |
| YS-119P8 internal filter                 | —            |

| Tested Configuration                                       | Cable Length |
|--|--------------|
| YS-119P9 fan filter  | —            |
| YJ-330Z nurse call connection cable                        | 0.4 m        |
| RS232C-9PM-9SM-ST1-E-2.5 RS232C cable                      | 2.5 m        |
| LD-CTS10/RS LAN cable                                      | 10.0 m       |
| KC-331Z cart L   | —            |
| YS-120P0 dual E-cylinder mount                             | —            |
| KH-330Z support arm  | —            |
| DH-330Z mount plate  | —            |
| DH-331Z rail hook  | —            |
| V460A pressure resistant oxygen hose (Kawasaki Technology) | 5.0 m        |
| ZS-600P transmitter  | —            |
| YJ-331Z transmitter connection cable                       | 0.15 m       |
| DH-333Z holder   | —            |
| PVM-4000 series bedside monitor                            | —            |
| YJ-334Z connection cable 10.0 m                            | 10.0 m       |



## Standard Accessories and Options

Use only Nihon Kohden specified parts and accessories to ensure optimal safety and performance of the ventilator, breathing circuit, patient interface, CO<sub>2</sub> sensor and SpO<sub>2</sub> probe.

### **WARNING**

Only use parts and consumables specified by Nihon Kohden for the ventilator. Refer to the operator's manual of the parts and consumables to handle and use them. Otherwise, the performance and safety of the ventilator cannot be guaranteed.

The standard accessories and options listed below may include discontinued products that are no longer available for purchase. Contact your Nihon Kohden representative for details.

For products where no catalogue number is listed, order them using the model or code no. To order products where no catalogue number, model or code no. is listed, contact your Nihon Kohden representative.

## Ventilator

|   | Name                       | Qty | Model/<br>Code No. | Catalogue<br>Number |
|---|----------------------------|-----|--------------------|---------------------|
| * | AC power cord              | 1   | 547748A            | —                   |
| * | Test breathing circuit     | 1   | 9000-066100        | —                   |
| * | Lithium ion battery        | 1   | SB-831V            | —                   |
| * | Battery pack               | 1   | SB-330Z            | —                   |
| * | Galvanic oxygen sensor     | 1   | YS-119P4           | —                   |
| * | Paramagnetic oxygen sensor | 1   | YS-119P5           | —                   |
| * | Air intake HEPA filter     | 1   | YS-119P7           | —                   |
| * | Air intake dust filter     | 1   | YS-119P8           | —                   |
| * | Internal filter            | 1   | YS-119P6           | —                   |
| * | Fan filter                 | 1   | YS-119P9           | —                   |
| * | Cable binder               | 4   | 6113-020829        | —                   |
|   | Software kit               | 1   | QS-330Z            | —                   |
|   | Grounding lead (DIN)       | 1   | 9000-050909        | —                   |
|   | Battery charger            | 1   | SB-801V            | —                   |
|   | Test lung 1L               | 1   | YS-120P2           | —                   |
|   | Test lung 0.5L             | 1   | YS-120P3           | —                   |
|   | Connection cable 2.5 m     | 1   | YJ-332Z            | —                   |
|   | Connection cable 5.0 m     | 1   | YJ-333Z            | —                   |
|   | Connection cable 10.0 m    | 1   | YJ-334Z            | —                   |

Items marked with “\*” are standard accessories.



## Related Equipment

| Name                       | Qty | Model/<br>Code No. | Catalogue<br>Number |
|----------------------------|-----|--------------------|---------------------|
| Cart M                     | 1   | KC-330Z            | —                   |
| Cart L                     | 1   | KC-331Z            | —                   |
| Dual E-cylinder mount      | 1   | YS-120P0           | —                   |
| Dual D-cylinder mount      | 1   | YS-120P1           | —                   |
| Mount plate                | 1   | DH-330Z            | —                   |
| Rail hook                  | 1   | DH-331Z            | —                   |
| Support arm                | 1   | KH-330Z            | —                   |
| Support arm mounting clamp | 1   | DH-332Z            | —                   |

## Breathing Circuit and Patient Interface Sets

| Name                                | Qty | Model/<br>Code No. | Catalogue<br>Number |
|-------------------------------------|-----|--------------------|---------------------|
| NPPV full face mask set L           | 1   | VM-310Z            | —                   |
| NPPV full face mask set M           | 1   | VM-311Z            | —                   |
| NPPV full face mask set S           | 1   | VM-312Z            | —                   |
| NPPV full face mask set XS          | 1   | VM-313Z            | —                   |
| Child/Infant NPPV full face mask XL | 1   | VM-321Z            | —                   |
| Child/Infant NPPV full face mask L  | 1   | VM-322Z            | —                   |
| NPPV cap-ONE mask set L             | 1   | VM-330Z            | —                   |
| NPPV cap-ONE mask set M             | 1   | VM-331Z            | —                   |
| NPPV cap-ONE mask set S             | 1   | VM-332Z            | —                   |
| NPPV cap-ONE mask set XS            | 1   | VM-333Z            | —                   |
| Single limb breathing set HW-EXH    | 10  | VB-310Z            | —                   |
| Single limb breathing set WT-EXH    | 10  | VB-311Z            | —                   |
| Single limb breathing set EXH       | 10  | VB-312Z            | —                   |
| Single limb breathing set HW        | 10  | VB-313Z            | —                   |
| Exhalation port                     | 30  | VA-300Z            | —                   |
| Breathing circuit filter            | 30  | VA-301Z            | —                   |
| Humidification chamber              | 20  | VA-302Z            | —                   |
| Flow sensor                         | 6   | TF-300Z            | —                   |



## Sensors and Probes

### CO<sub>2</sub> Sensors

| Name  |                                  | Length (m) | Qty    | Model/Code No. | Catalogue Number |
|---|----------------------------------|------------|--------|----------------|------------------|
| <b>Semi-quantitative method (TG-900P)</b>                                     |                                  |            |        |                |                  |
| CO <sub>2</sub> sensor kit (CO <sub>2</sub> adapter + CO <sub>2</sub> sensor) |                                  | 3          | 1      | TG-900P        | P903             |
| CO <sub>2</sub> adapter   |                                  | 2          | 1      | JG-900P        | K981             |
| CO <sub>2</sub> sensor  |                                  | 1          | 1      | TG-101T        | P922A            |
| Airway adapter  |                                  | —          | 50     | YG-101T        | R801             |
| <b>Semi-quantitative method (TG-920P)</b>                                     |                                  |            |        |                |                  |
| CO <sub>2</sub> sensor kit (CO <sub>2</sub> adapter + CO <sub>2</sub> sensor) |                                  | 3.5        | 1      | TG-920P        | P907             |
| CO <sub>2</sub> adapter   |                                  | 2          | 1      | JG-920P        | K984             |
| CO <sub>2</sub> sensor  |                                  | 1.5        | 1      | TG-121T        | P923             |
| Airway adapter  |                                  | —          | 30     | YG-111T        | R804             |
| Nasal adapter   | For nasal breathing              | —          | 30     | YG-120T        | V921             |
|   | For naso-oral breathing          | —          | 30     | YG-121T        | V922             |
|   | For oxygen cannula adjustment    | —          | 30     | YG-122T        | V923             |
| Oxygen cannula  | For YG-122T                      | —          | 25     | 1103           | V927A            |
| Surgical tape   |                                  | —          | 24/box | #1527          | Y242             |
| <b>Quantitative method (TG-980P)</b>  |                                  |            |        |                |                  |
| CO <sub>2</sub> sensor kit  |                                  | 2.9        | 1      | TG-980P        | P910A            |
| Airway adapter  | For adult                        | —          | 30     | YG-211T        | R805             |
| Pediatric cap-ONE mask  | For pediatric                    | —          | 10     | YG-232T        | V933             |
| Adult cap-ONE mask  | For adult                        | —          | 10     | YG-272T        | V938A            |
| Large adult cap-ONE mask  | For adult                        | —          | 10     | YG-282T        | V938C            |
| Adult cap-ONE nasal adapter   | For adult                        | —          | 30     | YG-220T        | —                |
| Adult cap-ONE nasal adapter   | For adult (with oxygen tube)     | —          | 30     | YG-221T        | —                |
| Pediatric cap-ONE nasal adapter   | For pediatric                    | —          | 30     | YG-230T        | —                |
| Pediatric cap-ONE nasal adapter   | For pediatric (with oxygen tube) | —          | 30     | YG-231T        | —                |



