MEK Focus on Life Care

User Manual

HFT700

Non-Invasive Respiratory Care System



This user manual is subject to change without notice to enhance the performance of the device.
Figures and illustrations in this document may be different from the actual appearance.

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1 About this User Manual

This user manual is provided to users of the HFT700 ventilator.

- This user manual applies to HFT700 ventilators only and may not be used with other devices.
- This manual specifies precautions and risk factors which users should be aware of before using this device.

  Read this user manual carefully before using the device to ensure safe and correct use.

  The table of contents allows users to search for desired information more rapidly.
- If this manual is damaged or lost, contact MEKICS Co., Ltd or a distributor.

For detailed information, contact our Customer Service Center:

URL: http://www.mek-ics.com

E-mail: service@mek-ics.com

Call: +82-70-7119-2520

1.1 Cautions

This document contains copyrighted and exclusive information. This manual is protected by copyright laws which prohibit any form of reproduction of the contents without the prior approval of MEKICS.

1.2 Disclaimer

MEKICS disclaims all responsibility for any problems caused by using accessories and parts which are not manufactured or approved by our company.

1.3 Revision History

Part numbers of accessories and revision numbers in this user manual indicate the current version. The revision number of the user manual shall not be changed even when the sub-document other than the upper-level document is changed or supplemented. The revision number of the user manual shall be changed only when there are major changes to part numbers or technical contents in the document.

1.4 Symbols

Below are symbols used in this user manual. As these symbols represent precautions and recommendations related to the device, check and refer to them when using or storing the device.



WARNING

This is a warning symbol.
It indicates a situation that may cause serious injury to a patient, major damage to the device, or an irretrievable result.



CAUTION

This is a caution symbol.
It indicates a situation that may cause injury to a patient or damage to the device.



NOTE

This symbol relates to matters that require attention regarding the surrounding environment or provides additional information. It is not related to any injuries or damage.

- There may be differences between the information in this document and the device in terms of functionality.
- We have a right to change the specifications without prior notice if needed for performance enhancement of the device, and we're not obliged to apply those specification changes to previously released devices.

2 Precautions

2.1 General precautions

Before using the HFT700 ventilator on a patient, become familiar with this user manual, particularly the safety considerations listed. Be aware, however, that this manual is a reference only. It is not intended to supersede the institution's protocol regarding the safe use of assisted ventilation.

WARNING

1. The HFT700 ventilator must only be used:
   - For the intended treatment specified in this manual and the instructions given by the responsible clinical personnel.
   - In accordance with the operating conditions specified in this manual.
   - Accessories specified or approved by MEKICS must be used in an unmodified state.

   Other uses may lead to risk of patient injury!



2. Whenever using the HFT700 ventilator, have immediate access to an alternative means of ventilation, such as another ventilator device or assisted ventilation. In case of a device failure or problems encountered while assisting a patient's respiration with the HFT700 ventilator, remove the device from the patient and immediately replace it with another ventilator device.
3. Use the HFT700 ventilator on patients capable of spontaneous breathing. While oxygen therapy through the HFT700 ventilator or assist ventilator may be helpful to a patient's respiration, it is not intended to provide for the total ventilatory requirements of the patient.
4. We do not recommend use of the HFT700 Ventilator on patients who require ventilation at precise tidal volumes. The device provides a high flow (HF) function and continuous positive airway pressure (CPAP) and bi-level modes and is indicated for assisted ventilation only. These modes do not provide ventilation with precise tidal volume delivery.

WARNING



5. The HFT700 is not suitable for the entire ventilatory demand of a ventilator-

dependent patient.

6. The patient interface of the HFT700 ventilator for HF function and CPAP and bi-level modes must be used separately. The patient interface is not compatible between the two respiratory therapies. Reversing the patient interface may harm the patient.
   - The patient interface for HF function is the high flow nasal cannula, HFNC.
   - The patient interface of non-invasive positive pressure ventilation is a non-invasive ventilation (NIV) mask. To perform non-invasive positive pressure ventilation, a non-vented mask or a vented mask must be used.

   For details, refer to "4.10 Connection of Patient Interface."

7. To reduce the risk of CO_2 rebreathing while using the non-invasive ventilation mode (CPAP/bi-level) of the HFT700 ventilator, make sure Expiratory Positive Airway Pressure (EPAP) and exhalation times are sufficient to clear all exhaled gas through the exhalation port. In non-invasive positive pressure ventilation, continuous airflow through the exhalation port flushes exhaled gases from the breathing circuit. The ability to completely exhaust exhaled gas from the breathing circuit depends on the EPAP setting and the Inspiratory: Expiratory ratio (I:E ratio). Higher tidal volumes further increase the volume of CO_2 rebreathed by the patient.
8. The exhalation port of the non-invasive ventilation mode (CPAP/bi-level) of the HFT700 ventilator must be installed between the patient circuit and the mask (Non-vented mask) or a mask with an exhalation port (Vented mask) must be used.
9. In the non-invasive ventilation modes of the HFT700 ventilator, the measured exhaled volume may differ from the End-tidal CO_2 ($EtCO_2$) due to leaks around the mask.
10. Do not add any attachments or accessories which are not listed in the instruction for use of the HFT700 ventilator to the breathing circuit (humidifier). The HFT700 ventilator might not function correctly affecting the quality of the therapy or injuring the patient.
11. Do not use the HFT700 ventilator (humidifier) at an altitude above 3,000 m or outside the temperature range of 18 ℃ to 26 ℃. Using the device outside this temperature range or above this altitude can affect the quality of the therapy or injure the patient.
12. To prevent the possibility of inadequate humidification, pay close attention to the humidifier's functioning when operating the ventilator at an ambient temperature > 26 ℃. The ventilator warms the air delivered to the patient

above ambient temperature, which may impair the humidifier's performance.

13. To prevent disconnection of the breathing circuit or breathing circuit system during use, especially during ambulatory use, only tubes in compliance with ISO 5367 or ISO 80601-2-74 should be used.

14. Covering the breathing circuit (heated circuit) with a blanket or heating them in an incubator or with an overhead heater can affect the quality of the therapy or injure the patient.

15. Always install an anti-bacterial filter at the gas outlet port to avoid contamination of the HFT700 ventilator and patient infection. However, filters not approved by MEKICS may impair device performance.

16. Set the alarm volume of the HFT700 ventilator above the ambient level. Setting the alarm volume too low may prevent recognition of alarm conditions. Avoid blocking the alarm speakers of the ventilator.



NOTE

If the anti-bacterial filter is missing, ruptured, or defective, the backflow of the patient's exhaled gas may contaminate the inside of the device, or the inflow of humidified gas may cause the device to malfunction. It may also increase the patient's risk of cross-contamination.

2.2 Precautions related to usage

WARNING

1. Do not disassemble the HFT700 ventilator without the approval of MEKICS. Any attempt to disassemble the device by unauthorized personnel voids the device warranty. If there is a problem with the device, contact our Customer Service Center.
2. Before using the HFT700 ventilator, make sure every accessory and function settings are correct.
3. Perform a regular function and performance check on the HFT700 ventilator.
4. Only personnel who have completed the training provided by MEKICS and get proper approval or who are familiar with the operation of the HFT700 ventilator are allowed to use the device.
5. Do not plug in the HTF700 ventilator until it is completely installed. Otherwise, the device may be damaged.
6. Before using the device, an end user or a person in charge of managing the HFT700 ventilator should ensure the compatibility of every component of the device to be connected to the patient.
7. Do not use the device for two or more patients at the same time.
8. Handling the device with wet hands may cause a shock hazard.
9. Take care to prevent dust, especially metallic objects, from getting inside the device during use
10. Avoid causing burns to the user from the device's heat plate and chamber.
11. Do not use the device with an inhalation anesthetic.
12. Do not use an anti-static or conductive breathing circuit on the HFT700 ventilator.
13. Always check the status of the oxygen cylinders before transporting and using the HFT700 ventilator.
14. Not every default setting by the manufacturer is appropriate for all patients. Before using the HFT700 ventilator, verify that the current alarm settings or defaults are appropriate for each particular patient.
15. To prevent possible patient injury, avoid setting alarm limits to extreme values, which can render the alarm system useless.

WARNING

16. To prevent the delivery of excessive pressure or volume occurring from a sudden increase in mask leak or inappropriate settings, set the P_limit appropriately. Conversely, insufficient treatment may result if limits are set too low.

17. Use only parts provided or approved by MEKICS on the breathing circuit and every accessory to the breathing circuit such as the anti-bacterial filter, the nasal cannula, and the mask. For the provided parts, observe the instructions for use from each manufacturer. As applying an incorrect part may result in the device's malfunction, do not use parts or accessories not listed in this user manual.

18. To prevent possible asphyxia and to reduce the risk of CO_2 rebreathing, take these precautions with respect to mask and exhalation port use (non-invasive ventilation mode only):



- Use only an oro-nasal mask with an anti-asphyxia valve or a nasal mask for noninvasive positive pressure ventilation.
- Do not occlude the exhalation port.
- Turn on the device and verify that the port is operational before application. Pressurized gas from the HFT700 ventilator should cause a continuous flow of air to exhaust from the leak port, flushing exhaled gas from the circuit.
- Never leave the mask on the patient while the HFT700 ventilator is not operating. When the device is not operating, the exhalation port does not allow sufficient exhaust to eliminate CO_2 from the breathing circuit. Therefore, substantial CO_2 rebreathing may occur.

19. If the bacterial filter is used, replace it more frequently to prevent increased resistance in the breathing circuit and blockage.

20. Do not connect the HFT700 ventilator to the battery of a battery-powered wheelchair. It can compromise the device performance which consequently can result in degradation of the health of the patient.

21. If a cart is used, use one dedicated to the HFT700 ventilator provided by MEKICS. Using a non-approved cart to move the ventilator can cause serious damage to the device and risk to the patient.

22. Due to unintended air leaks, the measured volume and the exhaled CO_2 value may differ from the actual value measured on the patient.

CAUTION

1. When using the device, we recommend using the humidifier all the time unless the patient is moving.
2. Refer to the installation instructions of the HFT700 ventilator and the optional parts to assemble the device correctly.
3. Take care when installing accessories like a mask, cannula, breathing circuit, and connector.
4. Do not attempt to modify or remove any part of the HFT700 ventilator. If the device is modified or used for a purpose not specified in this user manual or operated in a way not in compliance with the instructions in this manual, MEKICS is not responsible for the safe operation of the device.
5. Selecting the therapy settings must be determined based on the patient's conditions and requirements, and other clinical information must be also considered for precise diagnosis.
6. When using a Saturation of Percutaneous Oxygen (SpO_2) probe, do not over-tighten and cause pain to the patient. In addition, be careful that electrical or electronic sensor cables are not twisted or wound around part of the patient's body.
7. If the measured SpO_2 value in the screen is determined to not be correct, measure the value again using another device for comparison.
8. When measuring the SpO_2 value, do not use one device on two patients at the same time.

2.3 Electrical safety precautions

This part contains electrical safety precautions. Make sure to check before using the device.

WARNING



1. The rated power input of this device is 100 – 240 VAC, 50/60 Hz.
2. MEKICS is not responsible for any problems caused by not using the rated power input.
3. Do not use extension cords, adapters, or AC power cords for the HFT700 ventilator that are not approved by MEKICS. To prevent unintentional disconnection of the AC power cord, always use the correct, MEKICS-supplied AC power cord and lock it into place with the AC power cord stopper before switching the device on. The AC power cord clamp is designed to hold the connector end of the MEKICS-supplied AC power cord securely in place.
4. To reduce the risk of a power failure and full discharge of the HFT700 ventilator, pay close attention to the external power supply's charge level. The external power supply's operation time is approximate and is affected by the device settings, discharge and recharge cycles, the external power supply's age, and ambient temperature.
5. To reduce the risk of electric shock, power down the HFT700 ventilator and disconnect it from AC power before cleaning, disinfecting, or servicing it.
6. Turn off the device and disconnect it from the AC power before performing decontamination or maintenance procedures. Failure to do so may result in electric shock.

WARNING

7. To reduce the risk of fire, explosion, leakage, or other hazards, take these precautions with respect to the battery:
   - Do not drop or attempt to open or disassemble the battery.
   - Do not attempt to repair or modify the battery by bending, deforming, inserting foreign objects, making a hole, etc.
   - Do not immerse or expose the battery in water or other liquids.
   - Do not expose the battery to fire, excessive heat (including soldering irons); or put it in a microwave oven.
   - Replace the battery only with another battery specified by the manufacturer.
   - Follow all instructions for proper use of the battery.
   - Do not short-circuit the battery or allow metallic or conductive objects to contact the battery connector housing.



8. Only authorized service personnel should replace parts within the HTF700 ventilator or perform other service activities. Personnel working with the device without having received proper training are at risk of electric shock.
9. Using a damaged AC power cord or SpO_2 sensor cable can cause an electric shock, short circuit, or damage to the device. If an AC power cord or a SpO_2 sensor cable is damaged, stop using the device and replace the damaged part immediately.
10. Do not subject the device to impacts or move it when the AC power cord or a SpO_2 sensor cable is connected. Doing so may injure the patient or pose a risk of device malfunction or damage.
11. When the HFT700 ventilator is used with another device, use a separate AC power cord for each device for the patient's safety.
12. Do not use an anti-static or conductive breathing circuit on the HFT700 ventilator
13. MEKICS-supplied parts and accessories are certified items that comply with electrical safety standards. Using third-party devices or unproven items may injure the patient or pose a risk of device malfunction or damage.



WARNING

14. Do not use the device in a location where extreme temperature changes occur. Doing so increases the risk of battery explosion. The proper temperature range is between 5 ℃ and 40 ℃.
15. Do not touch the battery with wet hands.
16. To reduce the risk of electric shock from liquid entering the HFT700 ventilator, do not put a container filled with a liquid on the device.



CAUTION

For parts connected to the HFT700 ventilator such as the SpO2 probe sensor, use parts provided by MEKICS or a designated company representative.

2.4 Precautions related to use environment

WARNING

1. Do not use the device in a location that is exposed to chemicals or explosive gas.
2. Do not use the device near heating devices.
3. Do not use the device in a location where extreme temperature changes occur. The proper temperature range is between 5 ℃ and 40 ℃.
4. Do not use the device in a humid or unventilated location. The proper relative humidity range is between 10 % and 90 %.
5. We recommend using the device at an altitude between – 500 m to 3,000 m. Using the HFT700 ventilator outside this altitude range may affect the performance, which consequently may have an adverse effect on the patient.
6. Do not use the device in direct sunlight.
7. Do not use the device in a location subject to significant impacts or vibrations.
8. Do not install the device in a location that is out of eyesight or may affect the performance of other devices. For example, placing the device next to a curtain that blocks the flow of cooling air may cause the device to overheat.
9. Place the HFT700 ventilator on a clean, flat, and solid surface.
10. The HFT700 ventilator should be placed lower than the patient in order to prevent the device from falling on the patient, as well as preventing condensed water from reaching the patient.
11. Overnight, the HFT700 ventilator should be placed close enough to the patient's bedside to allow movements during sleep without dislodging the device.
12. Use the HFT700 ventilator in an upright position with the cart not to block the air intake.
13. Do not use the HFT700 ventilator in an MRI (Magnetic Resonance Imaging) environment. The HFT700 Ventilator is MR unsafe. Keep it outside the MRI scan room.

WARNING

14. Do not place anything next to the HFT700 ventilator that may block the air intake, fan intake, or alarm speaker. Failure to follow these instructions may cause harm to the patient.
    - Restricting air circulation inside the HFT700 ventilator may cause overheating.
    - The device's alarm sound is not transmitted to remote locations, so periodic checks of the patient's condition are required to prevent dangerous situations.
15. Install the breathing circuit according to the breathing circuit installation procedure provided in this user manual to prevent problems such as the patient being injured from tripping on the cable of the breathing circuit.
16. Do not use the HFT700 ventilator in a facility's hyperbaric chamber. The device is not designed to be used in a hyperbaric chamber environment.
17. To reduce patient risk of oxygen toxicity, keep the outside free-flowing oxygen from being introduced to the device's air inlet.
18. The HFT700 ventilator shall not be used with nitric oxide. Such use may cause the device to malfunction, causing harm to the patient or death.
19. Do not use the HFT700 ventilator during radiotherapy (for example, a cancer treatment using ionizing radiation). Such use may result in device malfunction.

2.5 Warnings for hoses, breathing circuits, and parts

WARNING

1. Do not add any parts or accessories to the HFT700 ventilator that are not intended for use in combination with the device, as stated in the instructions for use of the device or accessories. Doing so may cause the device to malfunction and a risk of performance degradation or loss of ventilatory support.
2. To reduce the likelihood of disconnection of the breathing circuit and to prevent adverse ventilation performance, use only accessories compatible with the HFT700 ventilator. Compatibility is determined by reviewing the user manual of either the HFT700 ventilator or authorized accessories.
3. To avoid an electrostatic discharge (ESD) and the possible fire hazard, do not use an antistatic or electrical conductivity hose or breathing circuit inside or near the HFT700 ventilator.
4. Adding accessories to the HFT700 ventilator changes the pressure resistance of the breathing circuit, which may affect the device's performance. Changes to the breathing circuit composition must not exceed the specified values to remain in compliance with the breathing circuit and overall circuit resistance stated in the user manual.
5. Using a humidifier may increase the resistance of the breathing filter. Inspect the filter regularly for foreign substances that may increase the resistance or blockage. Using a filter between the humidifier chamber and the device's patient interface is not recommended.
6. (When the user uses a water trap) empty the water trap chamber before it is filled with water to prevent water from flowing into the HFT700 ventilator through the high pressure oxygen Inlet.
7. Accessories connected to the analog and digital interfaces must be certified according to IEC60601-1. In addition, every composition must comply with IEC 60601-1.
8. In non-invasive ventilation mode, the circuit resistance is allowed below 25 cmH_2O (@150 l/min), and so is the compliance of the breathing circuit above 0.01 l/cmH_2O.

WARNING

9. When using a humidifier, breathing circuit filters and heat and moisture exchangers can require more frequent replacement to prevent increased resistance and blockage.



10. Each SpO_2 probe (Masimo/MEKICS) and SpO_2 probe extension cable of the HFT700 ventilator is designed for use with specific monitors.
    - The responsible organization or operator needs to verify the compatibility of the monitor, SpO_2 probe sensor, and SpO_2 probe extension cable before use. Otherwise, patient injury can result.
    - Placing the SpO_2 probe sensor on the patient negligently for prolonged periods can cause bedsores due to pressure.

2.6 Warning for source of gas supply

WARNING

1. Connect the HTF700 ventilator only to an appropriate medical-grade oxygen source.
2. To reduce the risk of hypoxia, connect only oxygen to the high pressure oxygen Inlet and low flow oxygen Inlet at the rear of the HFT700 ventilator.
3. The HFT700 ventilator is a high flow device. Connecting the device to the medical gas pipeline system or oxygen cylinder that can provide adequate flow to all terminal outlets will help ensure that the ventilator performs to its specifications.
4. To reduce the risk of fire, do not use a high pressure oxygen hose that is worn or contaminated with combustible materials like grease or oil.
5. The HFT700 ventilator is designed to use ambient air and 100 % oxygen. Use no other gases.
6. Do not use nitric oxide, helium, or mixed gas containing helium. The device is not approved to be used with this gas mixture. Such use may cause the device to malfunction, causing harm to the patient or death.
7. It is the responsibility of the attending physician to ensure that the oxygen source is compatible with the rated range of pressure, flow rate, and oxygen concentration as marked on the device; failure to comply with these requirements may cause the device to malfunction, causing harm to the patient or death.
8. Never use anesthetic gas (inhalant) to get rid of the risk of device malfunction, system error, measurement, and control.
9. To operate the HFT700 ventilator correctly using an outside oxygen source, use only clean and dehumidified medical oxygen when applying the device to the patient.
10. To ensure accuracy of oxygen administration and to monitor the presence of contamination (incorrect gas connected), use an external oxygen monitor to verify the oxygen concentration of the delivered gas.

2.7 Precautions related to storage

This part contains precautions related to storage.
Before use, make sure that the surrounding environment is in order.

WARNING

- Do not store the device in direct sunlight.
- Do not store the device near electric heating appliances.
- Do not use the device in a location where extreme temperature changes occur.
- (Optimal temperature range: −25 °C – 70 °C)
- Do not store the device in a location with high humidity or poor ventilation.
- (Optimal humidity range: 0 % – 95 % R.H)
- Do not install or store the device in a danger of falling.
- Do not store the device in a location that can harm the patient.
- Do not store the device in a location subject to significant impacts or vibrations.
- Take care to prevent dust, especially metallic objects, from getting inside the device.
- In case of failure, do not attempt to disassemble the device. Only service personnel of MEKICS or designated service technicians can disassemble the device for repair and battery replacement. Any attempt to disassemble the device by unauthorized personnel voids the device warranty.
- For storage, turn off the power of the device and disconnect and store the AC power cord.

2.8 Precautions regarding electromagnetic safety

This part contains precautions for electromagnetic safety. Read carefully before using the device. This device is certified to comply with the Electromagnetic Wave Safety Standard for Class IIb medical devices.

WARNING

1. Strong electromagnetic waves and magnetic fields can affect the performance of the device. The HFT700 ventilator is basically designed not to malfunction by blocking low electromagnetic waves in an ordinary environment. Nevertheless, problems like noise, miscalculation, or measurement error may occur when exposed to strong electromagnetic waves. If these problems persist, contact a MEKICS technical service center or an official store.
2. Portable and mobile radio frequency RF communication devices including cables designated by MEKICS must be used within 30 cm of all parts of the HFT700 ventilator. Failure to do so may degrade the performance of the device.



3. Avoid using the HFT700 ventilator near other devices that may affect its performance. If such usage is inevitable, closely monitor the performance of the HFT700 ventilator and other devices.
4. Do not use the device during an MRI procedure. Electromagnetic waves generated from the MRI may affect the values measured by the HFT700 ventilator.
5. Electrosurgical Unit (ESU) and other devices can deliver RF electromagnetic field or current to the patient intentionally. The radio frequencies of the HFT700 ventilator and ESU and other devices can be in the same range at the same time, which, in turn, may cause RF interference with the transducer circuitry. The use of an ESU may interfere with the device's performance and subsequently the patient's ability to breathe. Turning off the ESU removes this interference.

2.9 Fire hazard

WARNING

1. Keep the HFT700 ventilator and oxygen hoses away from combustible materials.
2. Do not use oxygen hoses that are degraded or contaminated with oil or combustible materials.
3. The high oxygen concentration of the gas supplied to the device poses a high risk of fire. If a burning smell is detected, immediately disconnect the oxygen hose from the medical gas pipeline system or oxygen cylinder, and turn off the HFT700 ventilator and disconnect the AC power cord.
4. To reduce the risk of fire, use the HFT700 ventilator in well-ventilated areas away from flammable anesthetics. Do not use the device in a hyperbaric chamber or other similarly oxygen-enriched environments. Do not use the device near an open flame.