## SpO<sub>2</sub> Probes

The probes in the following table are all Nihon Kohden probes.

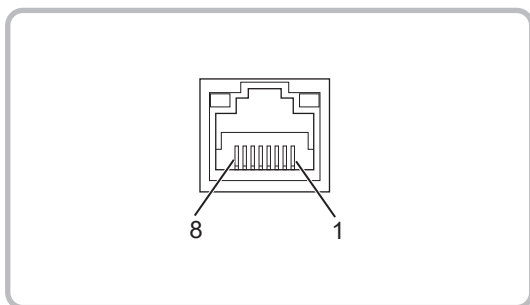
| Name                                   | Application, Patient (Approximate Weight), Features   | Length (m) | Qty        | Model/Code No.        | Catalogue Number |
|--|---|------------|------------|-----------------------|------------------|
| SpO <sub>2</sub> adapter               | For SpO <sub>2</sub> measurement  | 2.5        | 1          | JL-500P1 <sup>1</sup> | —                |
|  |   |            |            | JL-500P2 <sup>1</sup> | Y094A            |
| Finger probe                           | <ul style="list-style-type: none"> <li>For adults or children (20 kg or more): finger</li> <li>Waterproof, washable</li> </ul>  | 1.6        | 1          | TL-201T2              | P225F            |
|  | <ul style="list-style-type: none"> <li>For adults (50 kg or more), children (50 kg or more): thick finger</li> <li>Secure with attachment tape</li> <li>Waterproof, washable</li> </ul>   | 1.6        | 1          | TL-630T3              | P310C            |
|  | <ul style="list-style-type: none"> <li>Secure with attachment tape</li> <li>Waterproof, washable</li> </ul>   | 0.6        | 1          | TL-630T1              | P310A            |
|  | <ul style="list-style-type: none"> <li>For adults or children (20 kg or more): finger, toe</li> <li>Secure with attachment tape</li> <li>Waterproof, washable</li> </ul>  | 0.6        | 1          | TL-631T1              | P311A            |
|  | <ul style="list-style-type: none"> <li>Secure with attachment tape</li> <li>Waterproof, washable</li> </ul>   | 1.6        | 1          | TL-631T3              | P311C            |
| Multi-site probe                       | <ul style="list-style-type: none"> <li>For adults or children (3 kg or more): finger or toe</li> <li>For neonates (3 kg or less): instep and sole</li> <li>Secure with attachment tape</li> <li>Waterproof, washable</li> </ul>   | 1.6        | 1          | TL-220T               | P225G            |
| Disposable probe                       | For adults (30 kg or more): finger or toe   | 0.8        | 24/box     | TL-271T               | P203A            |
|  |   | 1.6        | 24/box     | TL-271T3              | P203E            |
|  | For children (10 to 50 kg): finger or toe   | 0.8        | 24/box     | TL-272T               | P203B            |
|  |   | 1.6        | 24/box     | TL-272T3              | P203F            |
|  | For adults (40 kg or more): finger or toe   | 0.8        | 24/box     | TL-273T               | P203C            |
| 1.6                                    |   | 24/box     | TL-273T3   | P203G                 |                  |
| Multi-site Y probe                     | <ul style="list-style-type: none"> <li>Attachment tape S<br/>For low birth weight infants (1,000 g or less): instep and sole</li> <li>For neonates or children (3,000 g or more): finger and toe</li> <li>TL-260T clip adapter<br/>For adults (30 kg or more): earlobe</li> </ul> | 1.6        | 5/box      | TL-260T               | P205A            |
| Disposable probe                       | For adults (50 kg or more): finger  | 0.8        | 5/box      | TL-051S               | P228A            |
|  |   | 1.6        | 5/box      | TL-052S               | P228B            |
|  | For children (15 to 50 kg): finger  | 0.8        | 5/box      | TL-061S               | P229A            |
|  |   | 1.6        | 5/box      | TL-062S               | P229B            |
| Attachment tape                        | For attaching TL-630T1, TL-630T3, TL-631T1, TL-631T3, TL-220T probes  | —          | 3 × 30/pkg | —                     | P263A            |
| Attachment tape for multi-site Y probe | Attachment tape S for TL-260T   | —          | 24/box     | YS-114P5              | P260A            |
|  | Attachment tape L for TL-260T   | —          |            | YS-114P6              | P260B            |
| TL-260T clip adapter                   | For TL-260T, earlobe<br>For adults (30 kg or more): earlobe   | —          | 1          | YS-087P9              | P256             |
| Attachment tape for disposable probe   | For attaching TL-051S, TL-052S, TL-061S, TL-062S probes   | —          | 4 × 25/pkg | —                     | P260D            |

<sup>1</sup> For the differences between JL-500P1 and JL-500P2, contact your Nihon Kohden representative.



# Socket Pin Assignment and Signal Names

## LAN Socket



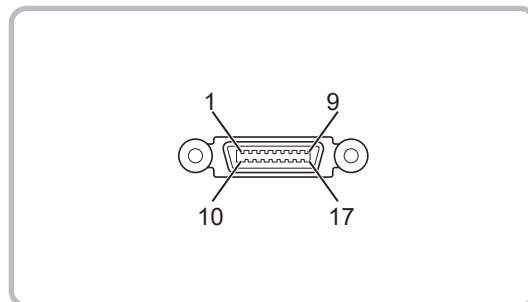
### Connection Cable

Network cable

### Pin Arrangement

| No. | Signal Name | No. | Signal Name |
|-----|-------------|-----|-------------|
| 1   | TD+         | 5   | NC          |
| 2   | TD-         | 6   | RD-         |
| 3   | RD+         | 7   | NC          |
| 4   | NC          | 8   | NC          |

## External Device Connection Socket 1



### Connection Cable

Nurse call connection cable

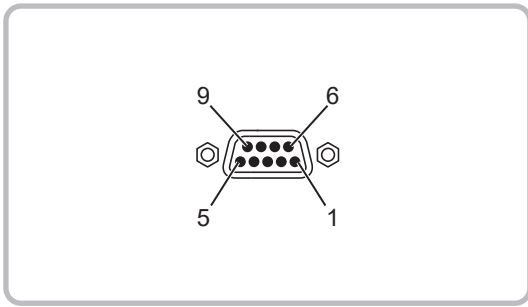
### Pin Arrangement

| No. | Signal Name    | No. | Signal Name   |
|-----|----------------|-----|---------------|
| 1   | GND            | 10  | NURSE CALL NC |
| 2   | NURSE CALL COM | 11  | NURSE CALL NO |
| 3   | GND            | 12  | GND           |
| 4   | TRUE IE        | 13  | NEBLIZER      |
| 5   | VCC5V0         | 14  | VCC5V0        |
| 6   | OP IN1         | 15  | ZS XCNFM      |
| 7   | ZS XRST        | 16  | ZS XINT       |
| 8   | ZS XTXD        | 17  | ZS XRXD       |
| 9   | GND            |     |               |



## External Device Connection

### Socket 2



### Connection Cable

YJ-332Z connection cable 2.5 m

YJ-333Z connection cable 5.0 m

YJ-334Z connection cable 10.0 m

### Pin Arrangement

| No. | Signal Name | No. | Signal Name |
|-----|-------------|-----|-------------|
| 1   | NC          | 6   | NC          |
| 2   | RXD         | 7   | NC          |
| 3   | TXD         | 8   | NC          |
| 4   | NC          | 9   | GND         |
| 5   | GND         |     |             |



# Nurse Call System

You can connect the nurse call connection cable to the **external device connection socket 1** of the ventilator and output alarm information of the ventilator to the nurse call. For details of connection method, contact your Nihon Kohden representative.

## ⚠ WARNING

Do not use the alarm information transmitted by the nurse call function of the ventilator to diagnose a patient. There may be misjudging of the patient condition. Check the alarm information on the ventilator.

NOTE • Nurse call output turns Off when the audio is paused.

- The nurse call output setting for each alarm can be set on the System Setup ► [Alarm] tab. When nurse call output is set to [Off], no nurse call output occurs. The delay time from occurrence of the alarm until output can also be set separately for each alarm.
- Connect the nurse call connection cable to a destination device which has a DC power supply of less than 30 V. If it exceeds 30 V, the ventilator may malfunction.

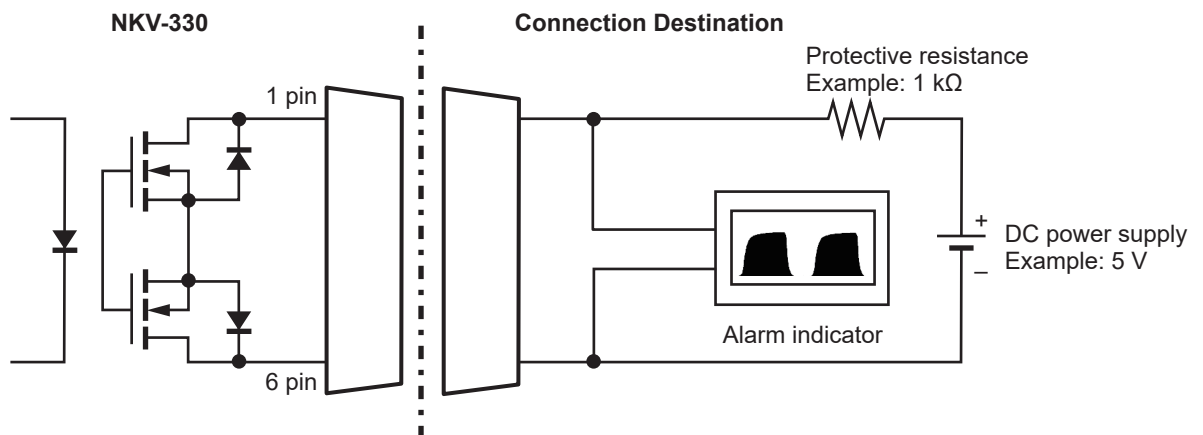


Refer to the following.

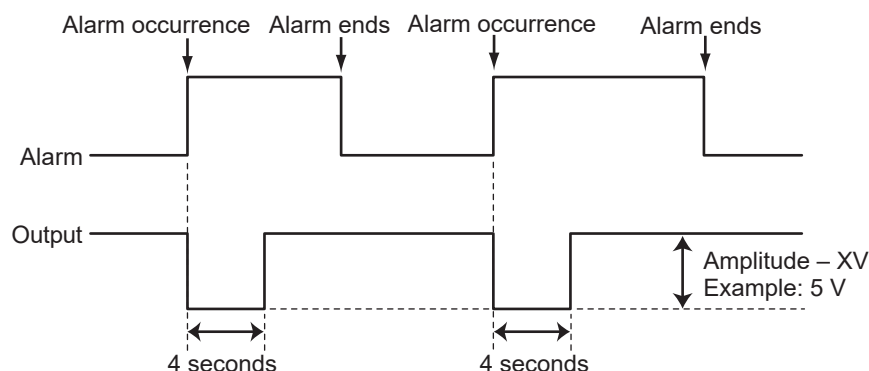
Administrator's Guide:

“Setting Nurse Call Output” in Section 3

## Block Diagram



## Alarm Information Transmission Flowchart





# Principle of Operation

## Ventilator

This ventilator uses outside air and a high pressure oxygen source or oxygen cylinder. Outside air which is taken in by the blower and oxygen which has a flow rate controlled by the proportional control valve are mixed in the mixing chamber and supplied to the patient. The microprocessor controls the blower and the proportional control valve to deliver the pressure and oxygen concentration which are set by the user.

The gas delivered from the ventilator is supplied to the patient through the patient breathing circuit, flow sensor, and patient interface. Expired gas from the patient is exhausted through the exhalation port or the blower in the ventilator.

## Ventilation Modes, O<sub>2</sub> Therapy Mode

### SPONT-PS Mode

During patient spontaneous breathing, pressure support ventilation is performed and the airway pressure is controlled to keep it at the set pressure. When there is no spontaneous breathing within the set time, mandatory ventilation is performed.

### S/T Mode

When there is no pressure support ventilation or spontaneous breathing within the set time, mandatory ventilation is performed.

### PCV Mode

When there is no assist ventilation or spontaneous breathing within the set time, mandatory ventilation is performed.

### PRVC Mode

Applied IPAP is automatically adjusted to obtain the set target ventilation. When there is no pressure support ventilation or spontaneous breathing within the set time, mandatory ventilation is performed.

### PPV Mode

Applied IPAP is automatically adjusted depending on the breathing effort of the patient. When there is no pressure support ventilation or spontaneous breathing within the set time, mandatory ventilation is performed.

### O<sub>2</sub> Therapy Mode

Supplies gas at the set flow rate.



## Flow Sensor

The flow sensor is designed to measure the flow rate, volume and pressure in the patient's airway. The inside of the housing has a thin film composed of a variable orifice structure whose opening diameter changes according to the flow rate. The flow rate and flow volume are obtained by measuring the pressure drop (differential pressure) in the vicinity of the orifice with a pressure sensor.