2.10 Auxiliary Equipment

CAUTION

1. All accessories and ancillaries holding the qualifications are:
   - Items recommended or supplied by MEKICS;
   - Items are in compliance with IEC 60601-1, 16; and are
   - IEC/ISO certified finished devices



2. Calculation of output values using ancillary devices
   - The use of ancillary devices that the HFT700 ventilator cannot recognize may result in values that are invalid.
   - If there are differences between the values measured with the HFT700 ventilator and those measured with ancillary devices, the HFT700 ventilator values should be given credence.
   - Rely on clinical experience as well as the values measured with the HFT700 ventilator. These values are to ensure the patient's assisted respiration is appropriate.

2.11 Communications interface

WARNING

1. Do not use the USB port to supply power to the device.
2. It is the responsibility of the end user to verify the compatibility of the information transmitted between the portable ventilator and the central monitoring system and its usage.
3. The data provided through the communications interface is for reference only. Decisions about a patient's care should be based on the clinician's observations and experience.
4. The HFT700 ventilator does not provide the following cyber security control, so physical access protection must be ensured. The device should be used in a restricted environment where only authorized users have access.
   - Unauthorized network communication block function
   - Separate access control through general user accounts
   - Data encryption communication
5. The HFT700 system does not use personal data that can be used to identify the patient, so there is little risk of exposure to a cyber-security threat. In case of a cyber-security event, however, stop using the device immediately and report the incident to a Customer Service Center.
6. Only use this device inside a closed network of an institution.

3 About the Device

3.1 Overview

This device is a medical device to provide spontaneously breathing patients with respiratory failure with non-invasive positive pressure ventilation and high-flow nasal cannula therapy.

Intended use

The HFT700 ventilator (CPAP and bi-level Mode) is a medical device to assist patients in breathing. This portable ventilator is intended for spontaneously breathing individuals who require mechanical ventilation. These patient groups also include patients with respiratory failure, chronic respiratory failure, or obstructive apnea.

This device (HF function) assists the patient's respiratory therapy by providing the spontaneously breathing patient with respiratory gas heated and humidified with a higher flow than the patient's ventilatory demand. This includes patients who have had their upper airways bypassed. The flow delivered to the patient may be from 1 – 60 l/min depending on the interface used.

HFT700 is intended for "in-patient use" in hospital or home, medically-used rooms for neonatal to adult.
- Age/Weight: All(>3 kg for HF mode, 20 kg for CPAP & bi-level mode)
- Gender: Male and female
- Healthy: N/A
- Nationally: N/A
- Patient state: N/A
- Intended part of the Body: Mouth and Nose

The device must be used by qualified medical professionals, such as physicians, nurses, and respiratory therapists. In addition, the combinations of the patient's breathing circuit, interfaces (nasal cannula), and other accessories must follow MEKICS's recommendations.

Intended applications

The HFT700 ventilator is an assist ventilator for use in an intensive care unit or ward and home health

care. It delivers therapy gas containing indoor air or high concentrations of oxygen to the patient after being properly warmed and humidified.

The HFT700 ventilator is designed for use under the direction of a physician in a hospital or other institutional settings.

Contraindications

This device, as a portable ventilator for non-invasive positive pressure ventilation, is contraindicated for use when:

- A patient is incapable of spontaneously breathing and shows signs of severe respiratory failure;
- One cannot ensure the patient's free airways or remove secretions;
- There is a risk of inhaling gastric secretion;
- The patient has acute sinusitis or otitis media;
- The patient is allergic to materials in the nasal cannula or has a history of hypersensitivity to them;
- The patient has nosebleeds following pulmonary aspiration; or
- The patient has hypotension.



WARNING

Users must read and understand all the user manual before using the device.

Therapy patient profile

This device is intended to assist the patient in spontaneous breathing and does not provide the required ventilation requirements.

Clinician's judgment is needed, however, as some monitoring functions may be limited depending on the patient's condition.

- Age/Weight: All(>3 kg for HF mode, 20 kg for CPAP & bi-level mode)
- Sex: Male/Female
- Health: N/A
- Nationality: N/A
- Patient's condition: N/A
- Body parts to be contacted: Facial area, nose



WARNING

1. Before applying the device to a patient who has received a tooth implant, make sure that three months have passed since the procedure was performed.
2. Check teeth stability in patients with tooth implants. If there is a wobbly tooth, consult a dentist to decide whether to apply the device or not.
3. When applying the device to the patient with tooth implants, check if there is a therapy recommended by a dentist such as using a dental protective gear.

CAUTION

1. There may be an error in respiratory rate (RR) measurement depending on a patient's breathing capacity during RR monitoring.
2. The SpO_2 monitoring is possible when the patient's perfusion index (PI) is higher than the measurable minimum PI. (See Annex E. SpO_2 Monitoring.)
3. If the inspiratory tidal volume of a patient in a bi-level mode is ≥ 100 ml, volume monitoring (Tidal volume Estimated, Vt est.) is possible.
4. The exact type of nasal cannula must be used in accordance with the patient's condition.
5. The patient's breathing efforts should be higher than the RR detection level measured by the device.
6. The therapy- and alarm setting ranges must be appropriately adjusted by the clinician's judgment depending on the patient type.

NOTE

1. Portable ventilators including high-flow therapy devices are used for adult critical patients or as an intermediate therapy to improve oxygenation in a respiratory care unit and a palliative treatment. Portable ventilators including high-flow therapy devices are increasingly used as they are easy to install and are well tolerated by patients.
2. With the onset of highly contagious diseases affecting the respiratory system, the demand for and use of portable ventilators has grown quickly. All types of portable ventilators including high-flow therapy devices for respiratory use are widely available in hospitals around the world.

User profile

This device must be used under the direction of a clinician and meet the requirement below:

Considerations	Requirements
Education level	• Expert clinician or therapist with the proper credentials
Knowledge level	• Knowledge about clinical diagnosis and respiratory therapy • Recognition and understanding about normal and abnormal situations - Hardware connection and software - Installation status or environment • Understanding the terminology used in the user manual and the device
Linguistic understanding	• Understanding how to use the user manual (English, Korean, Other languages)
Clinical experience	• Education on the principle and effects of a portable ventilator • Curative intent by means of the portable ventilator and information on the patient • Clinical diagnosis or prescription by means of the portable ventilator • Operating state of the portable ventilator • Understanding the user manual

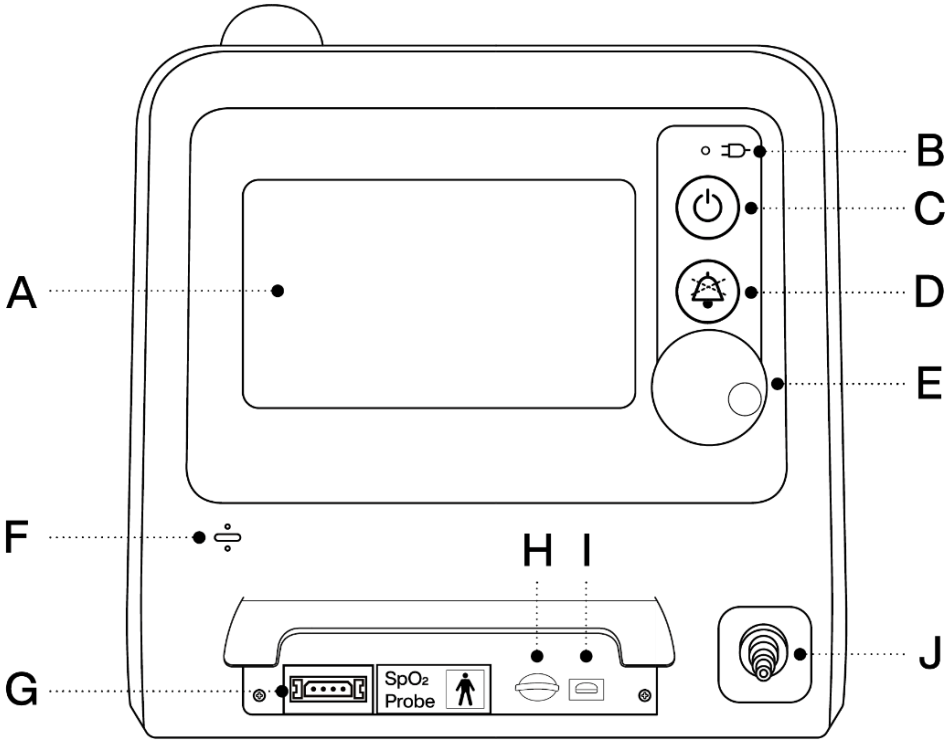
Display

Information on the respiratory therapy of a patient will appear on a 5-inch TFT color LCD screen.
Users can check various measured values such as flow and FiO_2 (Fraction of Inspired Oxygen) in real-time.
In addition, values can be set easily with a touchscreen and a dial.
In the event of alarms, visible alarms appear on the screen.

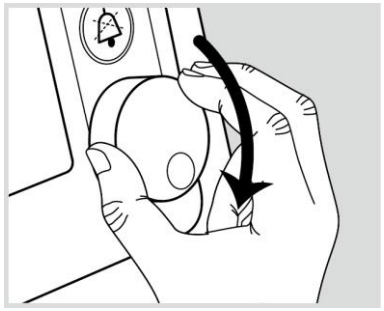
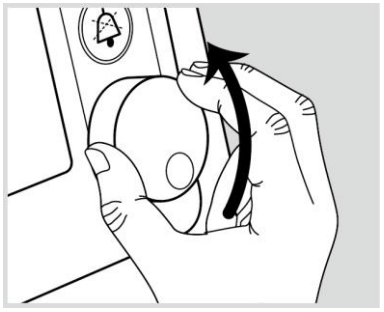
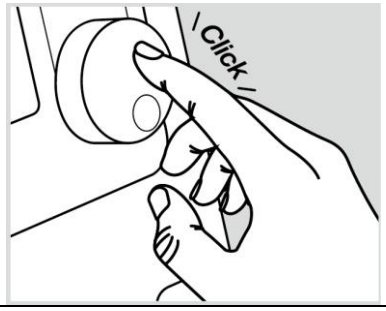
Connecting to external devices

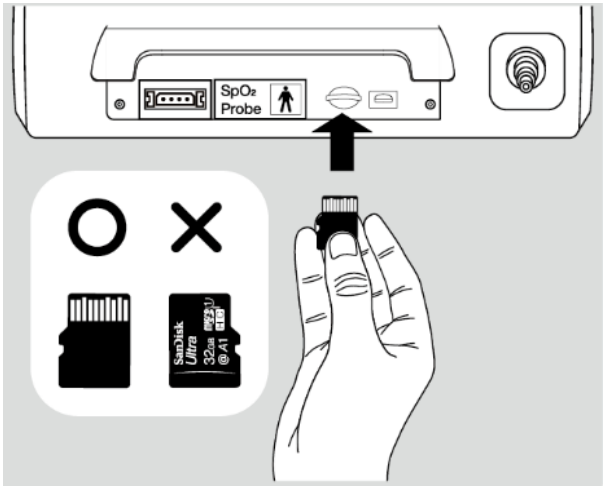
Every accessory, part, and system connected to the device must meet the standard IEC 60601-1.

3.2 Front view



Number	Component	Description
A	LCD	Displays various statuses of the device and the patient.
B	Device Status LED	[When AC power is connected] – Green LED is lit a few seconds after the power is connected [When AC power is not connected (or external power supply mode)] – LED is off [Under treatment] – Blue LED is lit

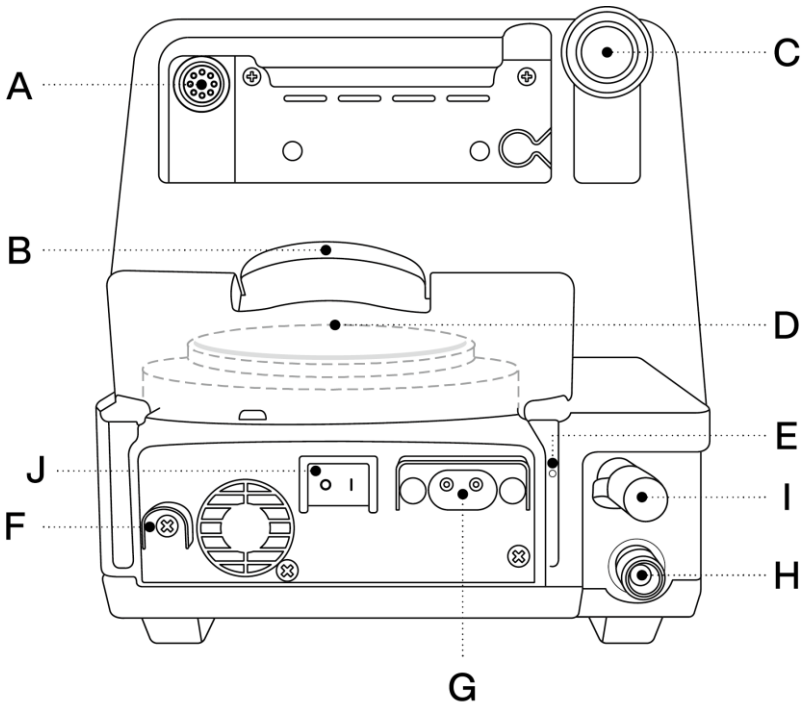
Number	Component	Description
C	Power On/Off button	1. Push and hold the button (about 2 sec) after the green LED is lit to turn the device on after an audible warning is heard. 2. If you push and hold the button (about 2 sec) during therapy, a pop-up saying "Do you want to stop the therapy?" will appear. If you click the "Confirm" button, the therapy will stop. 3. If you push and hold the button (about 2 sec) during the therapy, a pop-up saying "Do you want to turn off the system?" will appear. If you click the "Confirm" button, the device will switch off.
D	Audio Paused button	Turns off the alarm sound for 2 minutes. If you press the button again during the sound-off, the Audio Paused will be cleared.
E	Rotary knob	You can adjust the set points by turning a rotary knob and clicking the menu.  Clockwise -Bottom-up menu search -set point increases  Counterclockwise -Top-down menu search -Set point decreases  Click Press to apply a selected parameter or a value changed in the menu.

Number	Component	Description
F	Speaker	Outputs the alarm and the warning sounds.
G	SpO_2 probe connection terminal	A terminal to connect the SpO_2 probe to measure the oxygen saturation.
H	MicroSD slot	A slot to insert a microSD card to upgrade the mainboard software or to store data. Insert a microSD card upside down as in the figure below. 
I	COM1	A terminal to upgrade a Pneumatic board software (Pneumatic S/W) or to communicate with the PC.
J	Respiratory detection port	This is a port that connects a Respiratory detection line of external accessory to measure respiratory rate of patient. For more details, see "6.2.2 Settings menu."

CAUTION

1. Do not touch the SpO_2 probe connection terminal and USB ports with hands.
2. Do not turn off the device while the SpO_2 cable is connected and these ports are in use.
3. The input pressure range of the respiratory detection port is between −12.5 cmH_2O to +12.5 cmH_2O. Exceeding this pressure range may result in device damage or inaccurate measured values.

3.3 Rear view



Number	Component	Description
A	Heated circuit connector	A terminal to connect the Y cable. The Y cable is for power supply of the heat-wire located in the breathing circuit and for measuring the temperature of the chamber and breathing circuit.
B	Chamber release lever	A lever to connect and disconnect a chamber.
C	Gas outlet	A port to connect a gas outlet that also serves as an anti-bacterial filter that prevents bacteria and impurities.
D	Heat-plate	A heat-plate for warming and humidifying.
E	Reset button	A button to reset the power of the device.
F	AC power cord clamp	A section to fix an AC power cord.
G	AC power Inlet	A terminal to connect an AC power cord.
H	High pressure oxygen inlet	An inlet to connect a high-pressure oxygen hose.
I	Low flow oxygen inlet	An inlet to connect a low flow oxygen, such as Oxygen concentrator or Oxygen generator.
J	AC power switch	AC power On or Off.



WARNING

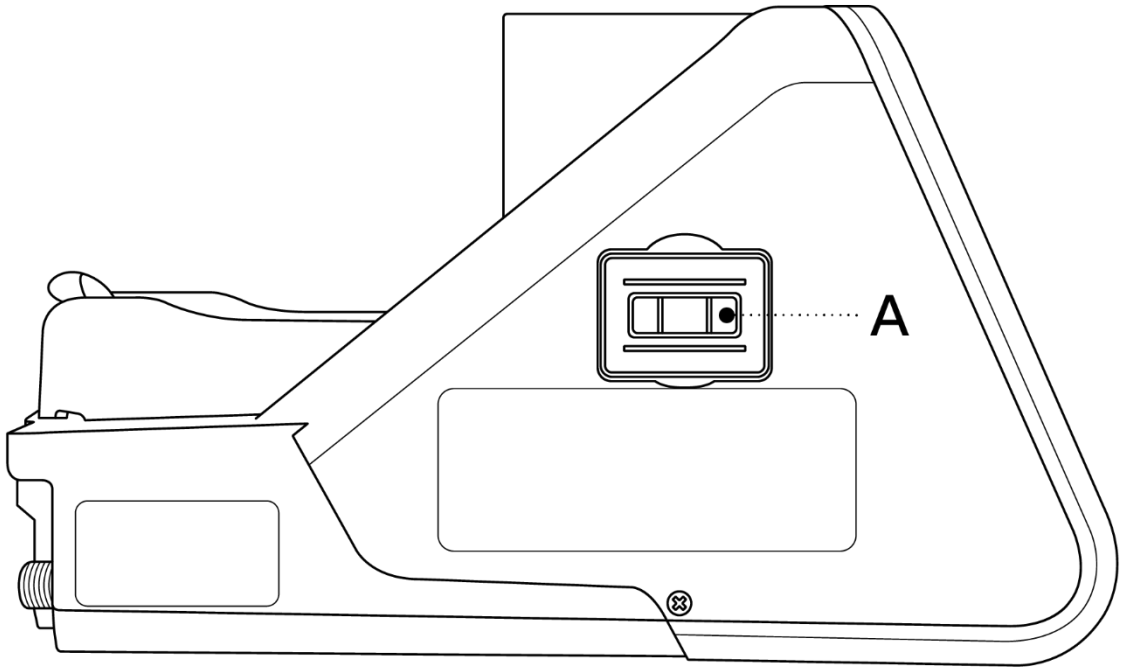
1. The HFT700 ventilator can connect to an oxygen cylinder with a pressure regulator or to a gas pipeline system that meets ISO 7396-1. The oxygen (O2) supply pressure range is from 241.3 kPa to 620.5 kPa (from 35 psi to 90 psi), and the maximum flow is 135 l/min at 344.7 kPa (50 psi).
2. The HFT700 ventilator must be connected to a gas pipeline system that meets ISO 7396-1 for the reason below:
   - If the HFT700 ventilator is installed in a gas pipeline system that does not meet ISO 7396-1, it can exceed the pipeline design flow capacity.
   - If the gas pipeline system does not meet ISO 7396-1, the HFT700 ventilator may interfere with the operation of other devices that use the same gas source.



NOTE

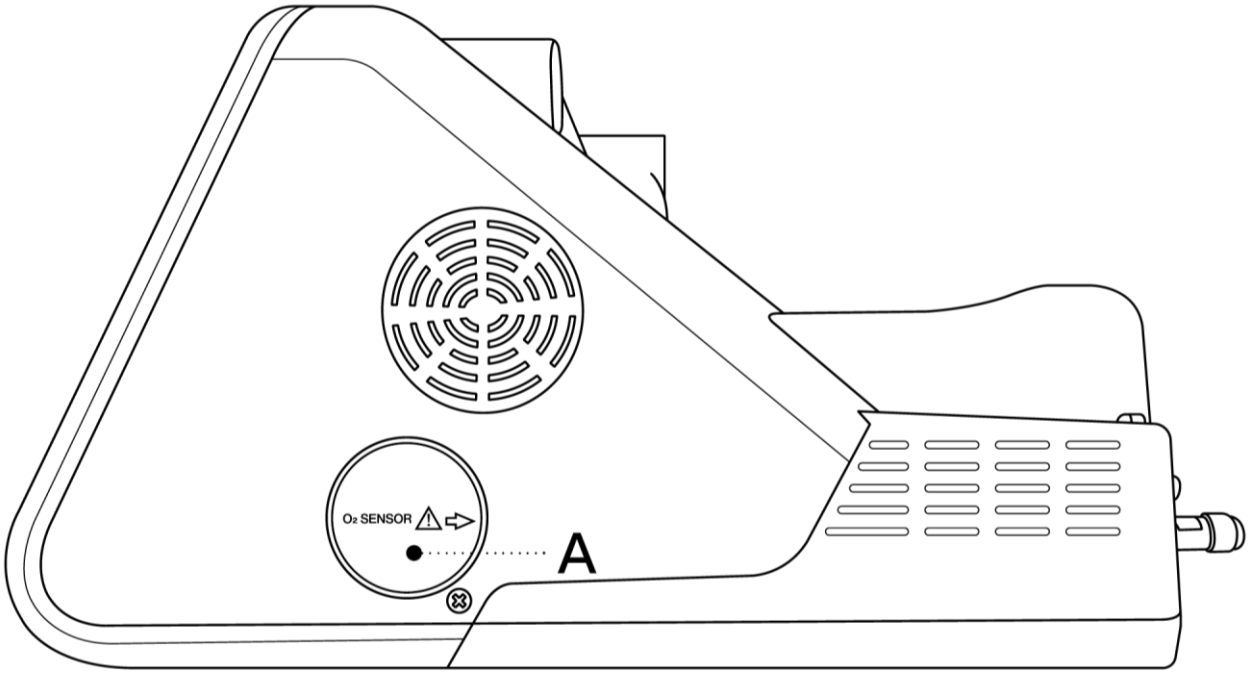
An anti-bacterial filter must be connected to a gas outlet.

3.4 Left side view



Number	Component	Description
A	Air intake filter	Filters alien substances from the inducted air. For the replacement, see "10.2.1 Changing the air intake filter."

3.5 Right side view

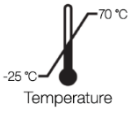
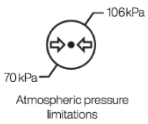


Number	Component	Description
A	Oxygen (O_2) sensor cover	The oxygen (O_2) sensor is integrated. Refer to "10.2.2 Changing the oxygen (O_2) sensor" for replacement.

3.6 Symbols

Below are the descriptions of symbols marked on the device. Check them carefully before using the device.

Printed symbols			
No.	Items	Symbols	Description
1	Device Status LED		Indicates a status such as AC power connection status and Under treatment. * Refer to "3.2 Front view" for more details.
2	Power On/Off button		Turns on or off the device when pressed and held. * Refer to "3.2 Front view" for more details.
3	Audio Paused button		Turns off the alarm sound for 2 minutes.
4	Cautions		Refer to "Cautions" in the user manual before using this device.
5	High temperature		This warning symbol indicates that the humidifier heat plate is hot during or after the operation.
6	Protection of the applied parts		Indicates insulation at human protection insulation level (BF: Body Floating).
7	Protection level against dust and water		Dust: Protected against solid objects bigger than 12 mm. Water: Protected against water sprayed from vertical to an angle of 15 ° or less.
8	Class II device		This is a "double insulated" device.

Printed symbols			
No.	Items	Symbols	Description
9	Refer to the user manual		Refer to the user manual or additional documents before using the device.
10	Manufactured date		Indicates the date of manufacture.
11	Serial number		Indicates the serial number of the device.
12	Manufacturer information		Indicates information about the manufacturer such as name, address, etc.
13	No reuse		Do not reuse this.
14	Disposal precautions		Do not dispose of in normal waste.
15	Humidity limited		Storage humidity limited: From 0 % to 95 % relative humidity, non-condensing
16	Temperature limited		Storage temperature limited: From −25 °C to 70 °C (From −13 °F to 158 °F)
17	Atmospheric pressure		Storage atmospheric pressure limited: From 70 kPa to 106 kPa (From 10.2 psi to 15.4 psi)
18	Keep dry		Protect from excessive humidity and keep covered when not in use.

Printed symbols			
No.	Items	Symbols	Description
19	No hook		Transportation packaging. Do not use a hook to lift freight or a package.
20	Installation orientation		Indicates the correct upright orientation of the freight.
21	Fragile		Transportation packaging. Handle with care. It is a fragile package.
22	Load limit per number		Transportation packaging. Do not stack more than the designated number of devices.
23	Recyclable		Indicates a recyclable material.
24	Medical device		Indicates a medical device.
25	Unique device identifier		Indicates a unique device identifier.
26	Cart warning		Do not push the device attached to a cart.
27	No sitting		Do not sit on the surface.
28	No heavy load		Do not put a heavy object on the surface.

Printed symbols			
No.	Items	Symbols	Description
29	MR Hazard		Use the ventilator outside the MRI scan room.
30	Hangable weight		Indicates the weight of a hangable object.
31	United States	Rx ONLY	U.S. federal law stipulates that this device can be sold only to a physician or under the direction of a physician.

4 Device Preparation

4.1 Pre-use checklists

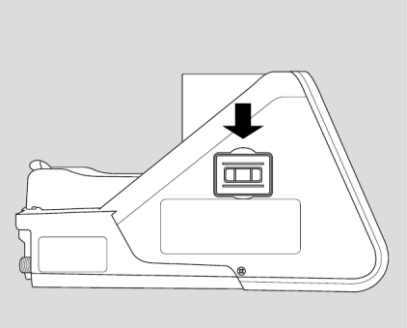
When you first use the device, you must:

1. Check that all basic parts are included, and accessories are corresponding to the specifications that you ordered.
   (See Annex D. "Basic Composition/Optional Accessories.")
2. Check that an air intake filter and an oxygen sensor are attached to the device.
3. Be careful not to expose the device to external impacts during installation and when moving.

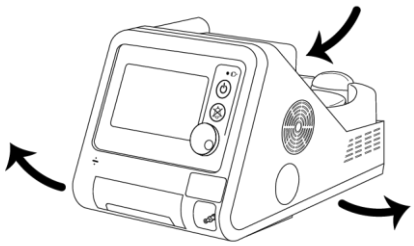
4.2 Placing the HFT700 ventilator

1. Do not place the device on a slope or an unstable surface. It must be installed lower than the patient.
   - Eliminate all risk factors of device malfunction or failure and patient injury.
   - Make sure that condensed water does not reach the patient.

2. Be careful that the air intake filter is not blocked.



3. Take care that the inlets/outlets for the air circulation inside the device are not blocked.

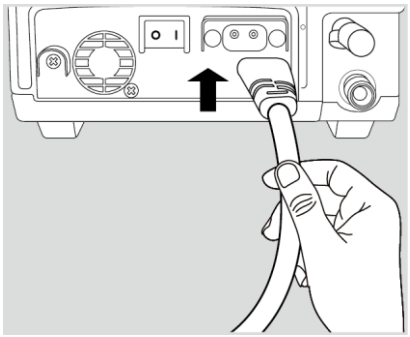


WARNING

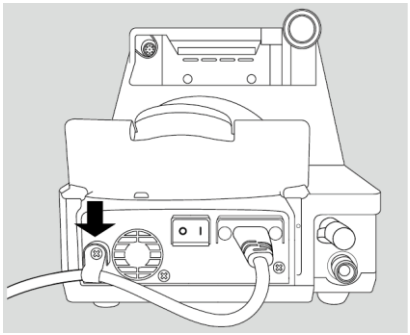
Refer to "2.5 Precautions related to use environment" and check that all requirements are met.

4.3 Power supply

This device uses a 220V AC power cord. Verify the type of country-specific power cords independently.
AC power inlet is on the back of the device.



Connect the AC power cord to the AC power inlet and turn on the AC switch.



After connecting the AC power cord to the device, hold it with an AC power cord clamp and fasten it with a screw.

WARNING

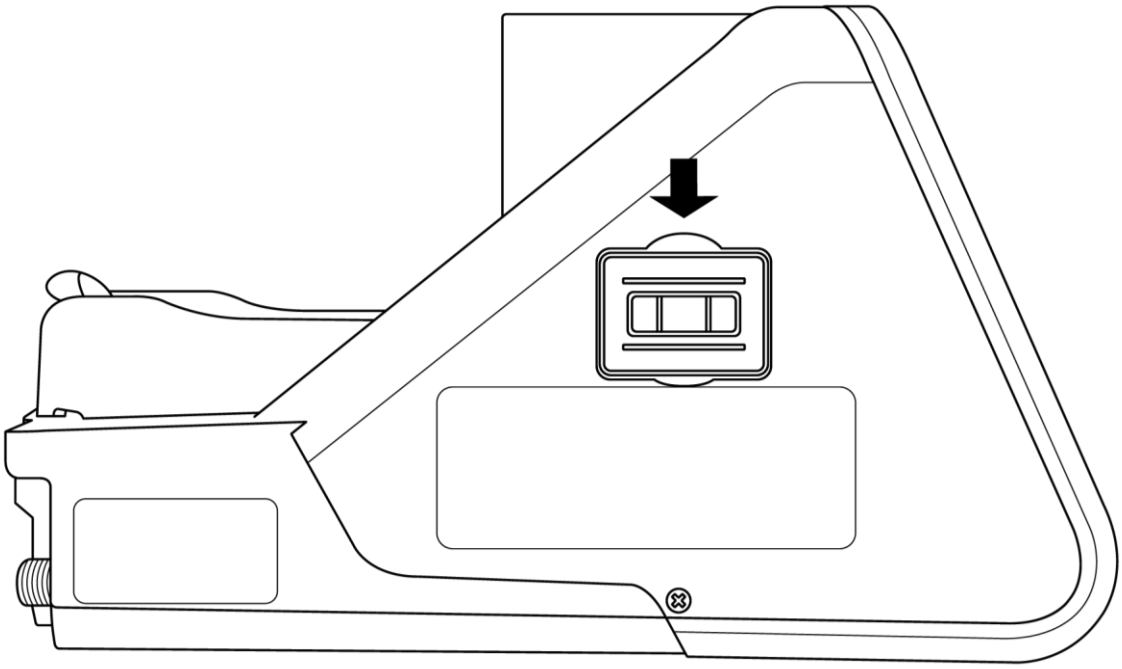
1. Before connecting an AC power cord to the device, verify that the power supply is 100 – 240 VAC.
2. An unstable power supply may result in device damage or patient injury.
3. If the power cord is damaged, make sure to change it before use.
4. When you connect the AC power to the device and turn on the AC switch, the power LED on the front will be illuminated in green.
5. To prevent unintended AC power cord disconnection, before turning on the HFT700 ventilator, make sure to use the correct power cord supplied by MEKICS at all times and hold the cord with the power cord clamp.
6. The AC power cord is designed to prevent inadvertent disconnection from the HFT700 ventilator under 100 N.

NOTE

The HFT700 ventilator can be used with an external power supply that is optional accessary. This external power supply is used to supply power to the device when the AC power is not connected or when the patient is moving. For more details, see "6.4 External power supply".

4.4 Installing an air intake filter

Before using the device, check that an air intake filter is installed.
When replacing the air intake filter with a new one, refer to "10.2.1 Changing an air intake filter" and change the air intake filter according to the instructions.

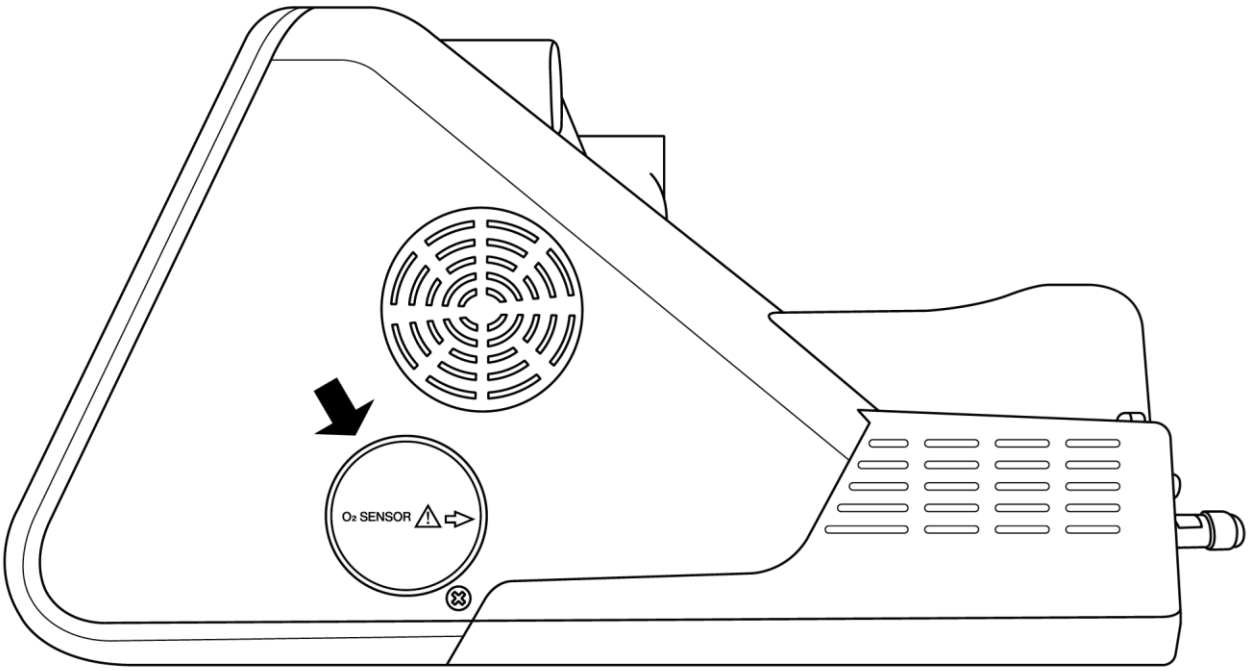


WARNING

1. If you operate the device without an air intake filter, foreign matters may enter the device, causing a malfunction.
2. Check the filter condition periodically according to the instructions in "10.2.1 Changing an air intake filter."

4.5 Installing an oxygen (O_2) sensor

Before using the device, use the FiO_2 measurement function to check that the oxygen sensor operates normally.
When replacing the oxygen sensor with a new one, refer to "10.2.2 Changing oxygen sensor" and change the oxygen sensor according to the instructions.



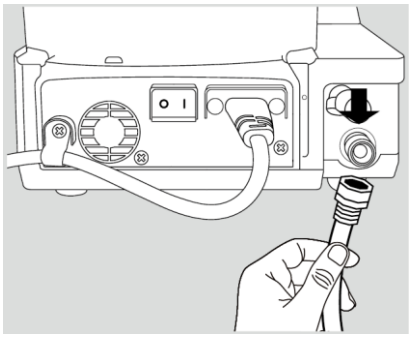
WARNING

1. After changing oxygen and before using the HFT700 device, make sure to check the FiO_2 measurement functions and set points.
2. If the device operates without the oxygen sensor or is damaged, it will display different output values from the set points.
3. Oxygen density is measured in the gas supply line of the device. If there is an incorrect connection or air leaks, the oxygen density delivered to the patient may differ.

4.6 Supplying oxygen

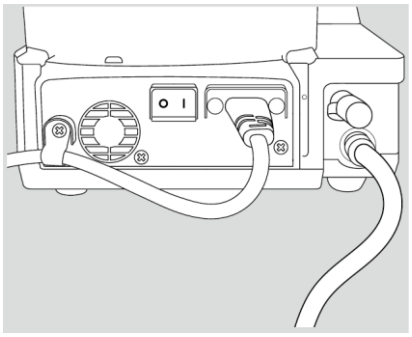
Oxygen is supplied through the high-pressure oxygen inlet or the low flow oxygen inlet.

[High pressure oxygen inlet]



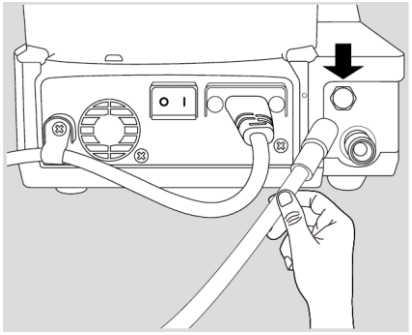
Connect a high-pressure oxygen hose to the high-pressure oxygen inlet.

Oxygen may also be supplied through a central oxygen supply system in a hospital or a high-pressure oxygen cylinder.



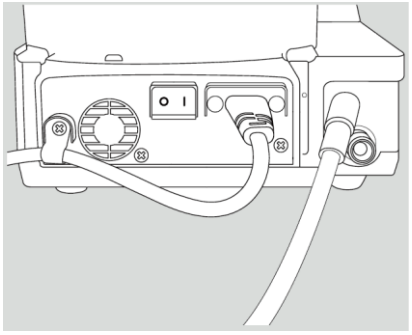
Input pressure range: From 241.6 kPa to 620.5 kPa (From 35 psi to 90 psi)
(*warning 3)

[Low flow oxygen inlet]



Connect a low pressure oxygen hose to the low flow oxygen inlet.

Oxygen may also be supplied through an oxygen concentrator or oxygen generator.



Input pressure range: 60 kPa (8.7 psi).

WARNING



1. Connect the HTF700 ventilator only to an appropriate medical-grade oxygen source.
2. To reduce the risk of hypoxia, connect only oxygen to the high-pressure oxygen input port at the rear of the device.
3. To reduce the risk of fire, do not use a high-pressure oxygen hose that is worn or contaminated with combustible materials like grease or oil.
4. The HFT700 ventilator generally uses a central oxygen supply system in a hospital to supply the high-pressure oxygen. When using a high-pressure oxygen cylinder (internal pressure is very high) in combination with a reducing valve or a pressure regulator, however, check that there is no oil or gas leakage from connections to eliminate explosion hazard.
5. When using it with a high-pressure oxygen cylinder, close the cylinder valve tightly before connecting to or disconnecting from a high-pressure oxygen hose from the HFT700 ventilator.
6. Verify that oxygen inlet pressure is within the appropriate range of 241.6 – 620.5 kPa (35 – 90 psi).
7. A high-pressure oxygen hose must be positioned to avoid getting entangled with people or surrounding installation structures when being used or moved.

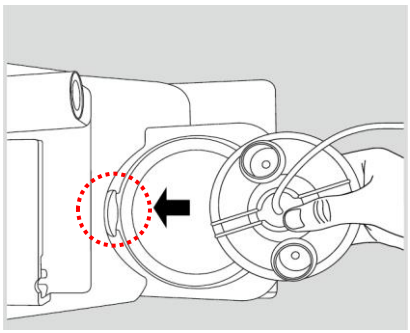
WARNING

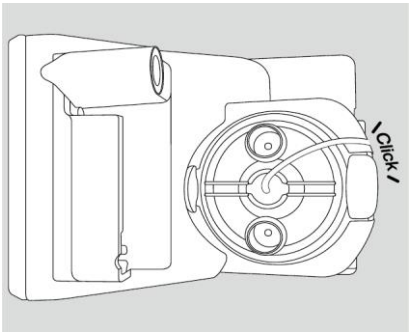


Explosion hazard: Do not use this device near combustible gases. The oxygen-enriched environment accelerates flammability.

4.7 Installing the chamber

When installing the chamber, insert the chamber to where indicated in the figure below and press down until it clicks to lock it.





WARNING

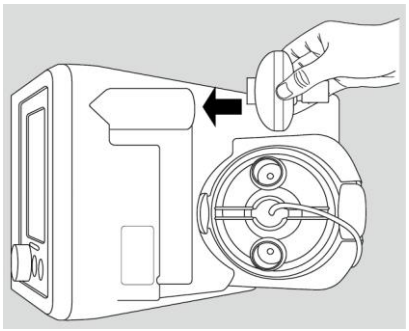
1. Overfilling the chamber with water may cause an operating malfunction, so keep the water level under the upper limit of the chamber.
2. Do not touch the heat plate or the chamber during or immediately after operation. You can be burned from contact with the heat plate or chamber because they are very hot during and immediately after operation.

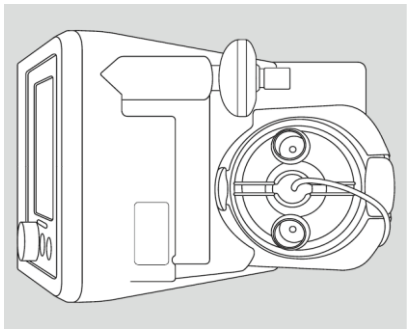
CAUTION

The size of the chamber may vary depending on suppliers. A chamber from some suppliers may not be possible to use or can operate incorrectly in the HFT700 ventilator. Only use parts supplied or approved by MEKICS.

4.8 Installing an anti-bacterial filter

This device uses two types of filters for the patient's safety:
One is an air intake filter and the other is an anti-bacterial filter that is connected to the breathing circuit.





WARNING

1. When using the HFT700 ventilator on the patient, you need to use an anti-bacterial filter.
   This symbol means a disposable device that is not recyclable.
2. Only use anti-bacterial filters supplied or approved by MEKICS. If you want to use a 3rd-party device, check with MEKICS or its official agency to confirm compatibility. MEKICS is not responsible for any problems caused by using nonstandard items.
3. Check the packaging and the exterior of the device and verify that there is no fault before using the device.
4. We recommend changing the anti-bacterial filter after treating each individual patient or seven days after using it.
5. A new anti-bacterial filter must be used for each patient.

4.9 Connecting the breathing circuit and parts

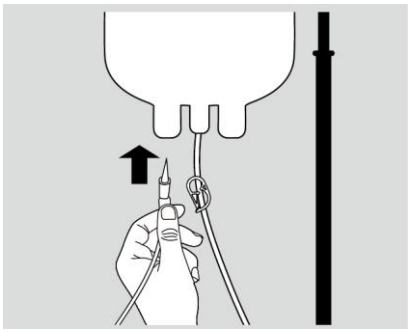
CAUTION

Ensure that sterilized distilled water in the chamber is not depleted in order to provide continuous humidification.

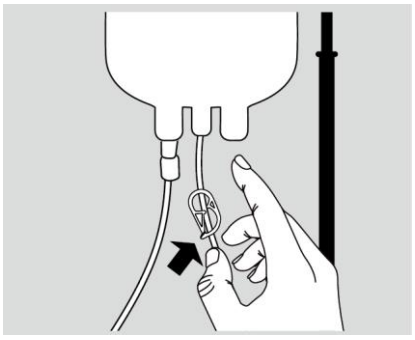
CAUTION

1. Before opening the sterile packaging of breathing systems, check that
   - The Breathing System is the correct type
   - The Breathing System is compatible with the Respiratory Device
   - No parts are broken or missing
   - The packaging is not open or damaged
   - The expiry date has not passed.
2. Do not remove from packaging of breathing systems until time of use.

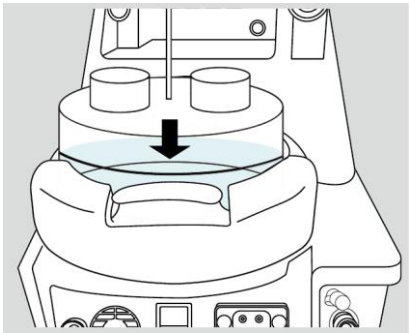
[Step 1]



Hang a fluid bag on a stand (at +60 cm height above the top of the device) and connect the fluid line of the humidifying chamber to the fluid bag.

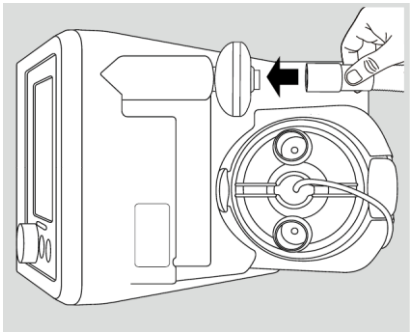


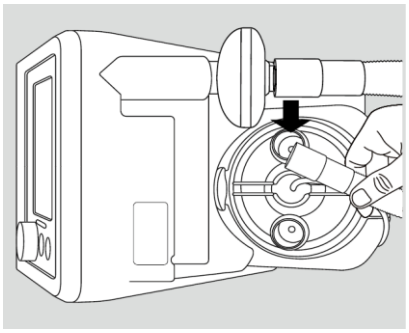
Open a clip and verify that the sterilized distilled water flows into the chamber.



The sterilized distilled water will fill up to the appropriate level marked on the chamber.

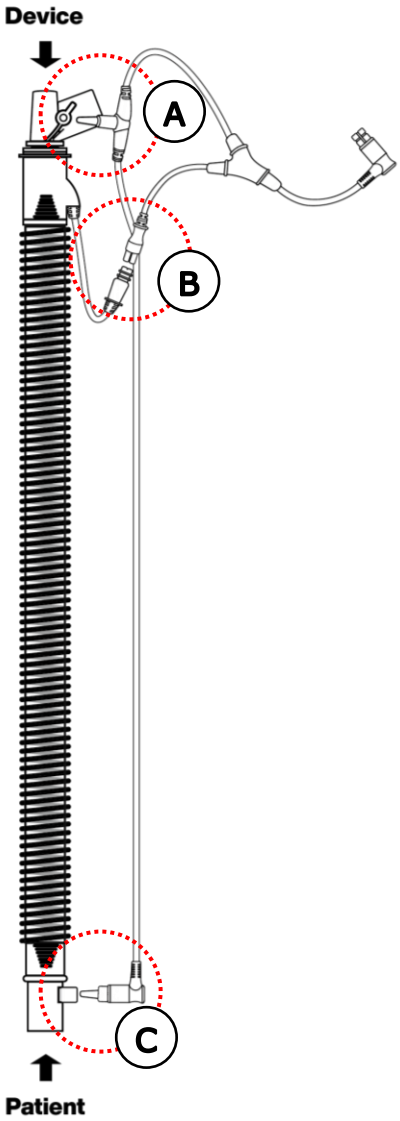
[Step 2]





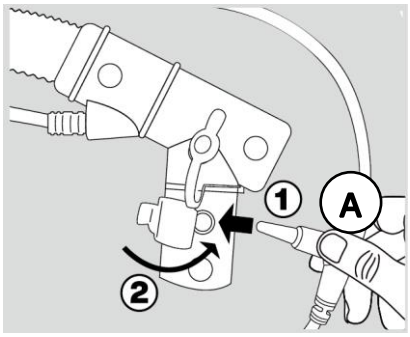
Install the breathing circuit between an anti-bacterial filter and the chamber.