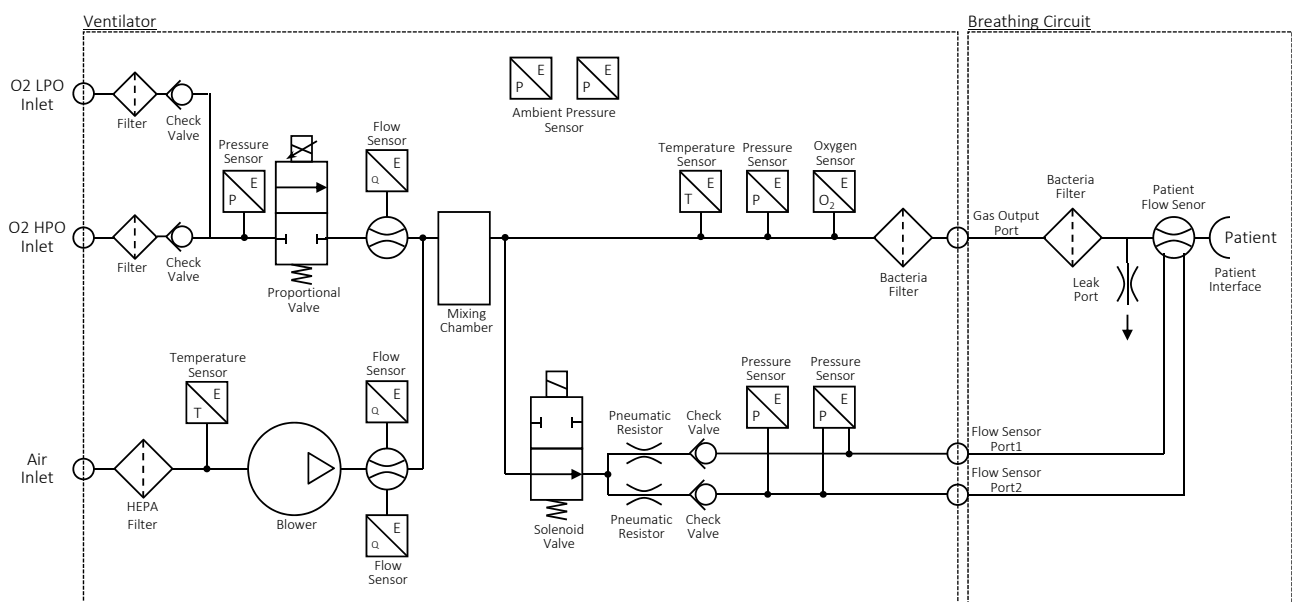
## Galvanic Oxygen Sensor

The galvanic oxygen sensor uses a battery composed of a positive electrode (gold), negative electrode (lead), electrolyte solution and diaphragm. Oxygen that permeates through the diaphragm is reduced on the gold electrode and current flows between it and the lead electrode according to the oxygen concentration. The oxygen concentration is obtained by measuring the current by voltage conversion.

## Paramagnetic Oxygen Sensor

The paramagnetic oxygen sensor utilizes the fact that oxygen exhibits paramagnetism. The oxygen concentration is obtained by measuring reference cell displacement caused by differences between the gas in the reference cell and the oxygen concentration to be measured.

## Pneumatic Diagram





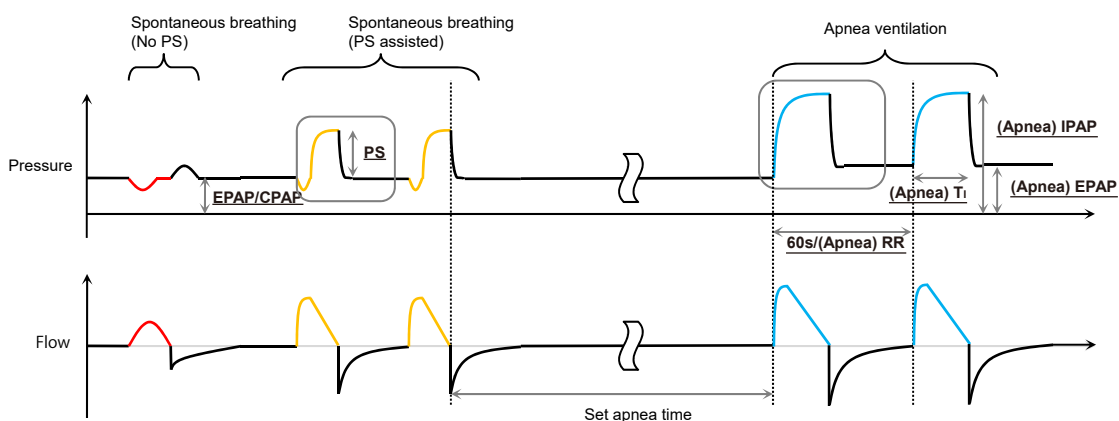
# Ventilation Mode Description

## SPONT-PS Mode

This mode keeps the airway pressure at the set pressure (EPAP/CPAP). When spontaneous breathing is detected, it is assisted by the set pressure support (PS). In addition, when the apnea ventilation function is activated, mandatory ventilation is applied when breathing is not detected even after the apnea time (Apnea) elapses.

NOTE: The following alarms are not generated in the first 60 seconds after apnea ventilation starts and ends.

- Low PIP
- High/Low MV
- High/Low RR<sub>TOT</sub>
- High/Low VT
- High/Low FiO<sub>2</sub>
- High/Low PEEP



### SPONT-PS Mode Valid Control Settings

| BASIC SETTINGS |                  |                                      |        |                  |
|----------------|------------------|--------------------------------------|--------|------------------|
| Parameters     | EPAP/CPAP        | PS <sup>1</sup><br>(above EPAP/CPAP) | Slope  | FiO <sub>2</sub> |
| Settings       | 4 to 25<br>[hPa] | 0 to 36<br>[hPa]                     | 1 to 6 | 21 to 100<br>[%] |

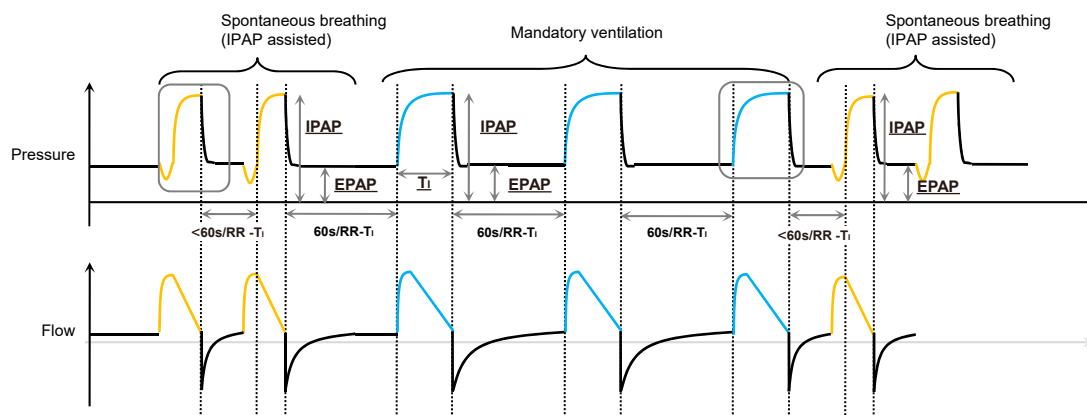
<sup>1</sup> The PS upper limit is restricted so that PS+EPAP/CPAP does not exceed 40 hPa.

| APNEA VENTILATION |                  |                  |               |                   |                   |
|-------------------|------------------|------------------|---------------|-------------------|-------------------|
| Parameters        | (Apnea) IPAP     | (Apnea) EPAP     | (Apnea) Slope | (Apnea) RR        | (Apnea) Tl        |
| Settings          | 5 to 40<br>[hPa] | 4 to 25<br>[hPa] | 1 to 6        | 4 to 60<br>[/min] | 0.3 to 7.5<br>[s] |



## S/T Mode

This mode keeps the airway pressure at the set expiratory pressure (EPAP) and inspiratory pressure (IPAP). When spontaneous breathing is detected, spontaneous breathing is assisted by the set IPAP. If there is no spontaneous breathing within a certain period of time, mandatory ventilation is applied according to the set IPAP and inspiratory time (Ti) so that the respiration rate (RR) does not fall below the set rate.