[Step 3]

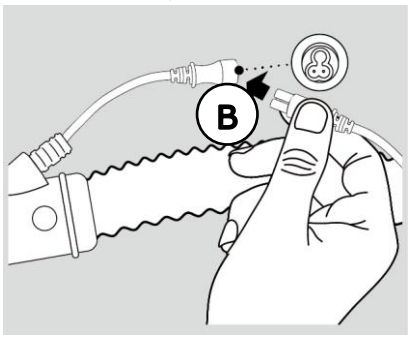


Connect the Y cable to the breathing circuit.
The Y cable consists of a 9-pin connector that connects to the product, the heat-wire power supply cable (3-pin), and temperature probes (T-shaped and L-shaped).

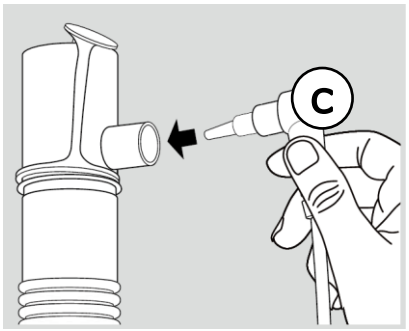
A) Connect the T-shaped temperature probe to the tip of the breathing circuit where a curved connector is attached. Once connected, fasten a locking device.



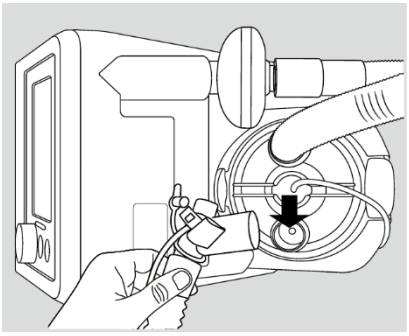
B) Connect the heat-wire power supply cable (3-pin) to the heat-wire power cable of the breathing circuit.



C) Connect the L-shaped temperature probe to the tip of the breathing circuit where a straight connector is attached.

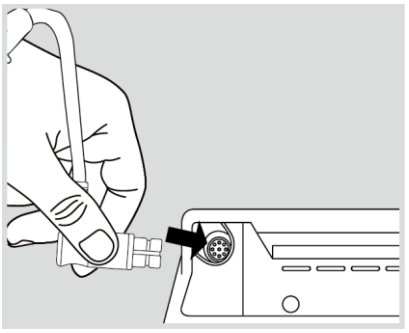


[Step 4]



Connect the curved connector part of the breathing circuit to the other port.

[Step 5]



Connect the 9-pin connector of the Y cable to the connection terminal of the heated breathing circuit at the back of the device.

NOTE

For more details about the accessory composition, see "Annex D Basic Composition/Optional Accessories."
Make sure to install an anti-bacterial filter by connecting it to a gas outlet.

4.10 Connecting the patient interface

Once installing the breathing circuit, connect the patient interface appropriate to the mode and functions to be used.
For the usage of individual accessories, refer to the manufacturer's instructions.

WARNING

1. In any event, never modify the mask, nasal cannula, or breathing circuit.
2. Do not use the breathing circuit and accessories for long periods.
3. It is possible to be severely harmed by overheating of the breathing circuit and mask, nasal cannula, or accessories.
4. Do not use any accessories, parts, and breathing circuits not approved by MEKICS. Doing so may influence the device's therapeutic effect or injure the patient.
5. If flow values are measured too high or too low or the gas pressure is too high during use of the device, check for a defect in the accessories themselves or if there is gas leakage or blocked parts in the accessory connections.

4.10.1 HF Function

Use a nasal cannula suitable for the age and nostrils size of the patient when connecting the breathing circuit.
In HF function, nasal cannula and T-piece(Tracheostomy-piece, tracheostomy interfaces) are supported.

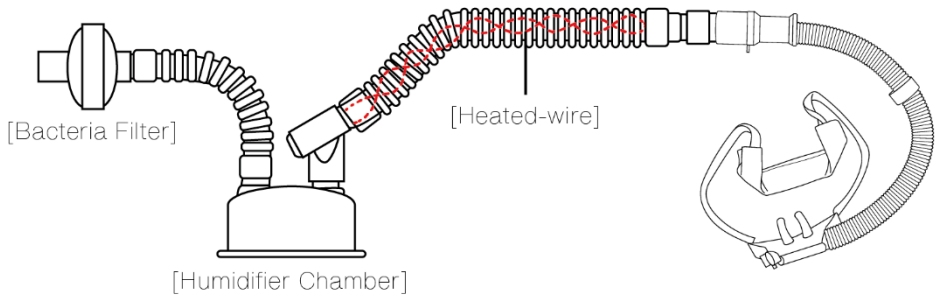


Figure 4.1 The composition of the non-invasive patient breathing circuit system including a heated wire and the nasal cannula

4.10.2 CPAP, bi-level mode

Connect a mask suitable for the patient's face size when connecting the breathing circuit.

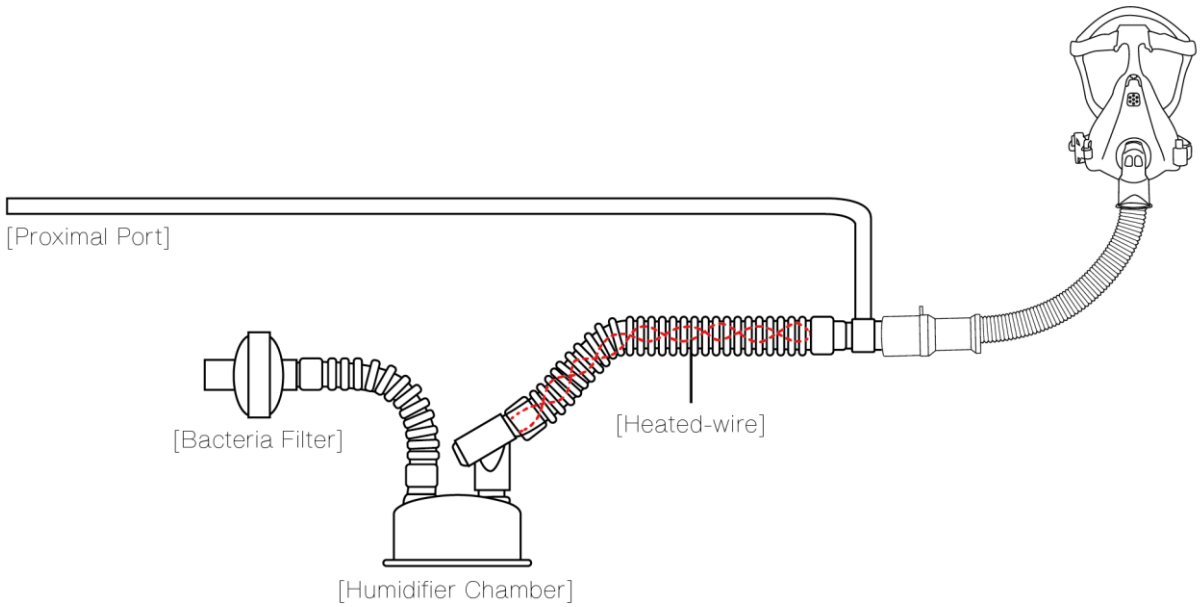


Figure 4.2 The composition of the non-invasive patient breathing circuit system including a heated wire and the vented mask with an anti-asphyxia valve

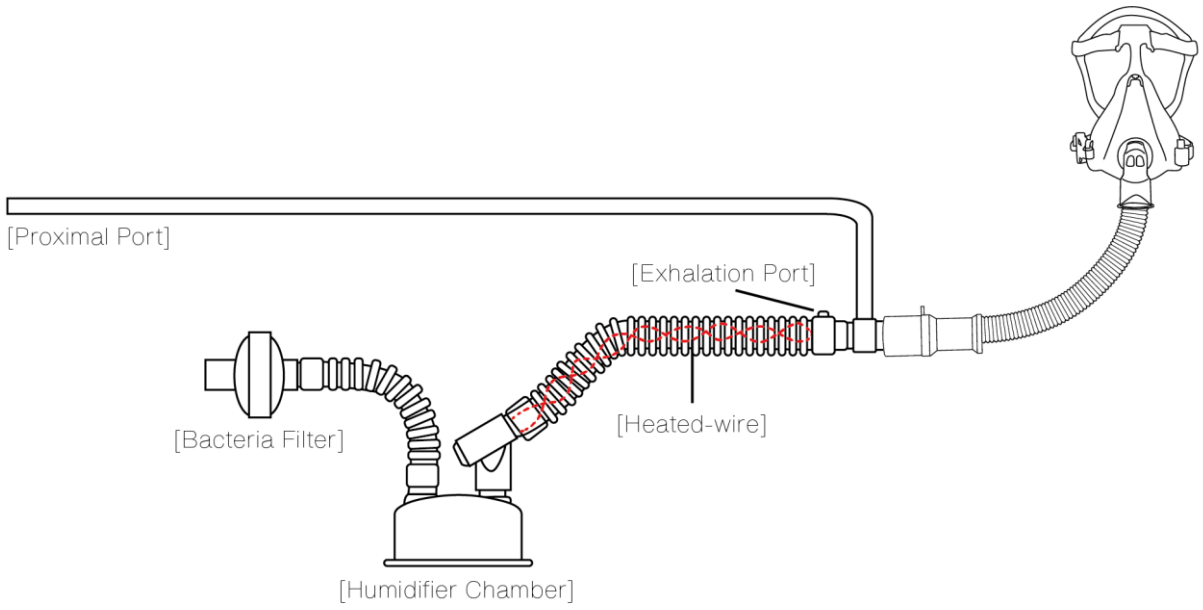
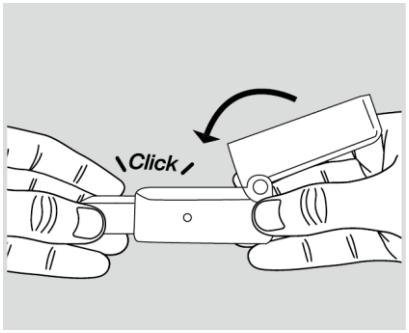


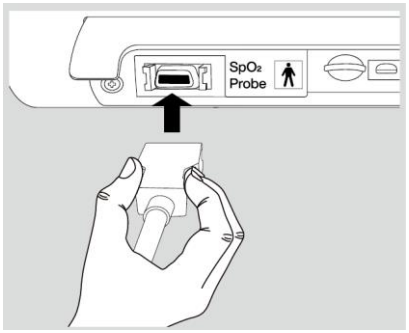
Figure 4.3 The composition of the non-invasive patient breathing circuit system including a heated wire and the non-vented mask with an anti-asphyxia valve and exhalation port

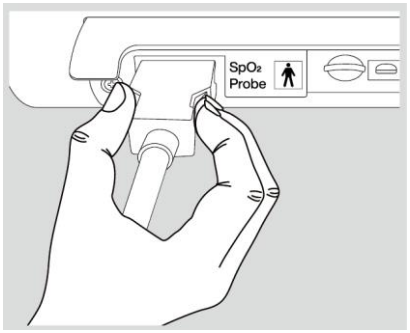
4.11 Connecting a SpO_2 probe sensor

Connect a SpO_2 probe sensor and SpO_2 probe extension cable.

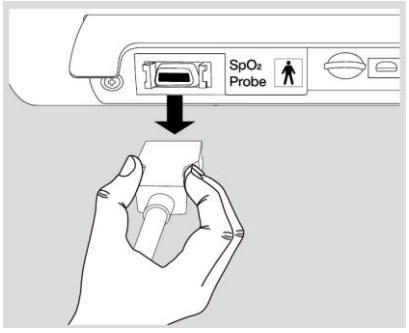


For connecting, press the lever of the SpO_2 probe extension cable to the device until it clicks in place.





To disconnect, press the lever and pull out the cable.



CAUTION

The SpO_2 probe sensor and the probe extension cable from the same manufacturer as the SpO_2 module must be used. If using a SpO_2 probe or a probe extension cable from a different manufacturer from the SpO_2 module in the device, a severe system error may occur or an incorrect monitoring value may be displayed on the screen.
Make sure to configure and use the device as below.

- MEKICS SpO_2 module: Use the MEKICS SpO_2 probe sensor and the extension cable dedicated to the HFT700 ventilator.
- MASIMO SpO_2 module: Use the MASIMO SpO_2 probe sensor and the extension cable.

CAUTION

1. When using a SpO_2 probe sensor, do not tighten excessively and cause pain to the patient. Also, use care when locating the patient cable to avoid restriction or entanglement with the patient.
2. If the measured values in the screen are determined to deviate from the tolerance stated in the user manual, cross-measure the value again using another device for inter-comparison.
3. Use only accessories approved by MEKICS. Using unapproved accessories may degrade the device's performance.

5 Turning On / Off

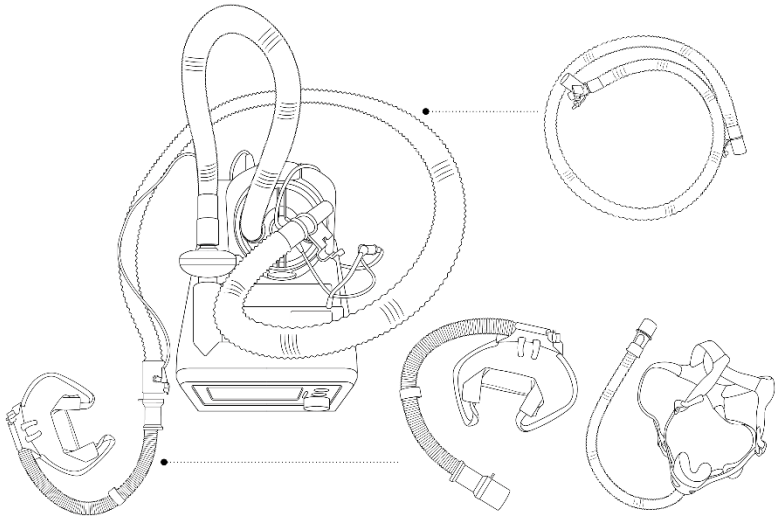
CAUTION

If the device stops during use and does not operate normally, press the reset button to restart the device. Reset button is on the back of the device. For more details, see "3.3 Rear view."

5.1 Turning on the device

[Step 1]

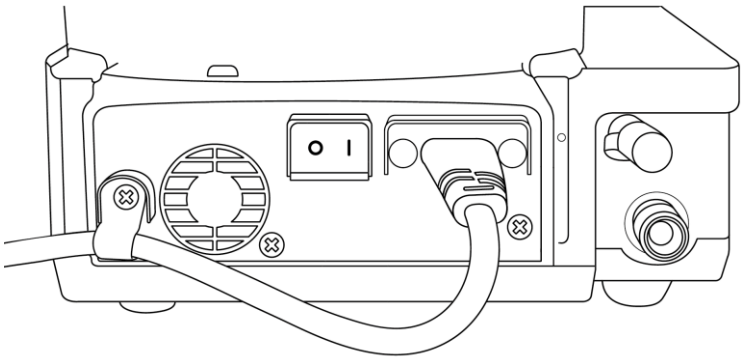
Prepare the breathing circuit and accessories.



Refer to "4 Preparation" and connect the breathing circuit and appropriate accessories.

[Step 2]

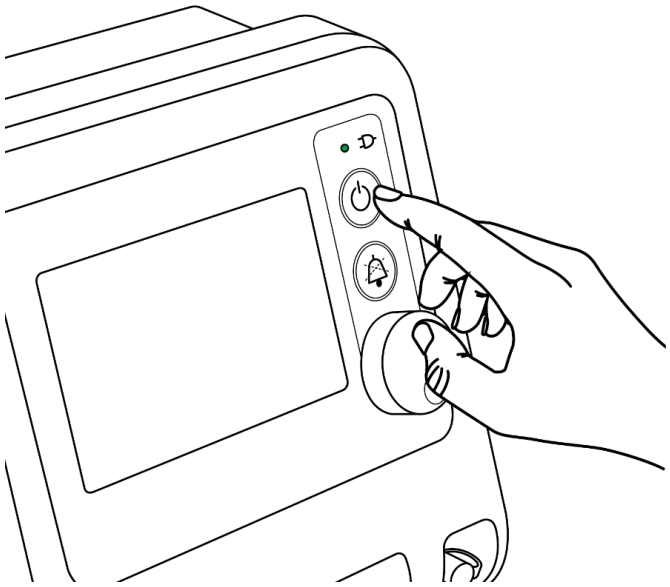
Connect the AC Power Cord.



Connect the AC power cord to the AC power outlet and turn on the AC switch. After a few seconds, when the device is ready to be turned on, the device status LED will be illuminated in green.

[Step 3]

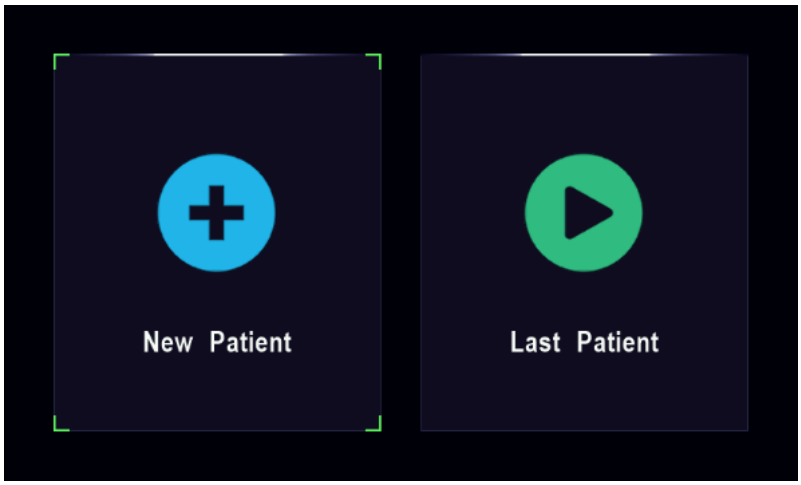
Turn on the device.



Press and hold the Power On/Off button for about 2 seconds to turn on the device. Then, one short alarm sound will be emitted and the system will be 100 % booted up within 10 seconds after the software loading screen is displayed. When the system is completely booted, the patient selection screen will be displayed.

[Step 4]

Basic screen after turning on the system

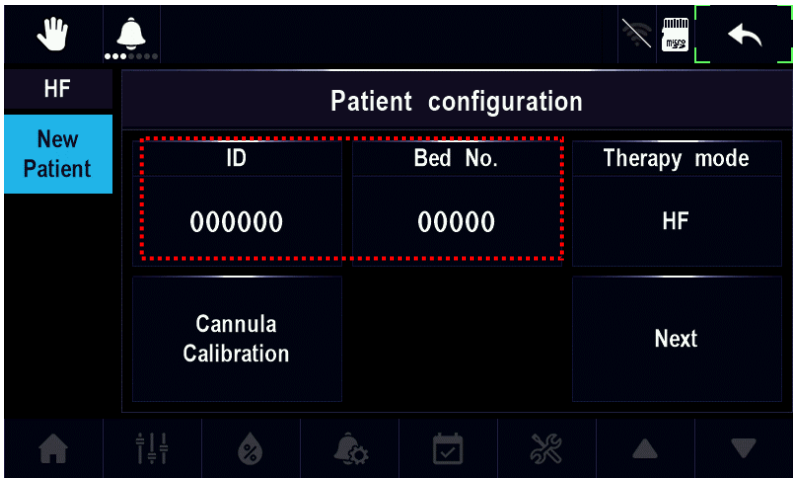


If you select [New Patient], the Patient Settings screen appears.

If you select [Previous Patient], the monitoring screen appears. Here, every setting is maintained at the last saved set points.

[Step 5]

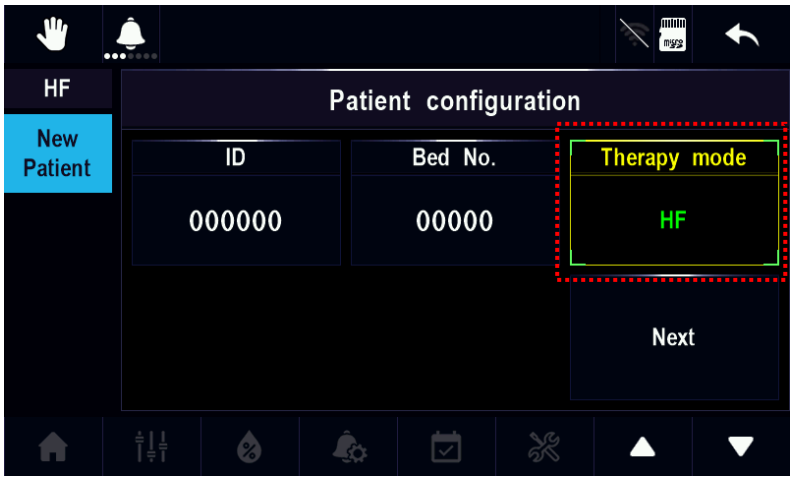
Enter the patient information.



You can enter an ID and a bed number.

[Step 6]

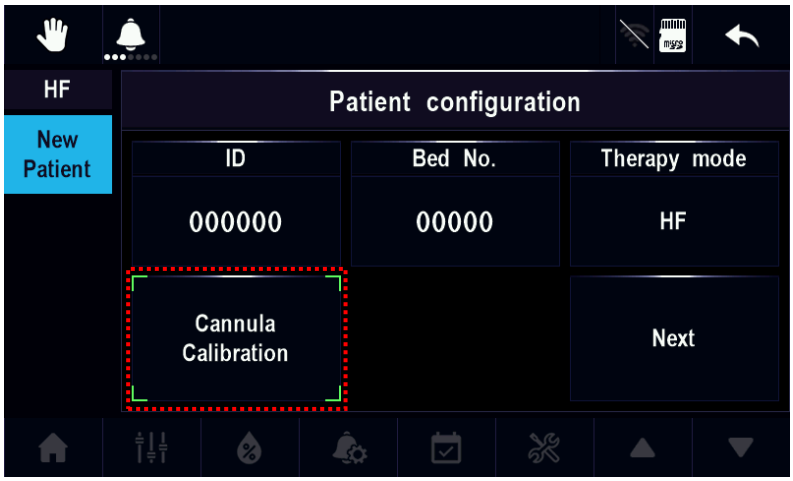
Select a therapy mode.



Click and activate the [Therapy Mode] button and use the rotary knob to change the therapy mode and click the button again to display a pop-up on the screen saying "Do you want to change to a therapy mode?" If you select the [Confirm] button, the therapy mode is changed.
Go to the next step by clicking the [Next] button.

[Step 7]

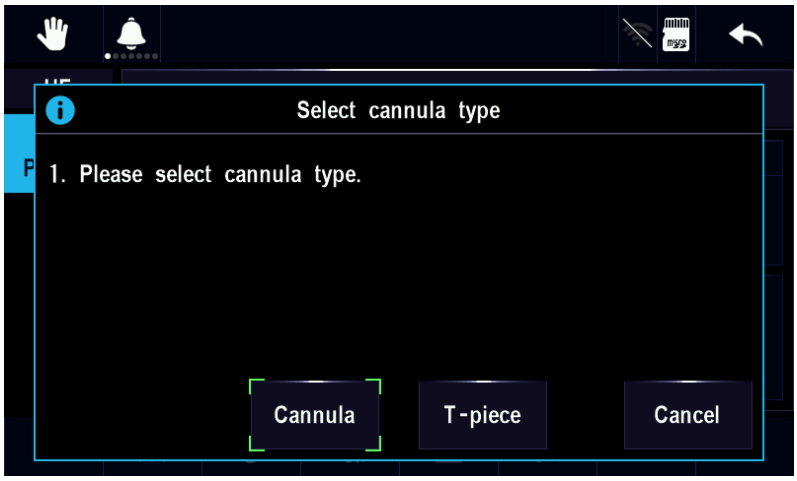
Calibration (cannula/breathing circuit)



You can perform calibrations of the nasal cannula or the breathing circuit that is currently installed.
HF Function: Cannula calibration
CPAP & bi-level mode: Circuit calibration

[Step 8]

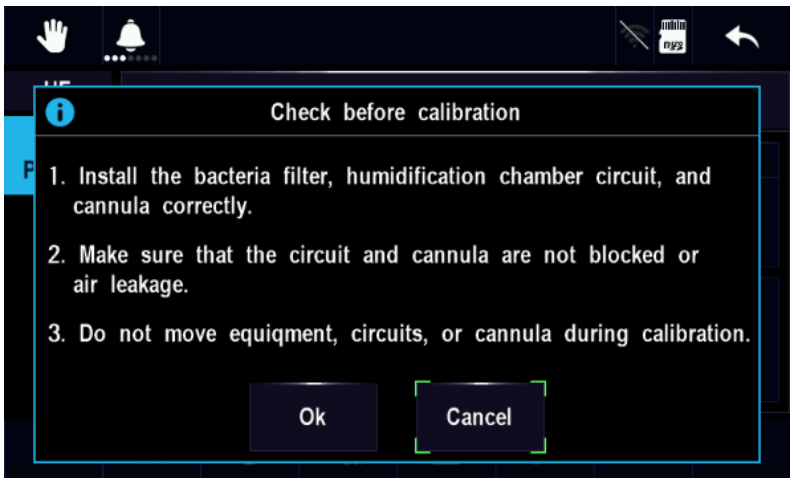
Select a nasal cannula type. (HF function only)



If you select the nasal cannula calibration in the HF function, select a nasal cannula type in the next step.

[Step 9]

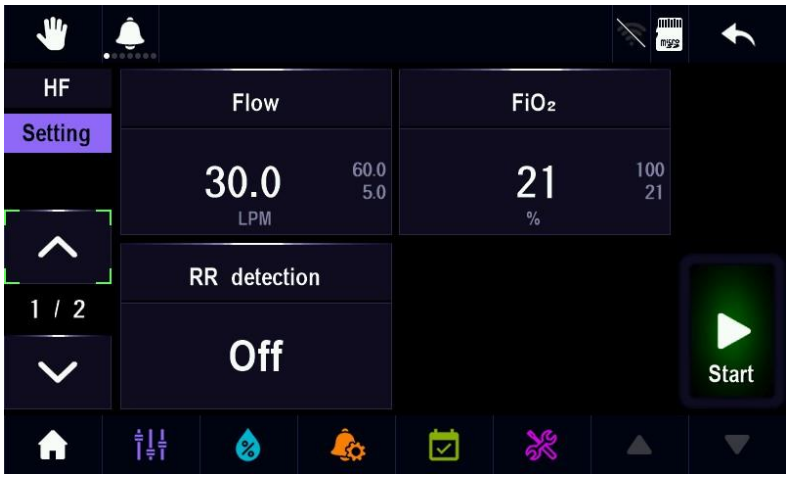
Perform a calibration.



A notice will be displayed on the screen. If you click the [Confirm] button here, a calibration is performed and the calibration status is displayed on the screen. Touch the screen after the calibration is completed to close the pop-up.
Once the calibration is completed, go to the next step by clicking the [Next] button.

[Step 10]

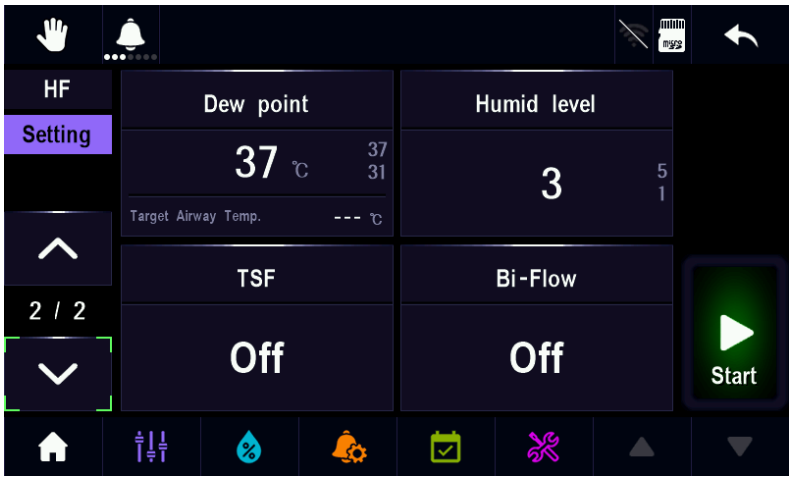
Setting



You can check or change the default values of a therapy. If you click a parameter, the selected parameter is activated as shown in the figure. At this time, you can use the rotary knob to change the set points. Adjust to the desired value and click the dial.

[Step 11]

Settings screen (1)



In the Settings screen, you can press the [Page Move] button as shown to change the Settings page. Setting items vary according to the therapy mode.

[Step 12]

Starting therapy



If you click the [Start] button on the right of the screen after adjusting all set points, a pop-up window to confirm the therapy start appears. Pressing the Confirm button will start the therapy.

5.2 Turning off the device

[Step 1]

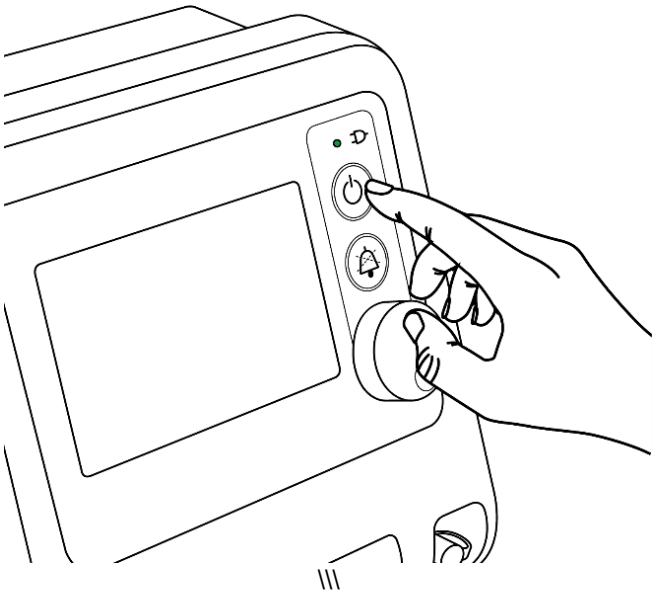
Ending Therapy



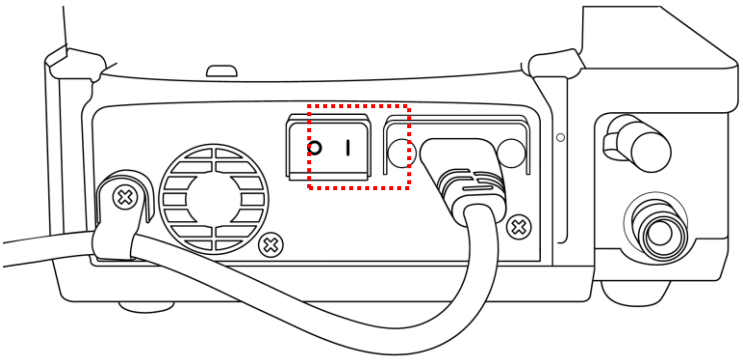
If you press the [Therapy Stop] button (or press and hold the Power On/Off button), a pop-up window to confirm the therapy stop appears. If you click the "Confirm" button, the therapy will stop.

[Step 2]

Ending Therapy



If you press and hold the Power On/Off button for about 2 seconds, a pop-up window is displayed to confirm that power is off. If you want to turn the system off, select [Confirm].



Turn off the AC power switch on the back of the device.
(Do this step only after performing above step "Power Off")

5.3 5.3 Abnormal power off

If when AC loss occurs due to abnormal power off, the system operates as follows after AC power is resupplied.

[AC loss during the therapy]

- After power is resupplied, the system will automatically turns on and start therapy with the last set value.

[AC loss during the stop of therapy]

- After power is resupplied, the system will automatically turns on.

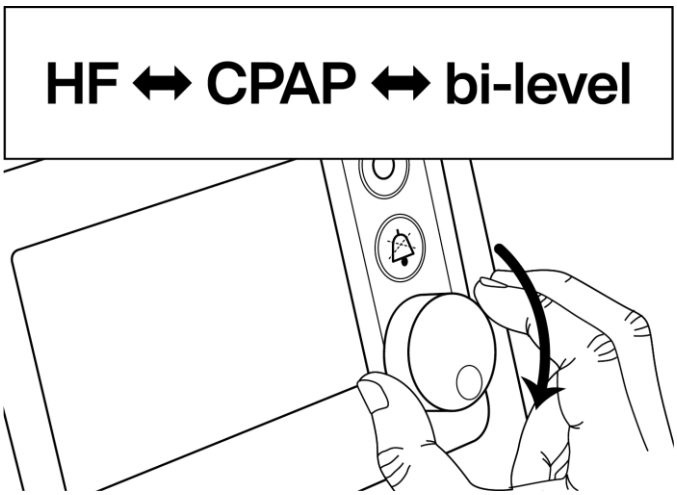
6 How to Use

6.1 Setting therapy modes and functions

You can set the therapy modes and functions on the monitoring screen.
If you touch the part shown below, the screen is activated so you can change the therapy mode.



In this state, you can use the rotary knob or the buttons on the bottom of the screen to change the therapy modes and functions.



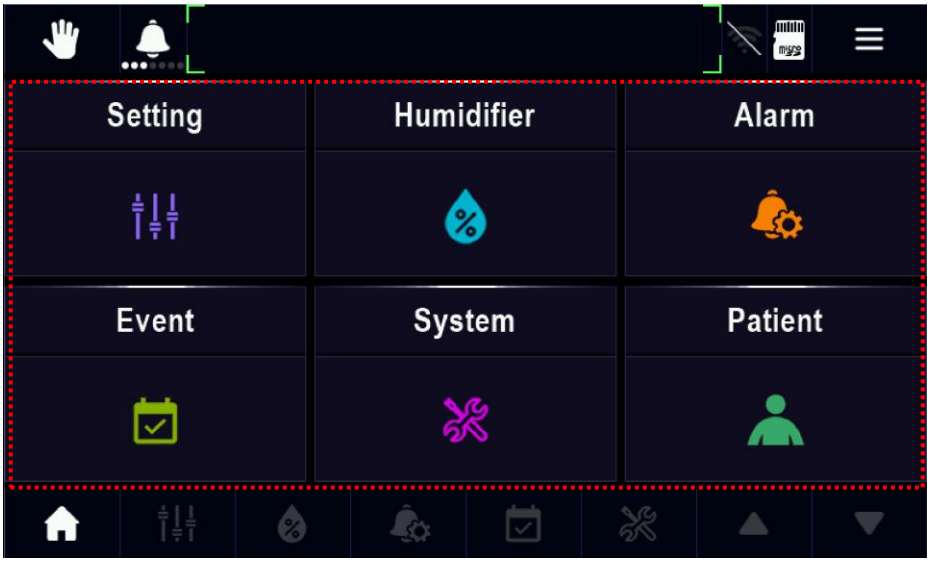
You cannot change the therapy modes and functions during therapy.

6.2 Main menu

Press a main menu button on the main monitoring screen to display the main menu screen.



The main menu consists of Settings, Humidifier, Alarm, Event, System, and Patient in order. Click the desired item to display its submenu screen.


Setting
Humidifier
Alarm
Event
System
Patient

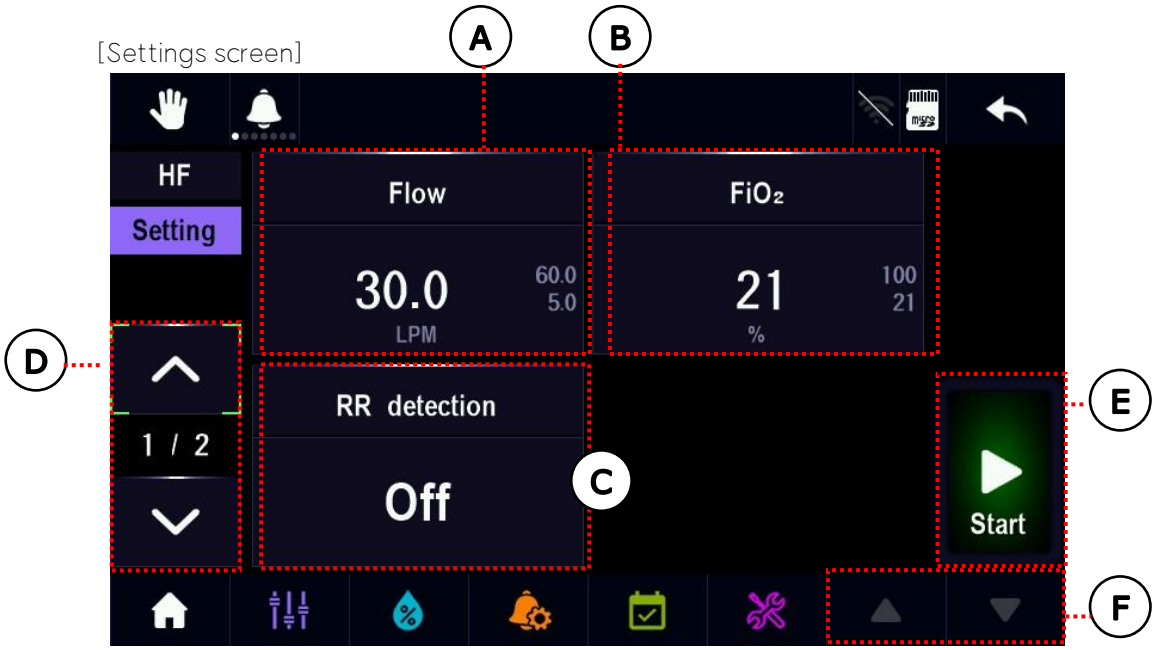
6.2.1 Symbols on the main menu

No.	Items	Symbols	Description
1	Main Menu		Located in the top right of the monitoring screen. Can enter the main menu. (See "7.2.1 Symbols and shortcuts of the monitoring screen.)
2	Exit		Exits the menu.
3	Home button		Moves to the monitoring screen.
4	Setting		Can set the therapy values.
5	Humidifier		Can set the values and perform the monitoring related to the humidifier.
6	Alarm		Can set the values related to the alarm.
7	Event		Can check the events such as alarm, changes to set points, and therapy start/stop.
8	System		Can set the system such as a calibration or device configuration.
9	Patient		Can set the ID and Bed No. and perform a calibration related to the selected therapy.

6.2.2 Settings menu

A submenu related to the therapy settings is displayed on the screen. For more details, see "A.5 Setting parameter specifications."

[Settings screen]



[Common items of the Settings menu]

No.	Items	Description
A	Parameters	Can check the current set point of each parameter.
B	Parameter Setting Change	Click and activate a parameter. Change the set points by turning and clicking the rotary knob in the activated state. Or, use the [Set Point Change] button to change the values and click the parameters to change.
C	RR detection	Can select the respiratory rate detection Off or On. When RR detection is off, the RR value is displayed as "---" and no related breathing alarms are operating
D	Page Move	Move to a page of the menu.
E	Therapy Start/Stop button	If you click the [Therapy Start] button after completing the settings, the therapy starts with the changed set points.
F	Set Point Change (Increase/Decrease)	It is activated when the set point is changeable. Tap: The set point changes by one. Press and hold: The set point changes continuously while pressing the button.

6.2.2.1 HF Function Setting Parameters

HF Function Setting Parameters		
Page	Items	Description
1 / 2	Flow	Sets the flow delivered to the patient. The flow setting range is from 1 to 60 l/min and the appropriate maximum flow of the installed nasal cannula changes according to the calibration result of the nasal cannula. The setting condition changes in accordance with the maximum flow value as below.
		Setting Range: 1 to 8 l/min or 5 to 40 l/min or 5 to 60 l/min The increase or decrease interval of the flow settings varies according to the maximum flow. • If the maximum flow is 8 l/min or less, 0.5 l/min • If the maximum flow is 40 l/min or more, 1 l/min
	FiO_2	Can set the oxygen density provided to the patient.
		Setting Range: Low Flow, 21 %; 25 to 100 %
	RR detection	Can select or deselect RR detection type. If the "RR detection" is selected to Off, it displays "---" and the related respiratory alarm does not work. See * Precautions and Notes.
		Setting Range: Off, On

HF Function Setting Parameters			
Page	Items	Description	
2 / 2	Dew point	Can set the dew point temperature which is the baseline of the humidification volume. The dew point temperature is a reference temperature to the absolute humidity of the supplied gas.	
		Setting Range:	HF: 31℃ to 37℃ CPAP & bi-level: Off, 31℃ to 37℃
	Humidity level	Can set the humidity level of the respiratory gas delivered to the patient. This is the concept of relative humidity at the set dew point. The higher the level, the higher the relative humidity of the delivered gas.	
		Setting Range:	1 to 5
	Bi-Flow [Optional]	Can select On or Off of the Bi-Flow function. For more details, see "9.1 Bi-Flow [HF function]."	
		Setting Range:	Off, On
	TSF [Optional]	Can select On or Off of the TSF function. For more details, refer to "9.3 TSF [HF function]."	
		Setting Range:	Off, On

CAUTION

When selecting accessories, keep in mind the following:



A) Accessories must satisfy all the medical device regulations related to patient safety.
B) Use only accessories supplied or approved by MEKICS.
C) MEKICS is not responsible for any consequential problem caused by using accessories or parts not manufactured or approved by MEKICS.
D) For more details about accessories, contact the service provider or MEKICS.

6.2.2.2 CPAP Mode Setting Parameters

CPAP Mode Setting Parameters		
Page	Items	Description
1 / 3	CPAP	Sets the positive pressure airway pressure.
		Setting Range: 4 to 20 cmH_2O
	FiO_2	Can set the oxygen density provided to the patient.
		Setting Range: Low Flow, 21 %; 25 to 100 %
	Inspiratory support pressure (PA(+))	Can set the (positive) pressure value of the gas supplied to the patient during the inspiratory time in a spontaneous breath.
		Setting Range: Off, 1 to 3 cmH_2O
	Expiratory pressure relaxation (PA(−))	Can set the (negative) pressure value of the gas supplied to the patient during the expiratory time in a spontaneous breath.
		Setting Range: Off, −3 to −1 cmH_2O
2 / 3	Trig. Level	Can set the trigger flow that detects the spontaneous breath of the patient during inspiratory.
		Setting Range: 3 to 20 l/min
	Rise time	Can set the pressure rise time that reaches the target pressure.
		Setting Range: Fast, Medium, Slow
	Auto Start	As the CPAP mode is a therapy mode that has a target pressure, a lot of flow will be supplied to reach the airway pressure if the patient interfaces, e.g., a mask, do not adhere to the patient. During Auto Start (patient's inspiratory effort detection auto start), no flow is supplied to the patient even if you press the [Therapy Start] button. This will then start the flow supply from the point of detecting the patient's spontaneous breath. This setting cannot be changed during therapy.
		Setting Range: Off, On

3 / 3	Dew point	Can set the dew point temperature which is the baseline of the humidification volume. The dew point temperature is a reference temperature to the absolute humidity of the supplied gas.	
		Setting Range:	HF: 31 ℃ to 37 ℃ CPAP & bi-level: Off, 31 ℃ to 37 ℃
	Humidity level	Can set the humidity level of the respiratory gas delivered to the patient. The humidity level is the concept of relative humidity at the set dew point. The higher the level, the higher the relative humidity of the delivered gas.	
		Setting Range:	1 to 5

6.2.2.3 bi-level Mode Setting Parameters

bi-level Mode Setting Parameters		
Page	Items	Description
1 / 4	Trig. Type	The bi-level mode provides three sub-respiratory therapy modes of S (Spontaneous breath mode), S/T (Spontaneous breath/Time mode), and T (Time mode). These respiratory therapy modes are classified according to how inspiration is started.
		Setting Range: S / T, S, T
	Volume Guarantee (VG)	This function is to change the target from pressure to volume during inspiration. It can be applied in S, S/T, and T modes, changing the inspiratory target set point from the inspiratory positive airway pressure to the tidal volume. The tidal volume supply is limited only by the set pressure limit.
		Setting Range: Off, On
	Trig. Level	Can set the trigger flow that detects the spontaneous breath of the patient during inspiration. Trig. Applied only in the S, S/T mode types.
		Setting Range: [Trig. Type: S, S/T] 3 to 20 l/min [Trig. Type: T] Inactive
	FiO_2	Can set the oxygen density provided to the patient.
		Setting Range: Low Flow, 21, 25 to 100 %

bi-level Mode Setting Parameters		
Page	Items	Description
2 / 4	Vi (VG "On" only)	Sets the tidal volume. Must be set according to the prescription of the clinician.
		Setting Range: 100 to 2,000 ml
	Upper Pressure Limit (VG "On" only)	Maximum airway pressure allowable to achieve the Vi. If the airway pressure reaches here before the tidal volume is supplied, the supply of the tidal volume is limited to this point. Must be set according to the prescription of the clinician.
		Setting Range: 10 to 45 cmH_2O
	PA(-)	Can set the (negative) pressure value of the gas supplied to the patient during the expiratory time in a spontaneous breath.
		Setting Range: Off, -3 to -1 cmH_2O
	EPAP	Can set the expiratory positive airway pressure.
		Setting Range: 4 to 20 cmH_2O

bi-level Mode Setting Parameters		
Page	Items	Description
3 / 4	Ti	Can set the IPAP time during the mandatory breathing.
		Setting Range: 0.3 to 3.0 s
	RR	[Trig. Type: S/T] If there is no spontaneous breath during the set RR time, initiate the mandatory breath. [Trig. Type: T] Initiate the mandatory breath at the set RR time. [Trig. Type: S] The S mode is a therapy mode driven by the patient's spontaneous breath, so the RR and Ti setting items are inactivated.
		Setting Range: [Trig. Type: S/T, T] 2 to 60 /min [Trig. Type: S] Inactive
	Rise Time	Can set the pressure rise time that reaches the target pressure.
		Setting Range: Fast, Medium, Slow
	Auto Start	As the bi-level mode is a therapy mode that has a target PIP, a lot of flow will be supplied to reach the airway pressure if the patient interfaces, e.g., a mask, do not adhere to the patient. During Auto Start, no flow is supplied to the patient even if you press the [Therapy Start] button. This will then start the flow supply from the point of detecting the patient's spontaneous breath. This setting cannot be changed during therapy.
		Setting Range: Off, On

Bi-level Mode Setting Parameters			
Page	Items	Description	
4 / 4	Dew point	Can set the dew point temperature which is the baseline of the humidification volume. The dew point temperature is a reference temperature to the absolute humidity of the supplied gas.	
		Setting Range:	HF: 31 to 37 ℃ CPAP & bi-level: Off, 31 to 37 ℃
	Humidity level	Can set the humidity level of the respiratory gas delivered to the patient. This is the concept of relative humidity at the set dew point. The higher the level, the higher the relative humidity of the delivered gas.	
		Setting Range:	1 to 5
	Backup ventilation	This function becomes active in the S / T and S modes and is operated when apnea occurs. If the patient's spontaneous breath is detected while the backup ventilation function is run, the backup ventilation function is stopped and automatically converted to S/T or S mode which is the previous set point.	
		Backup ventilation	IPAP: Can set the inspiratory positive airway pressure. Setting Range: 4 to 40 cmH_2O Ti: Can set the IPAP time during mandatory breathing. Setting Range: 0.3 to 3.0 s RR: Initiate the mandatory breath at the set RR time. Setting Range: 4 to 60 /min



NOTE

Before starting the therapy in the bi-level mode, verify the backup ventilation set points.