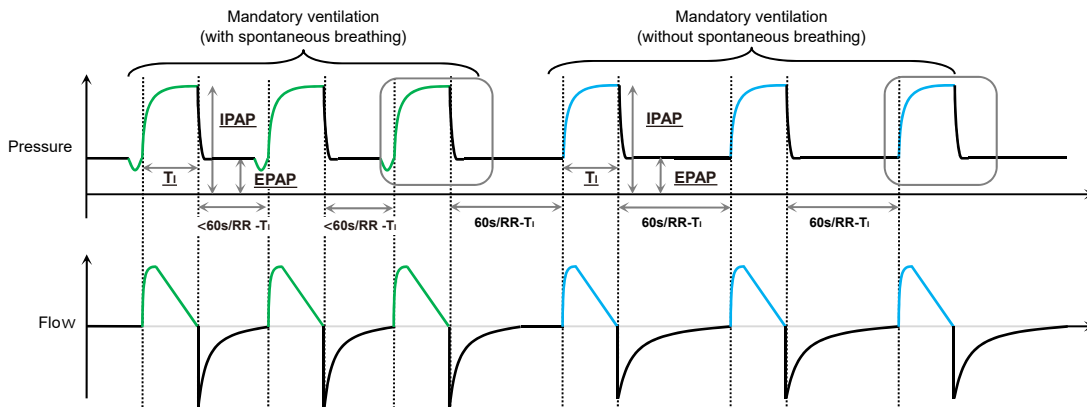
### S/T Mode Valid Control Settings

| BASIC SETTINGS |                  |                  |        |                  |                   |                   |
|----------------|------------------|------------------|--------|------------------|-------------------|-------------------|
| Parameters     | IPAP             | EPAP             | Slope  | FiO <sub>2</sub> | RR                | T <sub>i</sub>    |
| Settings       | 5 to 40<br>[hPa] | 4 to 25<br>[hPa] | 1 to 6 | 21 to 100<br>[%] | 4 to 60<br>[/min] | 0.3 to 7.5<br>[s] |



## PCV Mode

This mode keeps the airway pressure at the set expiratory pressure (EPAP) and inspiratory pressure (IPAP). When spontaneous breathing is detected or there is no spontaneous breathing within a certain period of time, mandatory ventilation is applied according to the set IPAP and inspiratory time (T<sub>I</sub>) so that the respiration rate (RR) does not fall below the set rate.



### PCV Mode Valid Control Settings

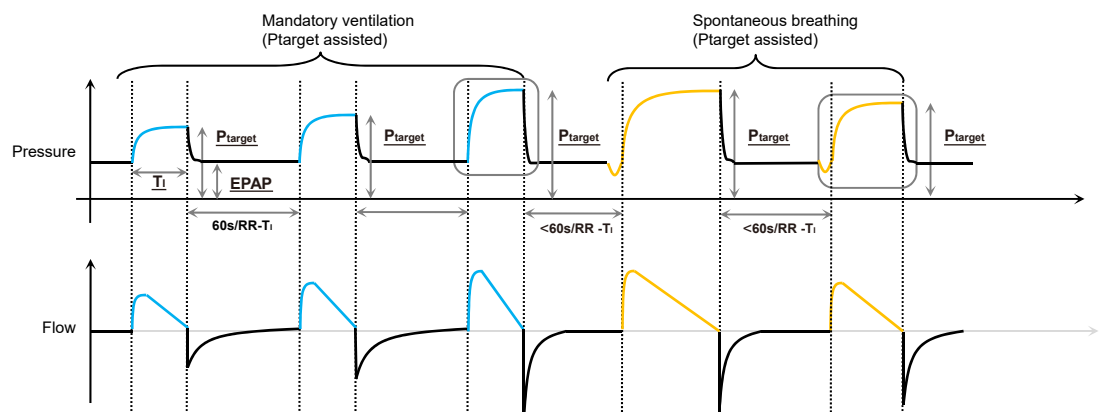
| BASIC SETTINGS |               |               |        |                  |                |                |
|----------------|---------------|---------------|--------|------------------|----------------|----------------|
| Parameters     | IPAP          | EPAP          | Slope  | FiO <sub>2</sub> | RR             | T <sub>I</sub> |
| Settings       | 5 to 40 [hPa] | 4 to 25 [hPa] | 1 to 6 | 21 to 100 [%]    | 4 to 60 [/min] | 0.3 to 7.5 [s] |



## PRVC Mode

This mode keeps the airway pressure at the set expiratory pressure (EPAP) and adjusts the IPAP ( $P_{\text{target}}$ ) to obtain the tidal volume. When spontaneous breathing is detected, it is assisted by the adjusted IPAP. If there is no spontaneous breathing within a certain period of time, mandatory ventilation is applied with the adjusted IPAP and the set inspiratory time ( $T_i$ ), and it operates so that the respiration rate (RR) does not fall below the set rate.

The target tidal volume is the average tidal volume of the past three breaths. To prevent sudden pressure change, the maximum change in one breath is  $\pm 3$  hPa.



### PRVC Mode Valid Control Settings

| BASIC SETTINGS |                     |                  |        |                  |                    |                   |
|----------------|---------------------|------------------|--------|------------------|--------------------|-------------------|
| Parameters     | VT                  | EPAP             | Slope  | FiO <sub>2</sub> | RR                 | Ti                |
| Settings       | 100 to 2000<br>[mL] | 4 to 25<br>[hPa] | 1 to 6 | 21 to 100<br>[%] | 4 to 60<br>[1/min] | 0.3 to 7.5<br>[s] |



## PPV Mode

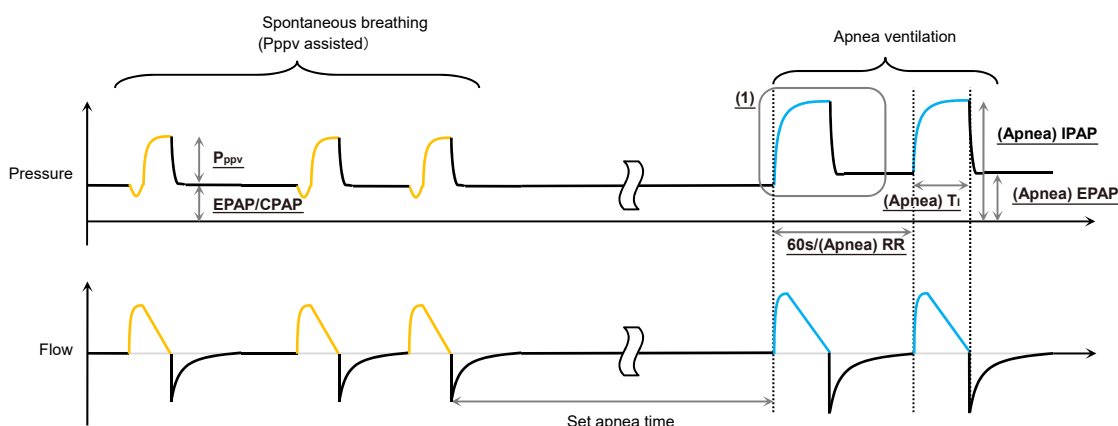
This mode keeps the airway pressure at the set pressure (EPAP/CPAP). When spontaneous breathing is detected, it is assisted by pressure support (P<sub>ppv</sub>) which is adjusted according to the respiratory effort. In addition, when the apnea ventilation function is activated, mandatory ventilation is applied when breathing is not detected even after the apnea time (Apnea) elapses. The support pressure (P<sub>ppv</sub>) is calculated by the following equation using the patient's flow (flow) and ventilation volume (volume).