6.2.3 Humidifier menu

Can check or change the set point of the dew point temperature or the humidity level.
Displays the connection status of cables or sensors and the status related to the humidifier's operation.
This device runs the humidifier according to the set points only when all the conditions are normal for the patient's safety.



Items	Description
A	Can set the dew point. When the therapy is in process, the airway temperature calculated according to the dew point set point is displayed on the bottom. If you click the screen, the set point display is activated. Change the set points by turning and clicking the rotary knob in the activated state. Or, use the [Set Point Change] button to change the values and click the parameters to change. At the start of therapy, the target airway temperature is displayed.
B	Can set the humidity level. The humidity level can be selected in the range of 1 to 5. The higher the value, the more humidification. If you click the screen, the set point display is activated. Change the set points by turning and clicking the rotary knob in the activated state. Or, use the [Set Point Change] button to change the values and click the parameters to change.
C	Displays the connection status of the airway temperature sensor.
D	Displays the power connection status of the breathing circuit heat wire.
E	Displays the chamber installation status.

Items	Description
F	Displays the connection status of the chamber temperature sensor.
G	Displays the status of the temperature sensor of the humidifier's heat plate.
H	Displays the current airway temperature.
I	Displays the temperature of the current chamber.
J	Displays the temperature of the current humidifier's heat plate.

WARNING

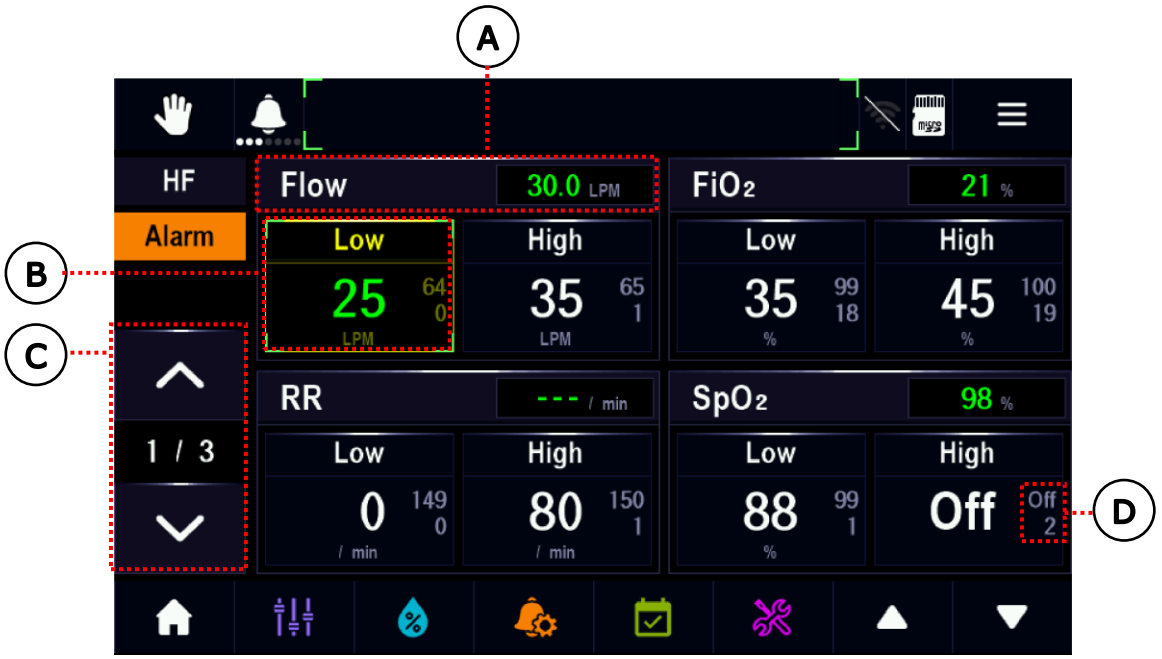
1. If the airway of the humidifier is blocked, note that it can cause a lower flow supply than the set point and influence the density of the supplied oxygen.
2. Do not add accessories not listed in the instructions for use of the humidifier or accessories to the humidifier. Using incorrect accessories may influence the therapeutic effect or injure the patient.
3. Do not use the HFT700 ventilator at an altitude above 3,000 m or outside a temperature of 18 °C – 26 °C. Using the humidifier outside of this temperature range or above this altitude can affect the quality of the therapy or injure the patient.
4. To prevent the possibility of inadequate humidification, pay close attention to the humidifier's functioning when operating the HTF700 ventilator at an ambient temperature > 26 °C. The device warms the air delivered to the patient above ambient temperature, which may impair the humidifier's performance.

CAUTION

1. The HFT700 ventilator runs the humidifier according to the set humidity level and dew point temperature only when all the conditions related to the humidifier are normal. If you set the dew point temperature off, every humidifying action stops, and the "Airway Temp. High (or Low)" alarm is not triggered.
2. The airway temperature displayed on the screen is the temperature measured with the temperature probe(L-shaped) installed on the tip of the breathing circuit. The airway temperature displayed on the screen may differ from the patient's airway temperature according to a nasal cannula or the type of the indoor environment.
3. If the ambient temperature is low and the flow set point is high, the humidification may not be enough to reach the set humidity level. If so, reduce the set flow value.

6.2.4 Alarm menu

Displays the alarm setting parameters that can be set according to the therapy mode. For the alarm list for each mode, see "A.8 Alarm specifications."



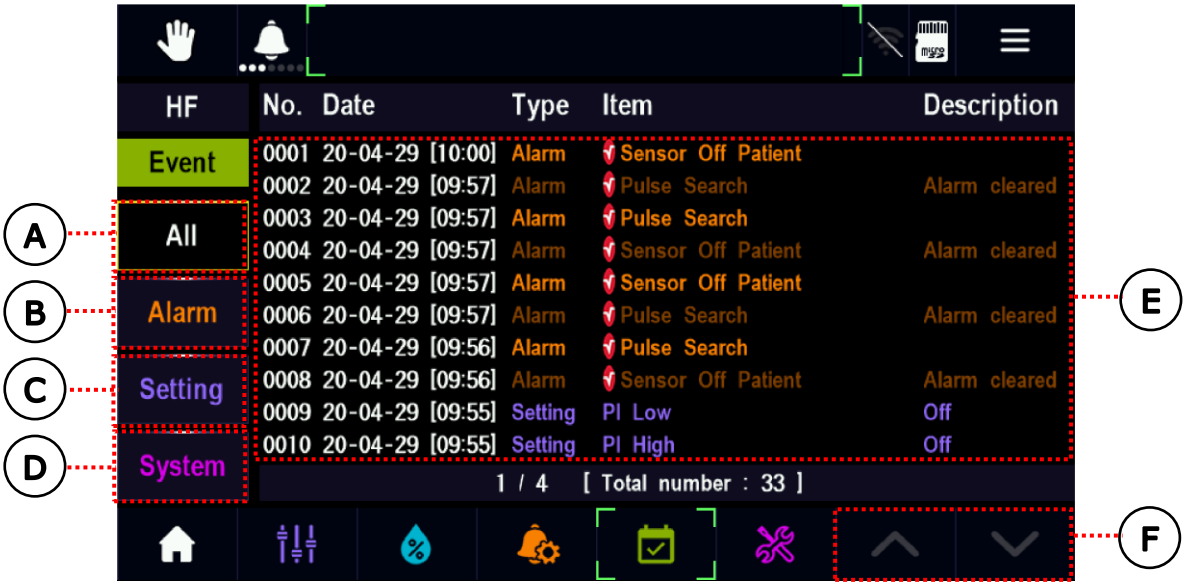
No.	Items	Description
A	Parameter	Can check the parameter types and the related monitoring values.
B	Parameters Setting Change	If you click the parameter whose set point you want to change, the selected parameter is activated. By turning and clicking the rotary knob in the activated state, you can change the set points. Or, you can use the [Set Point Change] button to change the values and click the parameters to change.
C	Page Move	Can move to the page of the menu.
D	Alarm Setting Range	Displays the alarm setting range. The numbers below are the lower limit and the numbers above are the upper limit.

WARNING

Verify that the appropriate alarm range is set according to the patient's condition and the therapy setting.

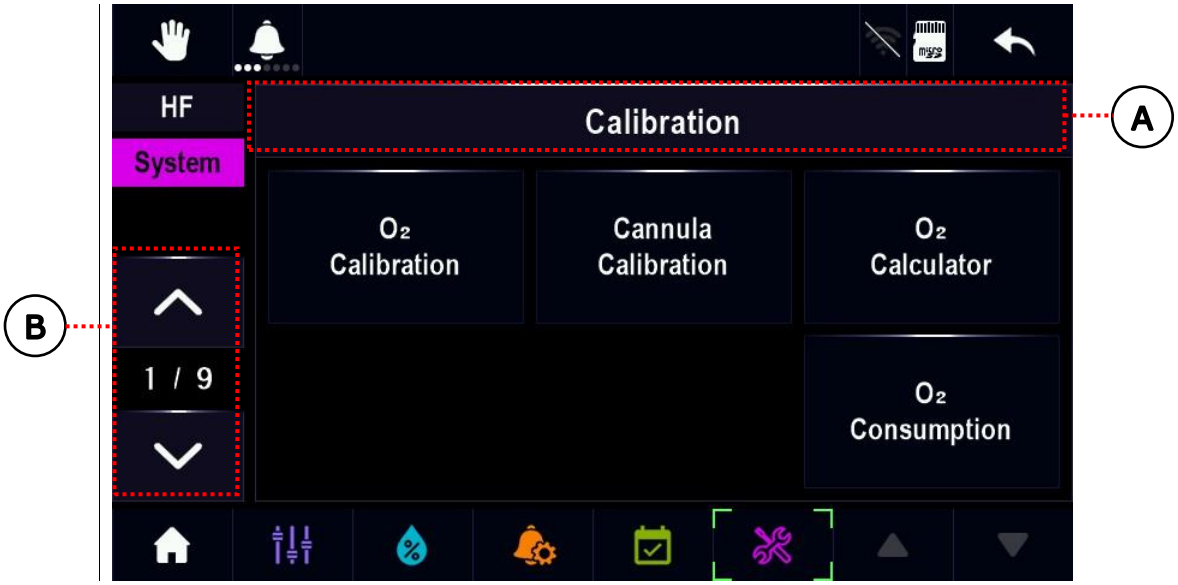
6.2.5 Event menu

Displays the events related to alarms, settings, and the system. 10 events are listed on one screen. Up to 3,000 events are stored. If the number of the stored events exceeds 3,000, the oldest events are deleted in order.



No.	Items	Description
A	All	Displays all events related to the alarms, settings, and system settings.
B	Alarm	Displays the alarm event that occurred.
C	Setting	Displays the set point change events.
D	System	Displays the system menu events such as calibration or device configurations.
E	Event Display Screen	Displays the event list. If you press the [Page Move] button or turn the rotary knob In the activated state by touching the corresponding screen, you can check the previous or next event lists.
F	Page Move	Can move the pages of the event list.

6.2.6 System menu



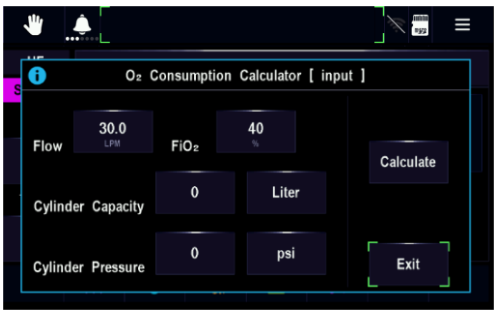
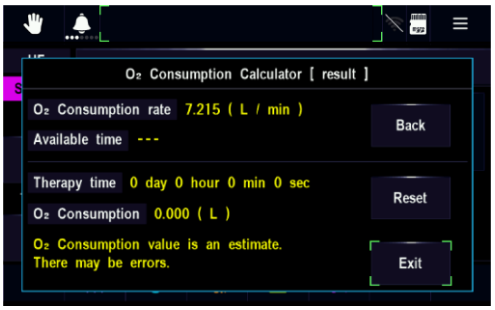
No.	Items	Description
A	Submenu	Displays the name of submenus.
B	Page Move	Can move to the page of the menu.

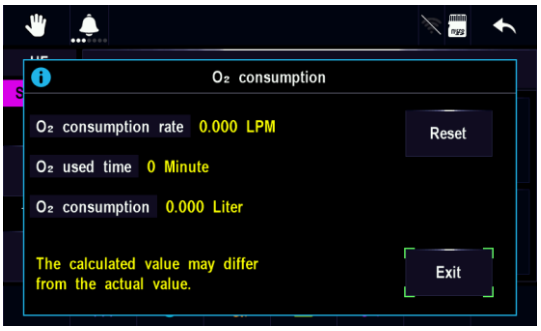
The system menu consists of 8 submenus in total.
To check the pages for each menu and item contents, see the table below.

Page	Submenu	Description	Items
1	Calibration	Can perform calibrations necessary for therapy.	O_2 calibration Cannula / circuit calibration O_2 calculator O_2 consumption
2,3	Device configuration	Can set the settings related to the device.	Sound. vol. Info. sound on, off SpO2 activate, inactivate Control the brightness Set screen off Set language
			Save data Format the microSD Set Default Erase data (event, trend) Set pressure unit
4	Patient & setting information	Can check the patient information and related set point information.	Patient information Therapy time Nasal cannula information Current therapy setting
5	System information	Can check the system information.	System information microSD card capacity
6	Technical configuration	Can calibrate the touchscreen or enter the service code mode.	Touchscreen calibration Service code
7	Wi-Fi	Can edit Wi-Fi communication connection status and the connection setting.	Wi-Fi connection setting
8	Date	Can set the date and time	Date and time setting
9	Masimo setting	Can perform the detailed setting related to the Masimo SpO_2 module.	Refer to "9.2.2 SpO_2 setting."

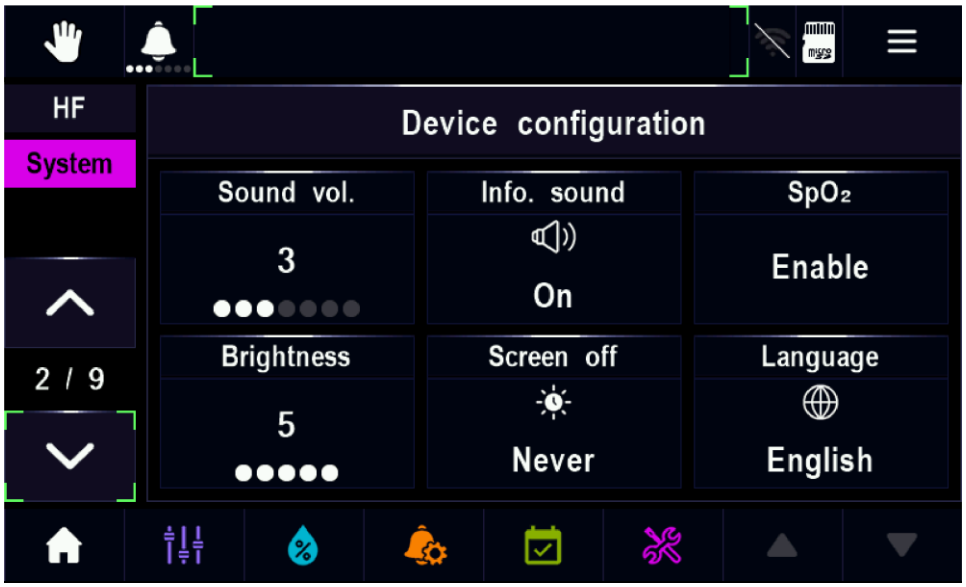
6.2.6.1 Calibration

No.	Items	Description
1	O_2 calibration	Needs to measure and supply the exact oxygen density. To obtain the exact calibration results, you must perform the O_2 calibration in well-ventilated areas. For more details, see "6.3.1 O_2 calibration."
2	Circuit calibration [CPAP & bi-level mode]	This calibration measures the circuit resistance necessary to operate the device correctly. For more details, see "6.3.2 Circuit calibration [CPAP, bi-level mode]."
3	Cannula calibration [HF function]	Measures the nasal cannula's resistance necessary to operate the device correctly. For more details, see "6.3.3 Cannula calibration [HF function]."

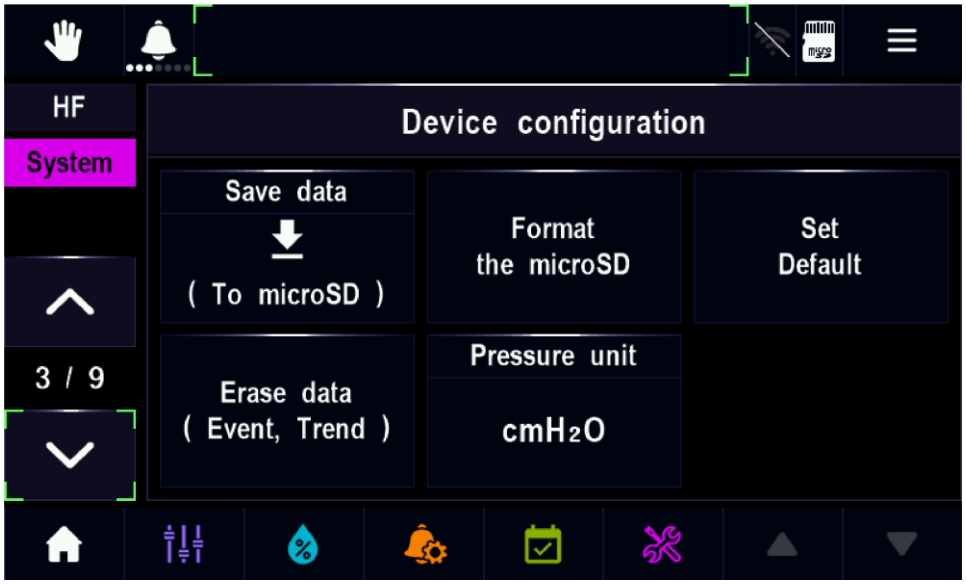
No.	Items	Description
4	O_2 calculator [HF function]	Measures the use time for the oxygen consumption based on the cylinder volume, cylinder pressure, and continuous flow. [Input]  To calculate the O_2 consumption, enter and calculate Flow / FiO_2 set points (or manually input values), cylinder volume, and cylinder pressure. A) FiO_2 If you enter 21 %, "O_2 not used" is displayed in [Results]. B) Volume 0 – 99999 liter C) Pressure 0 – 99999 (psi, Bar, kPa, MPa, kg/cm^2, atm) [Result]  O_2 consumption rate / available time - Displays the results calculated based on the values entered in [Input]. Therapy time / O_2 consumption

No.	Items	Description
5	O_2 Consumption	Provides O_2 consumption information used when performing therapy.  O_2 consumption rate / O_2 used time / O_2 consumption A) O_2 consumption rate : Displays the percentage of oxygen used during the therapy. B) O_2 used time : Displays the accumulated use time of oxygen used during the therapy. C) O_2 consumption : Displays the total amount of oxygen used during the therapy. D) Conditions for calculating consumption: When therapy is started, normal O_2 supply, if FiO_2 set point is not 21% O_2 consumption can be recorded up to 4 million liters.

6.2.6.2 Device configuration

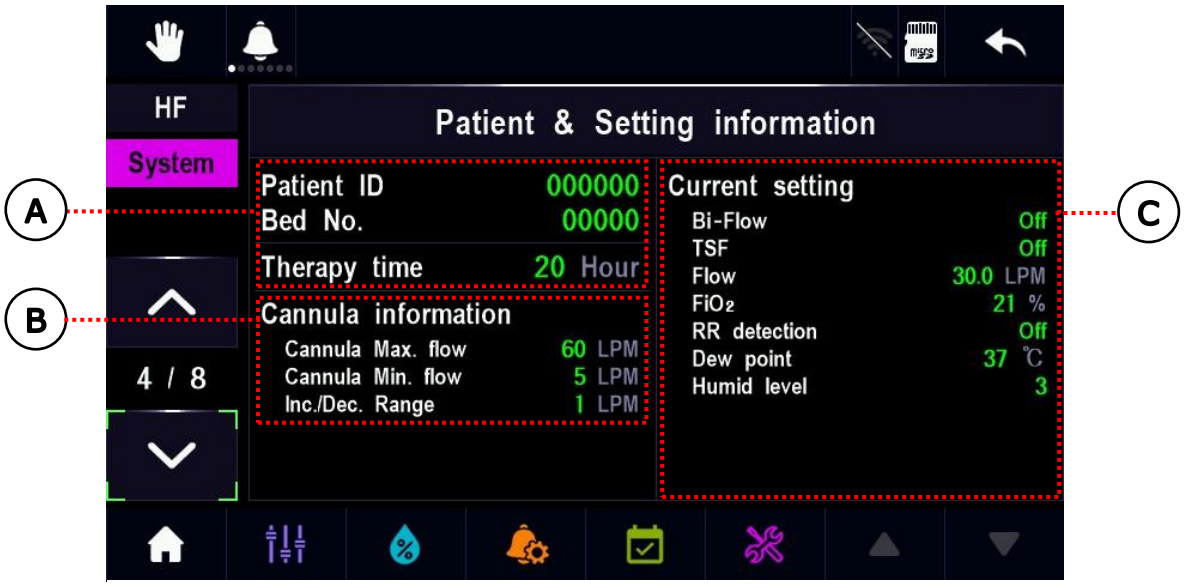


No.	Items	Setting Range	Description	Default values
1	Sound vol.	1 to 7	Can control the alarm sound volume in 7 levels. If an alarm with the alarm priority of medium or high occurs, the alarm sound is triggered over the 3rd sound level.	3
2	Info. sound	On, Off	Info. Can select the alarm sound to be on or off.	On
3	SpO_2	Activate, inactivate	Can activate or inactivate the SpO_2 monitoring function.	Activate
4	Brightness	1 to 5	Can control the brightness in 5 levels.	5
5	Screen off	15 s, 30 s, 1 min, 5 min, 10 min, and Always On	If there is no keystroke during the set time, the LCD screen is switched off automatically.	Always On
6	Language	English, Korean, French, Italian, German, and Spanish	Can set the language.	English



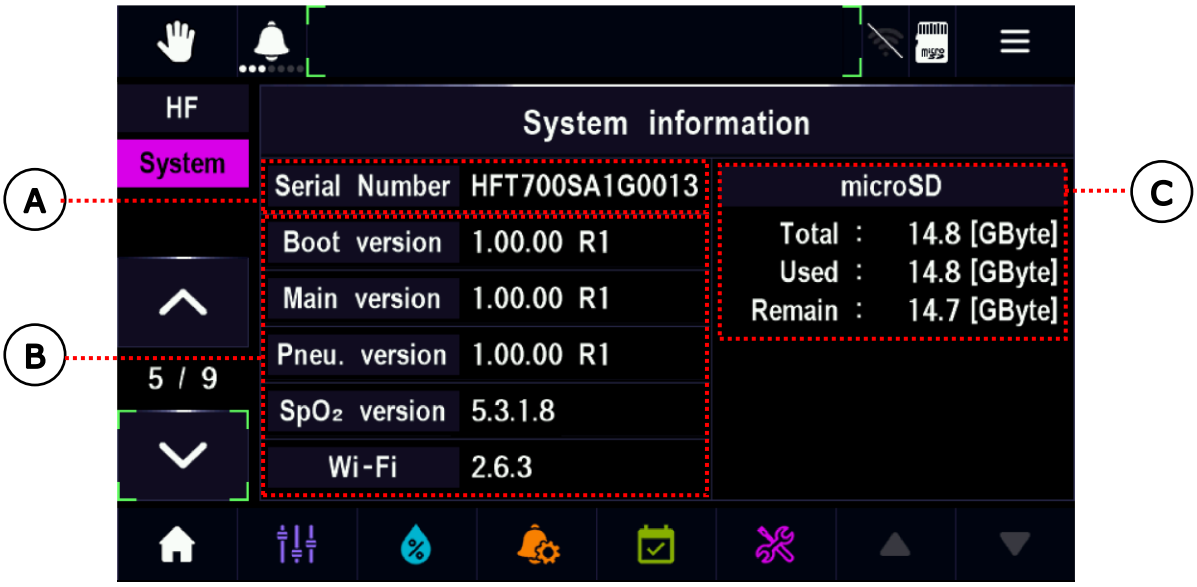
No.	Items	Setting Range	Description	Default values
1	Save data	–	Can save various data collected during the system operation on a microSD card. (For example, event history data, setting and patient information data, maintenance data, trend data, etc.)	–
2	Format the microSD	–	Can delete data in the microSD card.	–
3	Set Default	–	Can initialize the set point. (Initialization of configuration, system, alarm setting, and nasal cannula calibration data)	–
4	Erase data (Event, trend)	–	Deletes event and trend data stored on the internal memory of the device.	–
5	Pressure unit	cmH_2O, hPa, mbar	Can select the pressure unit.	cmH_2O

6.2.6.3 Patient & setting information



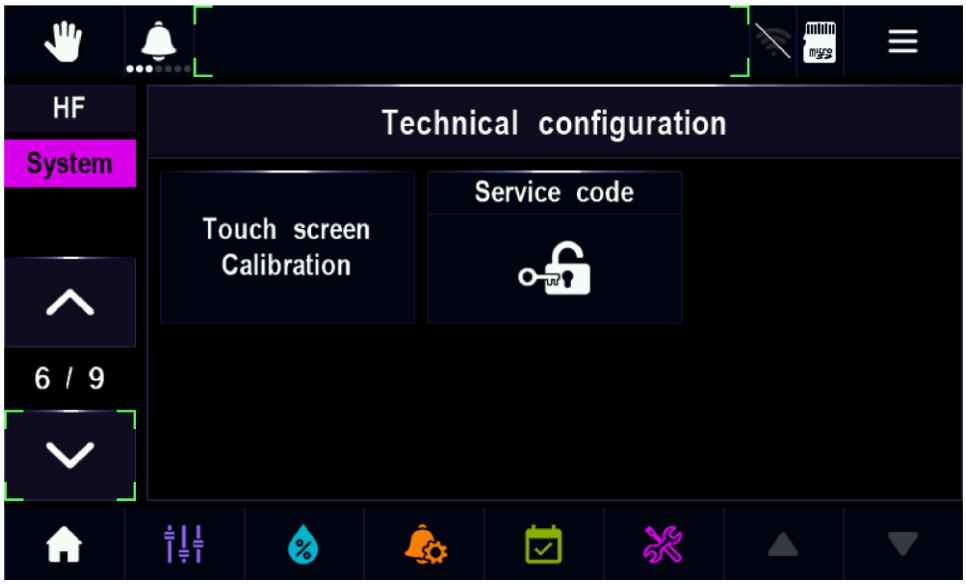
Items	Description
A	Can check the patient information and therapy time.
B	Can check the cannula calibration results. [HF function only]
C	Can check the current settings related to the therapy.

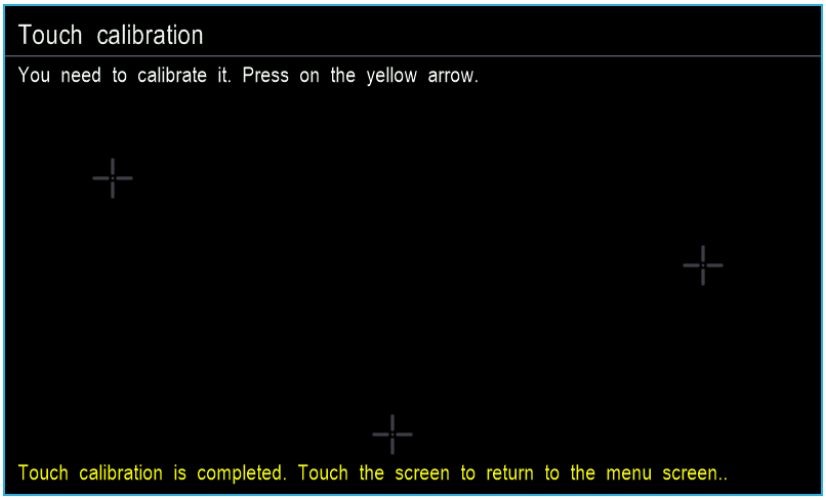
6.2.6.4 System information

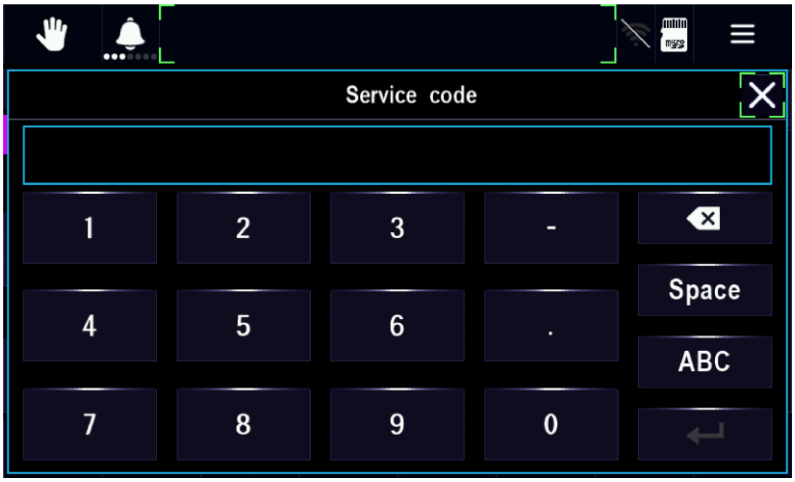


Items	Description
A	Can check the device serial number.
B	Can check the software version information.
C	Can check the microSD card information.

6.2.6.5 Technical configuration

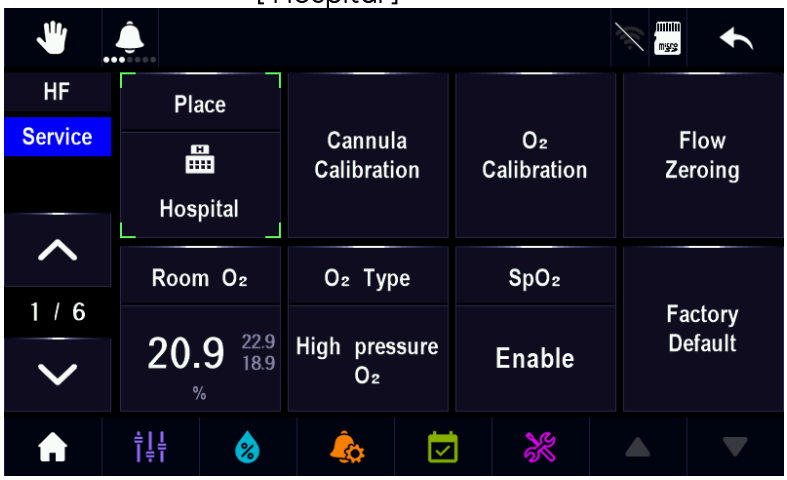


No.	Items	Description
1	Touchscreen calibration	Performs the touchscreen calibration. If you touch the touchpoint displayed on the screen, the calibration will be complete. 

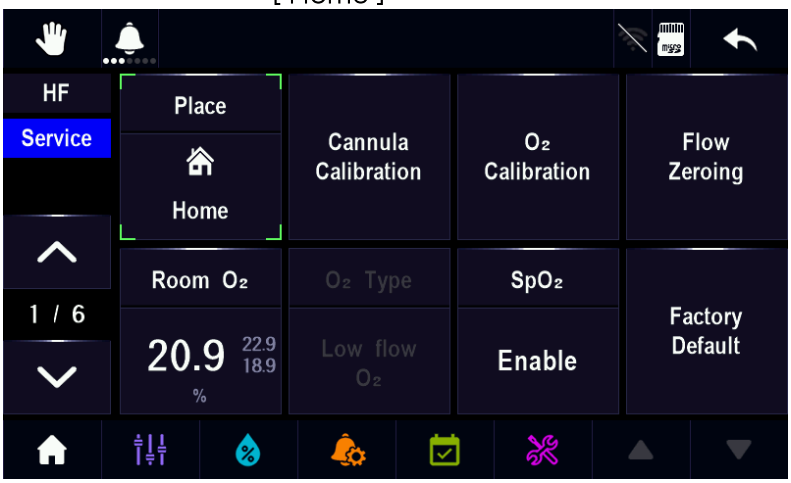
No.	Items	Description
2	Service code	The service code password is given according to the MEKICS service policy. If you enter the service code password, the submenu that only the service provider can access is activated. 

6.2.6.6 Service menu (It is activated when entering the service code.)

[Hospital]

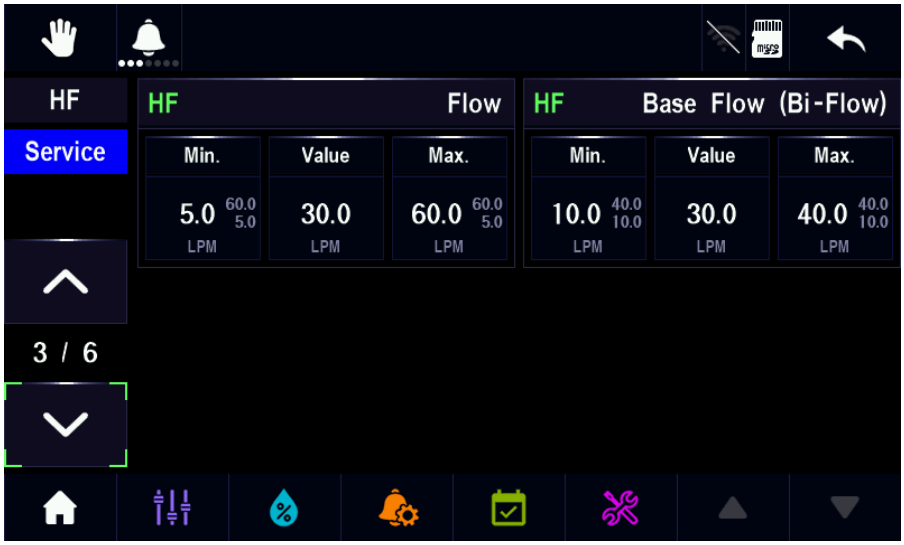


[Home]



No.	Items	Description
1	Place	You can choose a therapy place. Selecting "Home" changes some default settings in the "Settings" and "System" menus and limits some features that require management by your service provider. Also, the ability to change alarm ranges in the alarm menu is limited.
2	Cannula calibration	Refer to "6.2.6.1 Calibration"
3	O_2 calibration	Refer to "6.2.6.1 Calibration"
4	Flow zeroing	Calibrate the zero point of the flow sensor.
5	Room O_2	For more accurate oxygen calibration, users can set their own calibration criteria by entering the room oxygen concentration. In this case, it is necessary to accurately enter the measured value using a periodically maintained oximeter.

No.	Items	Description
6	O_2 Type	The default settings depend on the "Place" selection. – If "Hospital" is selected, the default setting is "High pressure O_2". – If "Home" is selected, the default setting is "Low flow O_2". [High pressure O_2] FiO_2 setting range: 21%, 25% to 100% (Refer to "3.3 Rear view") [Low flow O_2] The FiO_2 setting in the "Settings" menu is fixed to "Low Flow O_2". In this case, the device does not control the FiO_2 concentration, only measures it. The default settings for the FiO_2 alarm are automatically changed to 60% (upper limit) and 18% (lower limit). (Refer to "3.3 Rear view") ⚠ See installation and warnings for oxygen supply type in section "3.3 Rear view".
7	SpO_2	Refer to "6.2.6.2" Device configuration"
8	Factory Default	Change all settings and data to the default settings.

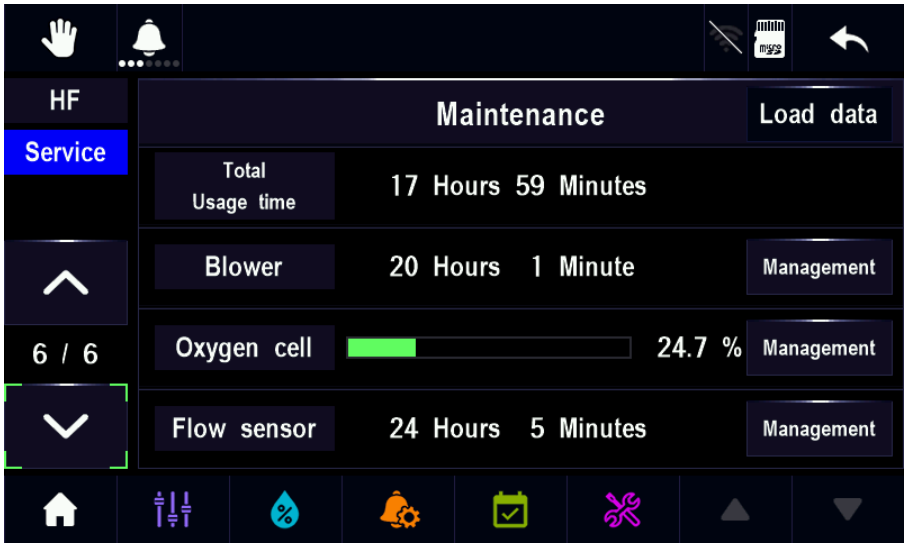


No.	Items	Description
1	Min.	You can limit the minimum value of the range of therapy settings that the user can change.

No.	Items	Description
2	Value	Can change setting value.
3	Max.	You can limit the maximum value of the range of therapy settings that the user can change.

NOTE

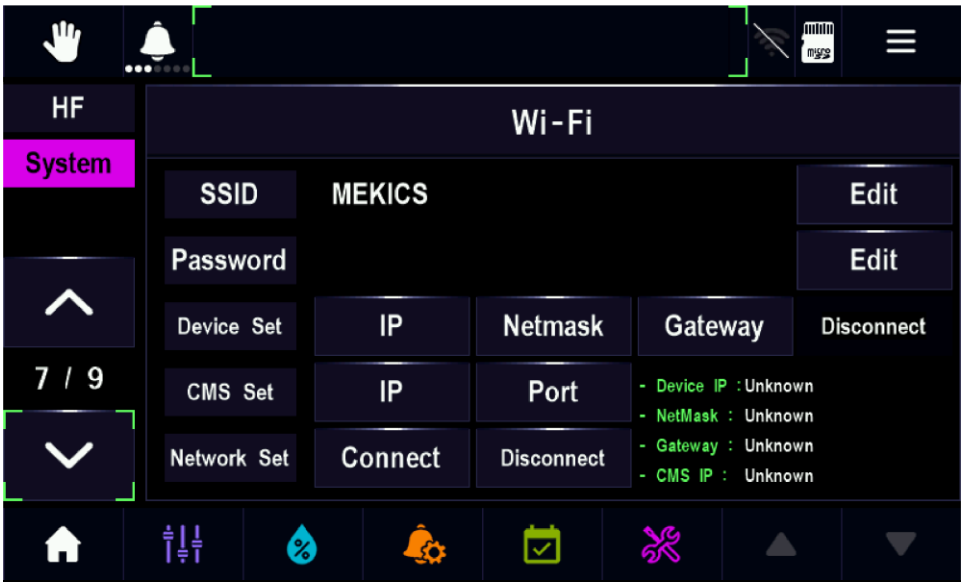
For detailed information on therapy settings, please refer to "6.2.2 Setting menu".



No.	Items	Description
1	Total usage time	Displays the total therpay time.
2	Blower	Displays the operating time of the blower.
3	Oxygen cell	Displays the remaining usage time of the oxygen cell (oxygen sensor) in percentage.
4	Flow sensor	Displays the usage time of the flow sensor.

6.2.6.7 Wi-Fi

You can edit Wi-Fi communication connection status check and the connection setting. For more details, contact the MEKICS service center or its sales agency.



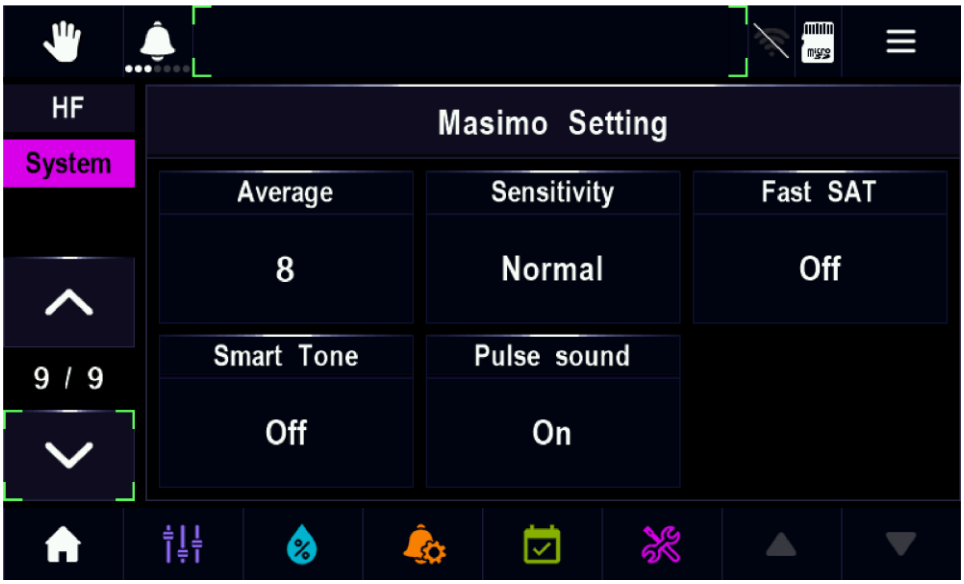
6.2.6.8 Date

You can set the date and time.



6.2.6.9 Masimo setting

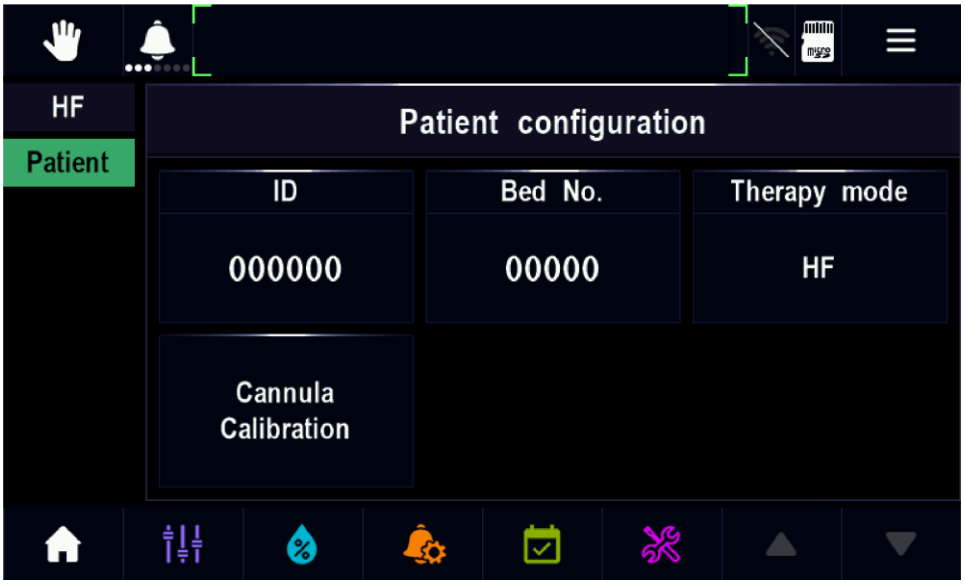
These are the Masimo SpO_2–related setting items. For more details, see "9.2.2 SpO_2 settings menu.".



6.2.7 Patient menu

In "Patient" menu, there are 4 submenus.

You can change the settings related to the patient information, select the therapy mode, and perform the calibration.
You can change the set points by turning the dial.
Change the value to the target value and select the item again to apply the changed values.



No.	Items	Description
1	ID	Can set the ID. The ID can consist of a 6-digit mix of alphanumeric and special characters.
2	Bed No.	Can enter the bed No. The bed No. can consist of a 5-digit mix of alphanumeric and special characters.
3	Therapy mode	Displays the currently set therapy mode. The therapy mode can be changed after therapy is completed by clicking the button.
4	Cannula/circuit calibration	The calibration items change according to the selected therapy mode. In HF function, perform the cannula calibration and in CPAP or bi-level mode, perform the circuit calibration. For more details, see "6.3 Calibration."

6.3 Calibration

Perform a calibration for proper use of the device. You can check the calibration items in the System menu.

6.3.1 Oxygen (O_2) calibration

CAUTION

1. The 21 % O_2 calibration must be performed in well-ventilated areas to monitor and control the exact oxygen density. In particular, performing the calibration at a place with a high oxygen density like an oxygen treatment room may affect the oxygen density control, resulting in harming the patient.
2. The 100 % O_2 calibration must use 100 % oxygen that meets the high-pressure oxygen pressure range from 241.3 kPa to 620.5 kPa (35 psi to 90 psi). If the oxygen density is not correct or the pressure is outside the usage range, you cannot perform the calibration. In addition, the exact oxygen density detection is not guaranteed.