NOTE: The following alarms are not generated in the first 60 seconds after apnea ventilation starts and ends.

- Low PIP
- High/Low MV
- High/Low RR<sub>TOT</sub>
- High/Low VT
- High/Low FiO<sub>2</sub>
- High/Low PEEP

$$P_{ppv} = \frac{PPV\%}{100} (\text{MaxR} * \text{flow} + \text{MaxE} * \text{volume})$$

Furthermore, if breathing is not detected during the set apnea time, mechanical ventilation will be activated (apnea backup ventilation function).



### PPV Mode Valid Control Settings

| BASIC SETTINGS |              |               |                  |                  |                   |
|----------------|--------------|---------------|------------------|------------------|-------------------|
| Parameters     | PPV%         | EPAP/CPAP     | FiO <sub>2</sub> | Max Elastance    | Max Resistance    |
| Settings       | 0 to 100 [%] | 4 to 25 [hPa] | 21 to 100 [%]    | 0 to 100 [hPa/L] | 0 to 50 [hPa/L/s] |

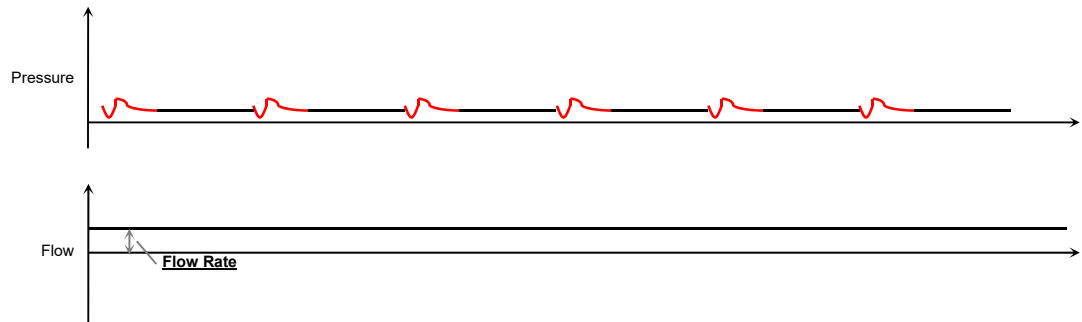
| APNEA VENTILATION |               |               |               |                |                        |
|-------------------|---------------|---------------|---------------|----------------|------------------------|
| Parameters        | (Apnea) IPAP  | (Apnea) PEEP  | (Apnea) Slope | (Apnea) RR     | (Apnea) T <sub>i</sub> |
| Settings          | 5 to 40 [hPa] | 4 to 25 [hPa] | 1 to 6        | 4 to 60 [/min] | 0.3 to 7.5 [s]         |



## O<sub>2</sub> Therapy Mode

This mode supplies the set oxygen concentration at the specified flow rate.

When a Blower Temp High alarm occurs, the flow rate is restricted to prevent overheating.



### O<sub>2</sub> Therapy Mode Valid Control Settings

| BASIC SETTINGS |                 |                  |
|----------------|-----------------|------------------|
| Parameters     | Flow Rate       | FiO <sub>2</sub> |
| Settings       | 1 to 60 [L/min] | 21 to 100 [%]    |

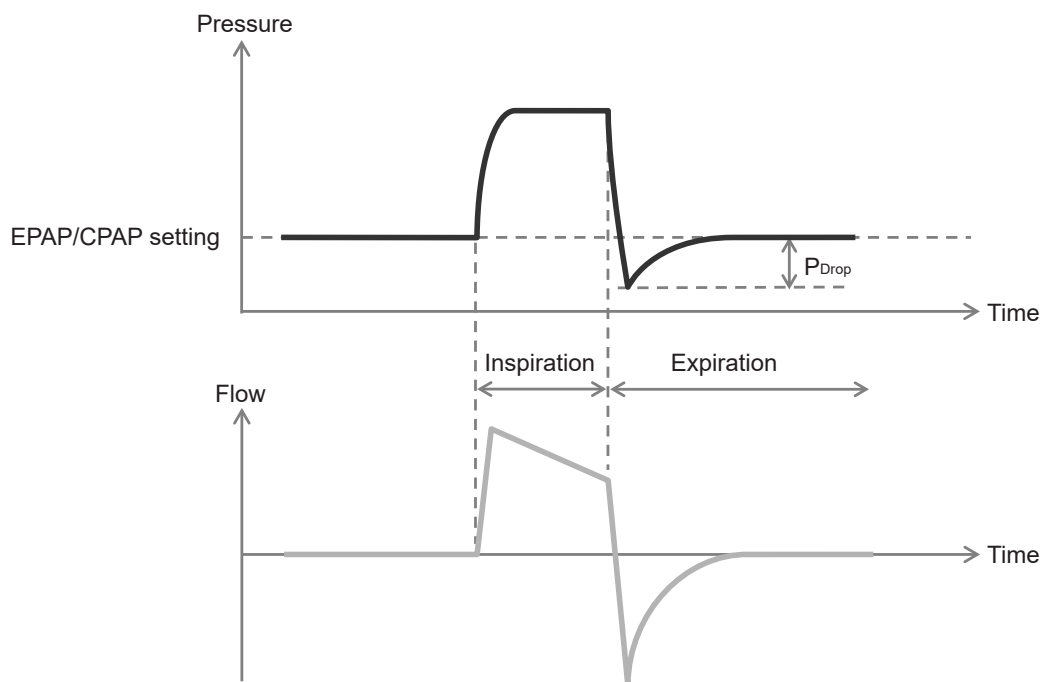


## Pressure Release

This is a function that supports the patient's exhalation by reducing the airway pressure at the start of exhalation from the set pressure (EPAP/CPAP) to a lower pressure. On this ventilator, this function can be used in SPONT-PS mode.

The amount of pressure relief at the start of exhalation ( $P_{\text{Drop}}$ ) is proportional to the patient's expiratory flow. This proportion can be adjusted in the Press. Release setting.

The Press. Release setting can be set to a value from 1 to 3. The larger the setting, the greater  $P_{\text{Drop}}$  becomes.



## Advanced Trigger

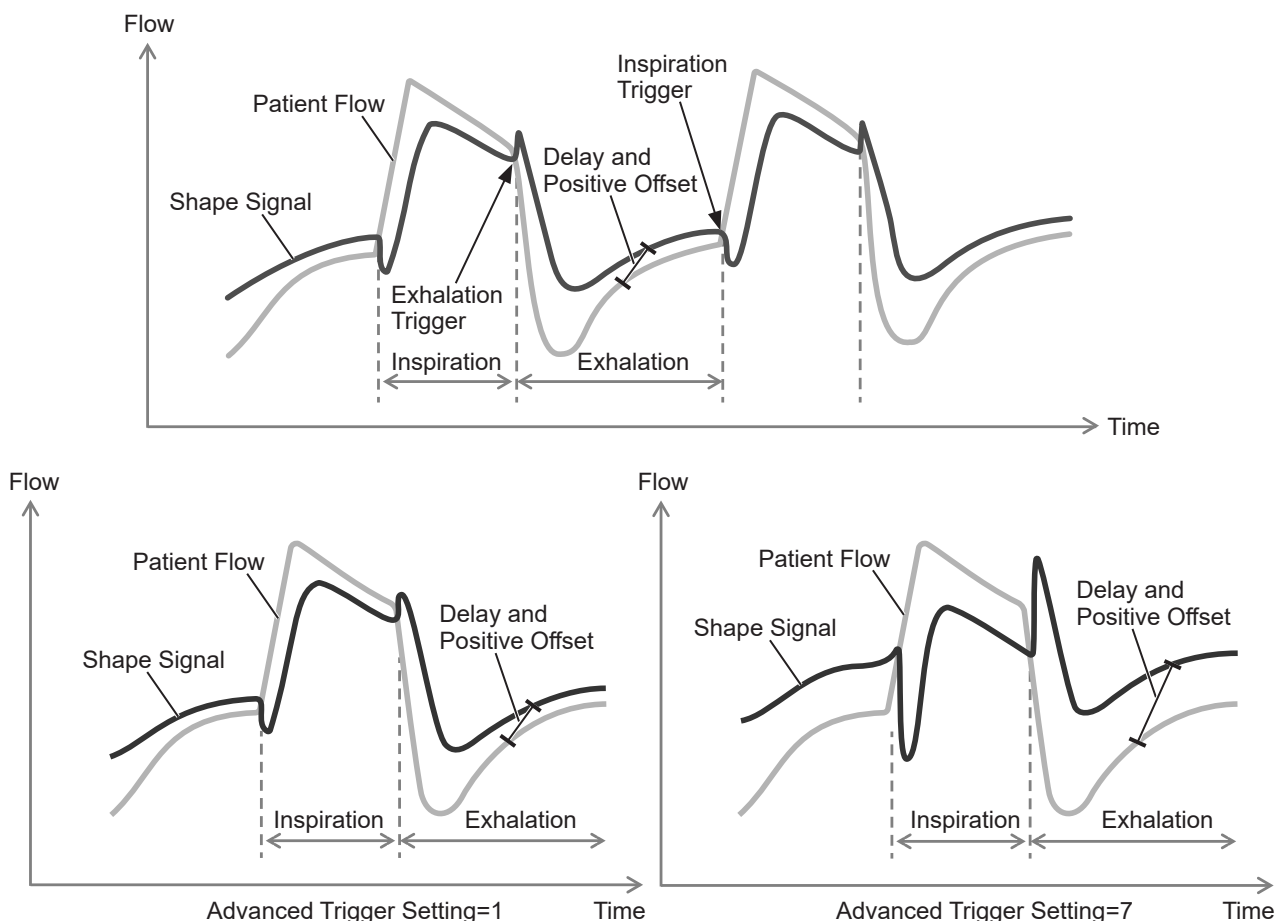
This is a function that detects the start of inspiration or exhalation from the intersection between the patient flow signal and the shape signal.

The shape signal is derived by delaying the patient flow signal and applying a positive or negative offset.

When inspiration is triggered during exhalation, the offset is positive. When exhalation is triggered during inspiration, the offset is negative. When patient effort occurs, the patient flow graph changes rapidly and intersects with the shape signal. That intersection is detected as the starting point of inspiration or exhalation.

The advanced trigger function allows the sensitivity to be adjusted so that the detection sensitivity is more sensitive when the offset value is small and less sensitive when the offset value is large.

The advanced trigger setting can be set to Auto or a value from 1 to 7. The lower the setting value, the greater the detection sensitivity. When advanced trigger is set to Auto, the offset is automatically calculated from the maximum inspiratory flow rate and the maximum expiratory flow rate, and used to derive the shape signal.





# Ramp Up Time

## Outline

The Ramp Up Time function gradually increases the inspiratory and expiratory pressures over a set time interval until the set pressures are reached. The initial pressures can be derived by the following formulas.

### When the ventilation mode is SPONT-PS

Initial EPAP/CPAP = EPAP/CPAP setting value  $\div$  2 (Min. 4 hPa)

Initial PS = PS setting value  $\div$  2

### When the ventilation mode is S/T or PCV

Initial EPAP = EPAP setting value  $\div$  2 (Min. 4 hPa)

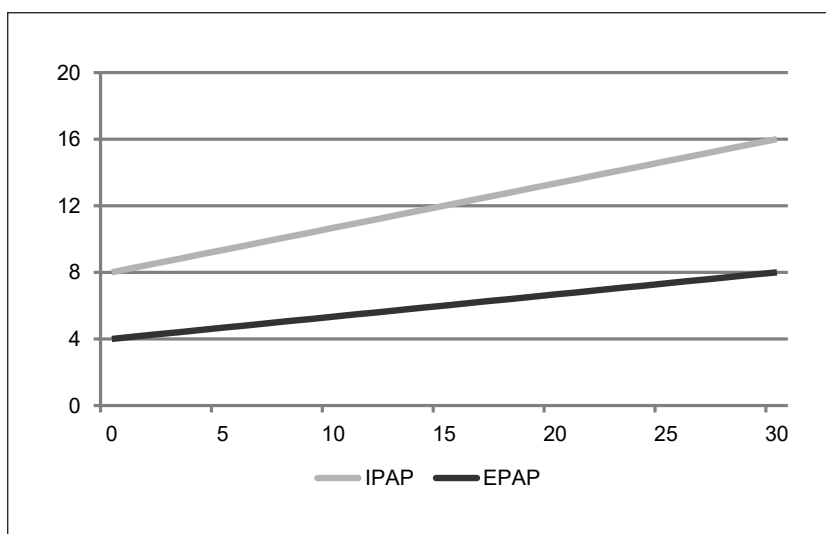
Initial IPAP = IPAP setting value  $\div$  2 (Min. 5 hPa)

The graph below shows the change in pressure when Ramp Up Time is started with the following settings.

IPAP: 16 hPa

EPAP: 8 hPa

Ramp: 30 min



## Available Ventilation Modes

Ramp Up Time is available for the following ventilation modes and pressure settings.

| Ventilation Mode | Pressure Settings |
|------------------|-------------------|
| SPONT-PS         | EPAP/CPAP, PS     |
| S/T              | EPAP, IPAP        |
| PCV              | EPAP, IPAP        |

## Starting Ramp Up Time

Ramp Up Time can be started by one of the following operations.

- Setting the Ramp Up Time during ventilation
- Setting the Ramp Up Time and starting ventilation
- Setting the Ramp Up Time and changing the ventilation mode

## Ending Ramp Up Time

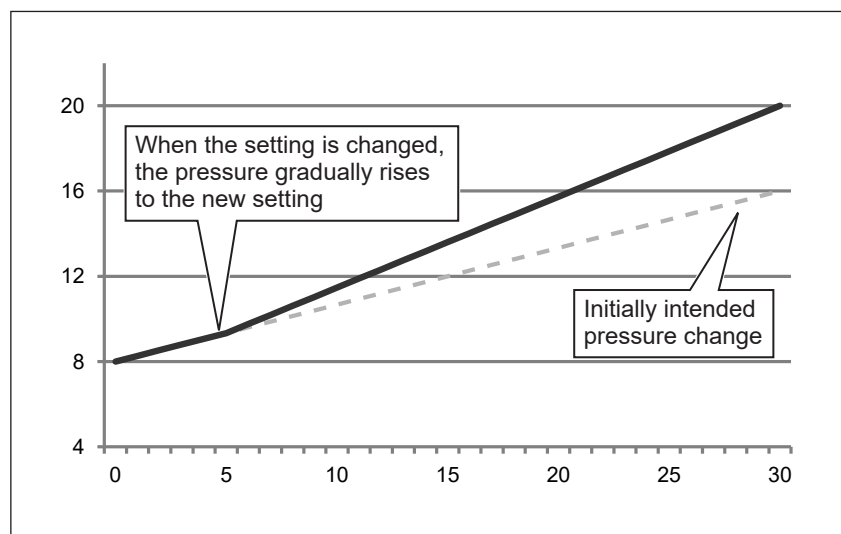
Ramp Up Time ends when one of the following operations is performed or one of the following conditions is met.

- The Ramp Up Time is exceeded
- The ventilator enters standby mode
- The ventilation mode is changed without setting the Ramp Up Time
- All available pressure settings are set to values below the current pressure

## Changing the Settings During Operation

The pressure settings can be changed after starting Ramp Up Time. When the pressure settings are changed, the pressure gradually increases from its current level until the new pressure setting is reached.

The following graph shows the change in pressure when Ramp Up Time is started with IPAP of 16 hPa and a Ramp Up Time of 30 min, and the IPAP setting is changed to 20 hPa after 5 minutes pass. Even though the settings are changed, Ramp Up Time continues without any sudden large changes in pressure.



## Precautions

- When apnea ventilation occurs during Ramp Up Time, the pressure immediately rises to the set pressure.
- When Low PIP and Low PEEP alarms occur during Ramp Up Time, there is no alarm sound (The alarm information is displayed as a screen message only).



## Definition of Ventilation Monitoring Parameters

The following table shows a definition of ventilation monitoring parameters. The display of monitored parameters is updated every second.

| Parameter (unit)                              | Definition   |
|---|--|
| Peak inspiratory pressure (hPa)               | Peak value of IPAP   |
| Positive end expiratory pressure (hPa)        | EPAP at the end of exhalation.   |
| Peak inspiratory flow (L/min)                 | Peak inspiratory flow in spontaneous and mandatory breaths.  |
| Peak expiratory flow (L/min)                  | Peak expiratory flow in spontaneous and mandatory breaths.   |
| Total inspiratory minute volume (L/min)       | Total inspiratory tidal volume in the past 1 minute, including both mandatory ventilation and spontaneous breathing.   |
| Spontaneous inspiratory minute volume (L/min) | Total inspiratory tidal volume from spontaneous breathing in the past 1 minute.  |
| Total expiratory minute volume (L/min)        | Total expiratory tidal volume in the past 1 minute, including both mandatory ventilation and spontaneous breathing.  |
| Spontaneous expiratory minute volume (L/min)  | Total expiratory tidal volume from spontaneous breathing in the past 1 minute.   |
| Inspiratory tidal volume (mL)                 | Inspiratory tidal volume in mandatory and spontaneous breaths.   |
| Expiratory tidal volume (mL)                  | Expiratory tidal volume in mandatory and spontaneous breaths.  |
| Expiratory tidal volume /kg (mL/kg)           | Expiratory tidal volume divided by estimated patient weight.   |
| Total respiratory rate (/min)                 | Respiration rate of the patient in the past 1 minute, including both mandatory ventilation and spontaneous breathing.  |
| Spontaneous respiratory rate (/min)           | Spontaneous respiration rate of the patient in the past 1 minute (not including assisted ventilation).   |
| Respiratory rate (%)                          | Inspiratory time divided by total respiratory time.  |
| I:E ratio                                     | Ratio of inspiratory to expiratory time in mandatory breaths.  |
| Inspiratory time (s)                          | Inspiratory time in mandatory breaths. The time from the start of inspiration to the start of expiration is measured.  |
| Expiratory time (s)                           | Respiratory time in mandatory breaths. The time from the start of expiration to the start of inspiration is measured.  |
| Total leakage flow (L/min)                    | The moving average of the total leak over the last 3 breaths.  |
| Patient leakage flow (L/min)                  | The moving average of the estimated patient leak and unintentional leak over the last 3 breaths.   |
| Leakage volume ratio (%)                      | The moving average of the percentage value of patient leak over total leak in the last 3 breaths.  |
| Spontaneous breathing ratio (%)               | Percentage of spontaneous breaths over total breaths in the last 1 minute.   |
| O <sub>2</sub> gas usage (L/min)              | The moving average of O <sub>2</sub> gas usage over the last 3 breaths.  |
| Flow (L/min)                                  | Flow delivered to the patient.   |
| FiO <sub>2</sub> (%)                          | Oxygen concentration of the delivered gas. It is measured by the oxygen sensor in the ventilator. This parameter is not displayed if the oxygen sensor is not installed. |



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## NKV-330 Ventilator Maintenance Check Sheet

**Serial No:** \_\_\_\_\_ **Person in Charge:** \_\_\_\_\_

**Hospital, Department:** \_\_\_\_\_

**Storage Location:** \_\_\_\_\_

| X                     |    | Inspection date                               |  |  |  |  |  |  |  |
|-----------------------|----|---|--|--|--|--|--|--|--|
|                       |    | Inspector                                     |  |  |  |  |  |  |  |
| Preoperational Check  | 1  | Surrounding environment check                 |  |  |  |  |  |  |  |
|                       | 2  | Alternative breathing assistance device check |  |  |  |  |  |  |  |
|                       | 3  | External appearance and connection check      |  |  |  |  |  |  |  |
|                       | 4  | Power check                                   |  |  |  |  |  |  |  |
|                       | 5  | Patient circuit check                         |  |  |  |  |  |  |  |
|                       | 6  | Oxygen supply check                           |  |  |  |  |  |  |  |
|                       | 7  | Vital signs measurement check                 |  |  |  |  |  |  |  |
|                       | 8  | Basic operation check                         |  |  |  |  |  |  |  |
|                       | 9  | Ventilation check                             |  |  |  |  |  |  |  |
|                       | 10 | Alarm check                                   |  |  |  |  |  |  |  |
| Operational Check     | 1  | Basic operation check                         |  |  |  |  |  |  |  |
|                       | 2  | Setup check                                   |  |  |  |  |  |  |  |
|                       | 3  | Heated humidifier check                       |  |  |  |  |  |  |  |
|                       | 4  | Breathing circuit check                       |  |  |  |  |  |  |  |
| Postoperational Check | 1  | Abnormality check                             |  |  |  |  |  |  |  |
|                       | 2  | Organization and storage check                |  |  |  |  |  |  |  |



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Contact information is accurate as of Mar 2023. Visit <https://www.nihonkohden.com/> for the latest information.

The model and serial number of your device are identified on the rear or bottom of the unit.

Write the model and serial number in the spaces provided below. Whenever you call your representative concerning this device, mention these two pieces of information for quick and accurate service.

Model \_\_\_\_\_

Serial Number \_\_\_\_\_

Your Representative

Note for users in the territory of the EEA and Switzerland:

Any serious incident that has occurred in relation to the device should be reported to the European Representative designated by the manufacturer and the Competent Authority of the Member State of the EEA and Switzerland in which the user and/or patient is established.



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