This is a necessary process to measure and supply the exact oxygen density. To obtain the exact calibration results, you must perform the O_2 calibration in well-ventilated areas. Do not move the device while performing the calibration.

There are two methods to perform the O_2 calibration. Select the one most suitable to your environment.

A. 21 % calibration: Use this in an environment where you cannot perform the 100 % oxygen calibration.
B. 100 % calibration: Use this at the place where you can make use of 100 % oxygen and cannot ensure that the indoor oxygen density is 21 %. (For example: An oxygen treatment room, a small place with poor ventilation)

Prepare as below and select the method to perform.

1. Disconnect the device from the patient.
2. Remove the breathing circuit from the device.
3. Ventilate the adjacent space.
4. [For 100 % calibration] Connect the high-pressure oxygen to the device.

6.3.2 Circuit calibration [CPAP, bi-level mode]

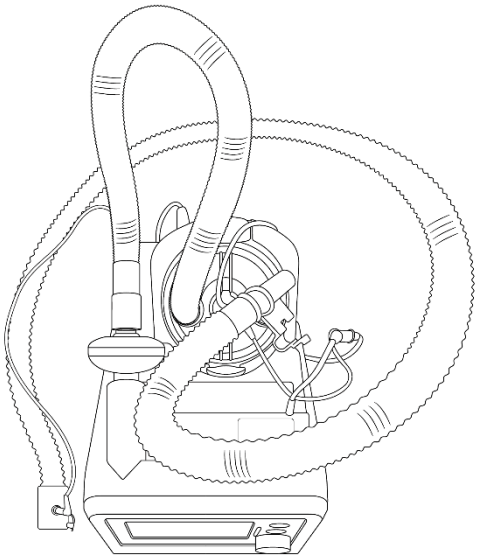
CAUTION

Configure the circuit correctly while performing the circuit calibration. The leak or the plugging in the breathing circuit causes incorrect calibration results.

This calibration measures the breathing circuit resistance necessary to operate the device correctly. Calibration results are used for related alarms and controls and are stored until a new calibration.

[Step 1]

Install the breathing circuit as shown below before performing the calibration.
(For more details, see "4 How to prepare.)



[Step 2]

Remove the mask from the breathing circuit and check if there is a plug, bend, or leak in the breathing circuit before starting the calibration.

[Step 3]

Perform the "Circuit calibration."

[Step 4]

If the breathing circuit resistance is not effective, the calibration failure message appears.

[Step 5]

When the calibration is completed, the calibration completion message appears.

6.3.3 Cannula calibration [HF function]

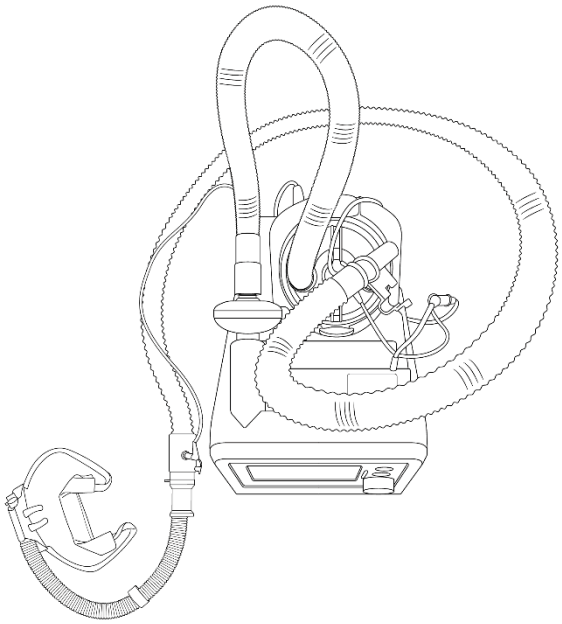
CAUTION

1. The HFT700 ventilator cannot use the nasal cannula with a resistance over 60 cmH_2O at 6 l/min.
   If you perform the calibration after installing a nasal cannula with higher resistance than the standard, the nasal cannula calibration failure message appears.
2. Configure the circuit correctly while performing the nasal cannula calibration. The leak or the plugging in the breathing circuit causes incorrect calibration results.

Measures the nasal cannula's resistance necessary to operate the device normally.
Calibration results are used for related alarms and controls and are stored until a new calibration.

[Step 1]

Install the breathing circuit as shown below before performing the calibration.
(For more details, see "4 How to prepare.")



[Step 2]

Check if there is a plug, bend, or leak in the breathing circuit and the nasal cannula before starting the calibration.

[Step 3]

Enter the Nasal cannula calibration and select the nasal cannula type (nasal cannula / T-piece). If you choose "T-piece", regardless of the nasal cannula calibration results, the flow setting range is 5 to 60 l/min, and the "Open Circuit" alarm is not triggered.

[Step 4]

Perform the nasal cannula calibration.

[Step 5]

If the measured nasal cannula's resistance is not effective, the calibration failure message appears.

[Step 6]

When the calibration is completed, the calibration completion message appears.

6.4 External power supply [Option]

The HFT700 can be powered by an external power supply that typically battery life of 9 hours (when using HF mode). When using an external power supply as an option, AC power is connected to the external power supply. The supplied AC power operates the HFT700 and the external power supply will be charged. When using without connecting AC power, DC power is supplied to the HFT700 from the external power supply.



WARNING

1. Avoid the user to the possibility of a problem with the battery explosion in an area where there is a high variation of temperature.
2. Avoid a damage or shock on the battery pack of the external power supply as it may cause the battery explosion. MEKICS takes no responsibility of it.
3. Avoid metal material on the battery of the external power supply. Do not touch the equipment with wet hand.
4. Disconnect AC power cord instantly to the possibility of a problem with the battery of the external power supply and contact to MEKICS customer service department.



CAUTION

1. Recharging the battery is strongly recommended when the battery has not been recharged for 2 or more months.
2. When storing HFT700, press for 3 seconds the power button on the bottom of the external power supply to turn it off.
3. Risk of explosion: If battery is replaced by an incorrect type.

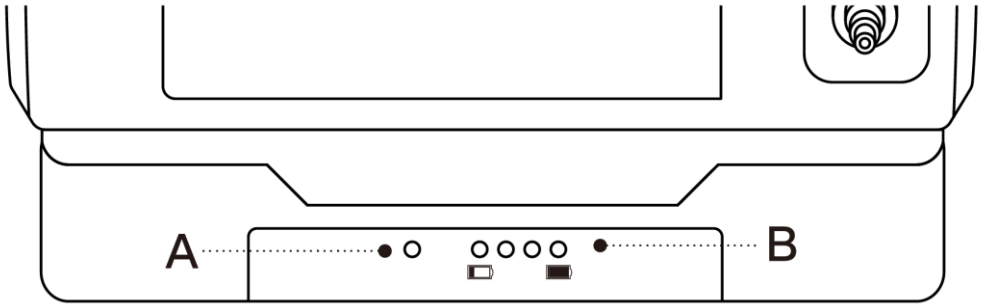


NOTE

External power supply (MPS100) is specified as a part of MEKICS equipment.

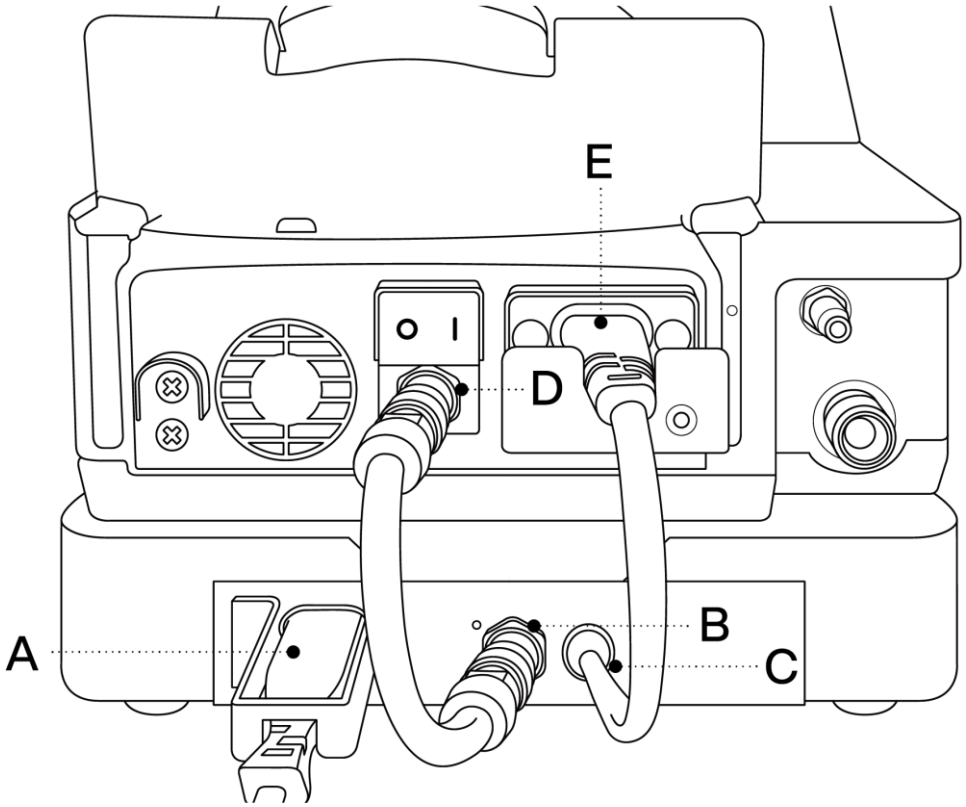
6.4.1 Appearance

6.4.1.1 Front view



Number	Component	Description
A	Battery mode indication LED	When battery is in use, orange LED lights up.
B	Battery level indication LED	0 – 100 % battery level in white LED.

6.4.1.2 Rear view



Number	Component	Description
A	AC Power Inlet of external power supply	Connect the AC power cord to the external power supply.
B	DC Output Connector	DC output from the external power supply to Main system.
C	AC Output cable	AC Output cable AC output from the external power supply to Main system.
D	DC Cable Connector	DC input from the external power supply.
E	AC Power Inlet	AC input from the external power supply to HFT700.

6.4.2 Power button of external power supply

There is the power button on the bottom of the external power supply . DC power can be connected or disconnected to HFT700 by pressing the power button. The external power supply automatically turns on when AC power is supplied to external power supply.

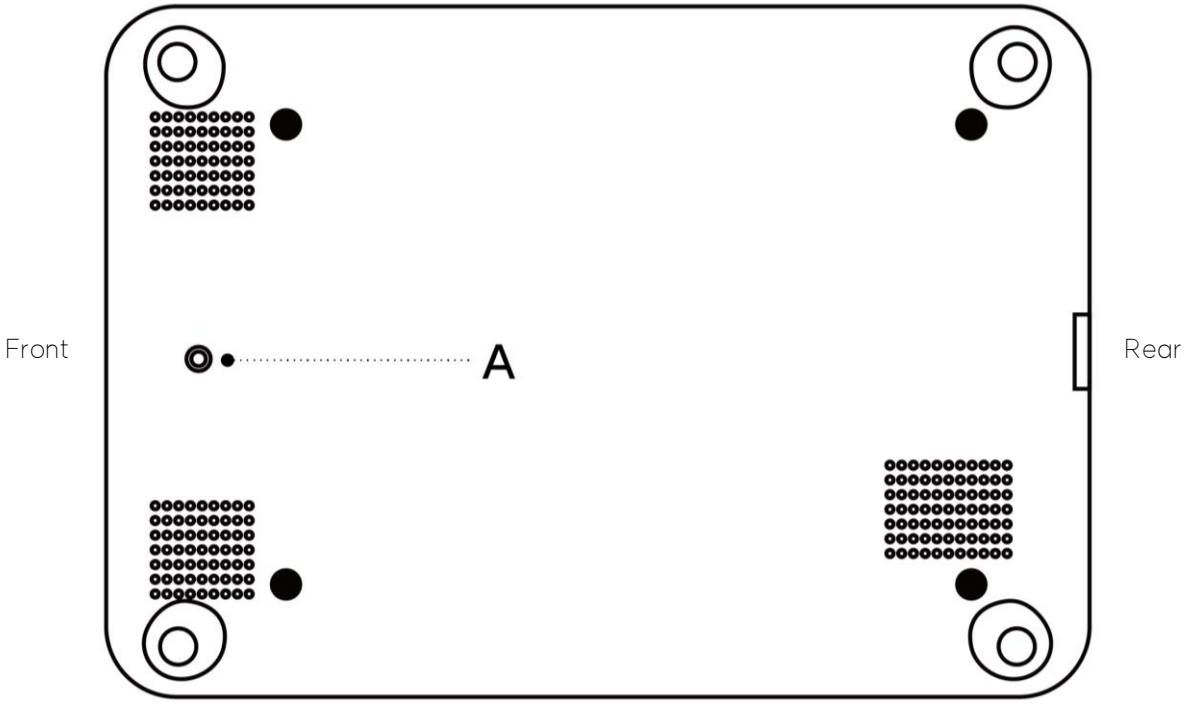


Figure 6.1 Bottom view of the external power supply

Number	Component	Description
A	Power button of external power supply	[One press] The external power supply is turned on. When the external power supply is turned on, the battery level indication LED lights up. [Press for 3 seconds] When it is pressed for more than 3 seconds, the external power supply is turned off.

CAUTION

When storing the product, keep the power off by pressing power button for 3 seconds.

6.4.3 Status display of external power supply

Remaining operation time of the battery is displayed on the front of external power supply. When battery state is low, the one of battery light indicator is displayed. In this case, external power supply should be replaced or, if possible, connect the external power supply to AC power. Information on external power supply is displayed as follows.

Indication LED	Color	Status	Description
Battery mode	Orange	On/Off	If the AC power is not connected and the HFT700 operates on batteries, the orange indicator lights up. The orange light turns off when AC power is connected.
Battery level	White	4 Ea	100 – 75 % Charging
		3 Ea	74 – 50 % Charging
		2 Ea	49 – 25 % Charging
		1 Ea	Low Charging
		0 Ea	Empty

If the battery is the lowest, Battery Low Alarm is occurred and one white indicator light flashes rapidly.

Low Battery Alarm type	Description
Medium priority alarm	The medium priority alarm is occurred at least 15 min prior to the loss of all power (Tone: CCC)
High priority alarm	The high priority alarm is occurred at least 5 min prior to the depletion of all power. (Tone: CCC CC, CCC CC)

6.4.4 Alarms related to external power supply

6.4.4.1 System alarm

Alarm Message [Priortiy]	Reason	Actions
Battery (Humidifier is Off) (No sound)	When the main power (AC power) is disconnected from the HFT700 and operates as power (DC power) from an external power supply. When operating with the power source of an external power supply (DC power), it is displayed because the Heat Plate and Heat Wire don't operate and don't provide heating and humidification.	Connect the main power (AC power) to the external power supply of HFT700.
Low battery alarm [MEDIUM -> HIGH] (No message, only sounds)	The medium priority alarm occurs at least 15 min prior to the loss of all power from the external power supply. The high priority alarm occurs at least 5 min prior to the depletion of all power from the external power supply. Finally power is off automatically after 5 minutes.	Connect the main power (AC power) to the external power supply of HFT700.

6.4.4.2 System alarm test

Alarm Message	Description
Battery (Humidifier is Off) (No sound)	• Install all accessories required correctly. • Connect AC output cable and DC output cable from an external power supply to the HFT700. • After operating, disconnect the AC power and HFT700. • Check if an alarm occurs after waiting for about 5 seconds.
Low battery alarm [MEDIUM -> HIGH] (No message, only sounds)	• Connect AC output cable and DC output cable from an external power supply to the HFT700. • Select bi level mode and install all accessories required for bi-level mode correctly. • Perform circuit calibration. • Set to IPAP 10 cmH_2O, EPAP 5 cmH_2O, FiO_2 21 % and keep the other setting values at the initial values and operate the HFT700. • When the battery level indication of the external power supply is 1Ea white LED, Check if an alarm occurs after waiting for about 5 seconds.

6.4.5 Operating time with external power supply

Therapy mode Operating	Time	Description
HF function	9 hours	Flow rate: 30 l/min and default setting
bi-level mode	8 hours	IPAP : 20 cmH_2O, EPAP : 5 cmH_2O, Rise Time : Medium, RR : 12 /min and default setting

NOTE

When operating with external power supply, the humidification of HFT700 are not provided.

6.4.6 Maintenance of external power supply

CAUTION

1. If external power supply is not charged for more than 2 months, it is recommended to charge it with AC power before use.
2. When changing the battery of external power supply, comply with the disposal and recycling regulation of the country for the disposal and recycling of the battery.

NOTE

1. If HFT700 is turned off, battery charging time is approximately 5 hours.
2. If HFT700 is not used for a long period of time, separate the external power supply and HFT700 for storage.

7 Monitoring

7.1 Measurement Information

Information on the value measured during the patient's treatment is displayed on the screen. Types of information displayed vary depending on the monitoring types.

- If the measured values are out of the alarming range, they are displayed in red.
- If the device is not able to measure the values, "---" is displayed.
- For more information on the measurement Information, see "A.7 Display parameter specifications."

Items	Description	Ranges	Mode / Function
Flow	Supplied Flow (Flow)	0 to 240 l/min	HF
S/F ratio	SpO_2/FiO_2 ratio	0 to 499	HF
ROX	respiratory rate-oxygenation (S/F ratio ÷ RR)	0 to 499	HF
PIP	Peak Inspiratory Pressure	0 to 100 cmH_2O	bi-level
PEEP	Positive End Expiratory Pressure	0 to 100 cmH_2O	CPAP, bi-level
Vt est	Estimated Tidal Volume	0 to 2500 ml	CPAP, bi-level (*NOTE)
FiO_2	Fraction of inspired Oxygen	18 to 100 %	Common
SpO_2	Saturation of Peripheral Oxygen	0 to 100 %	Common
PI	Perfusion Index	0.02 to 20 % (At Masimo SpO_2 Configuration)	Common
		0 to 20 % (At MEKICS SpO_2 Configuration)	Common
PR	Pulse Rate	0 to 300 /min	Common
RR	Respiratory Rate	0 to 300 /min	Common

Items	Description	Ranges	Mode / Function
Airway temperature	Airway Temperature	0.0 to 60 ℃	Common
Chamber temperature	Chamber Temperature	0.0 to 60 ℃	Common
Heat plate temperature	Heat-Plate Temperature	10 to 115 ℃	Common

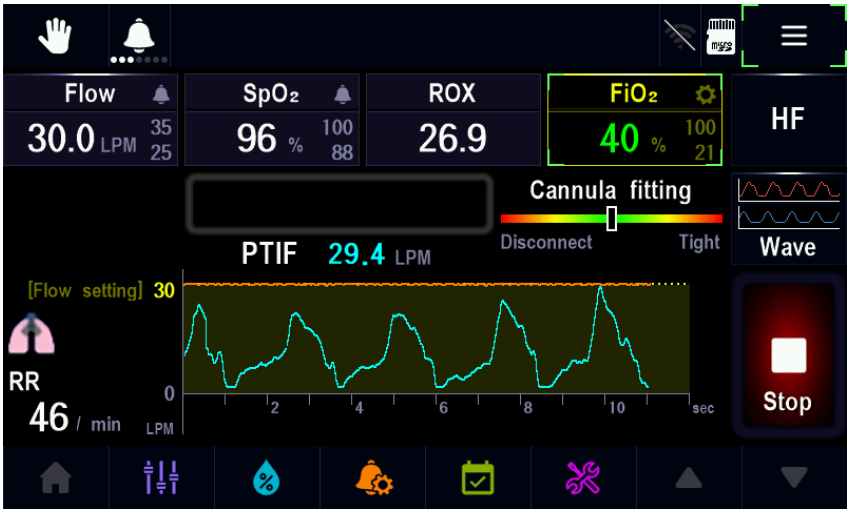
NOTE

1. The tidal volume estimated displayed in the bi-level mode is calculated by the leak flow calibration algorithm using the measured flow value. If the leak or the patient's condition is not stable, however, the accuracy cannot be guaranteed.
2. If you turn on the Volume guarantee function in the bi-level mode, "V delivery" is displayed instead of "Vt est."

7.2 Monitoring display

7.2.1 Symbols and shortcuts of the monitoring display

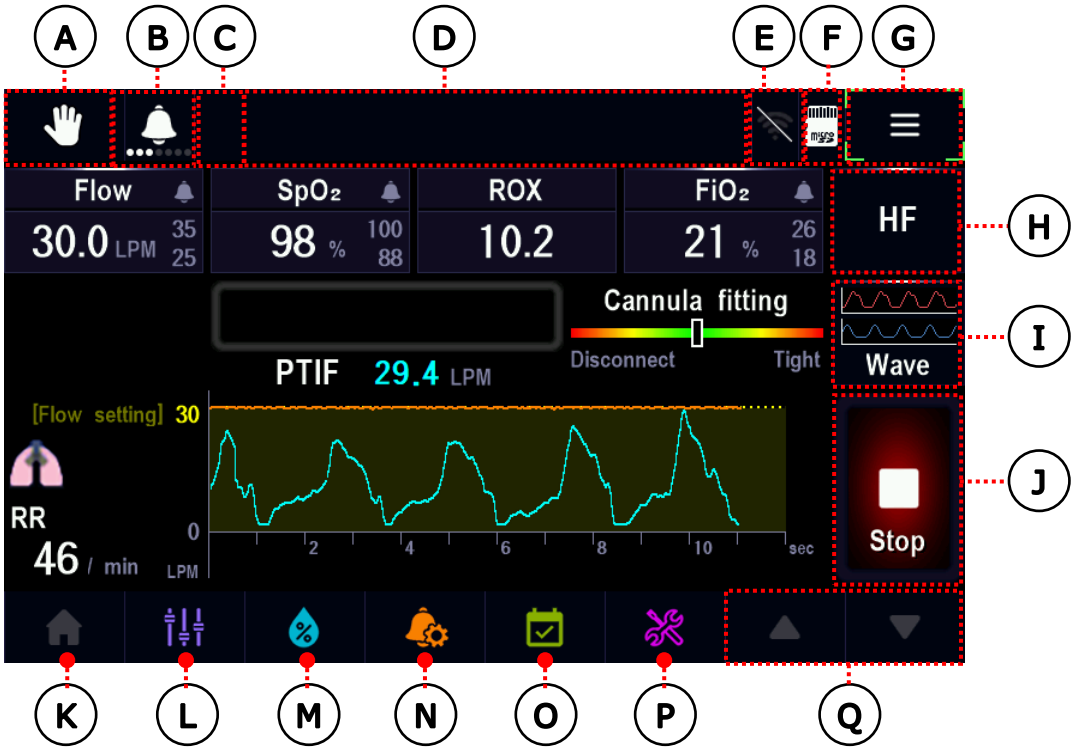
The monitoring display consists of shortcuts, an alarm display window, monitoring parameters, etc.



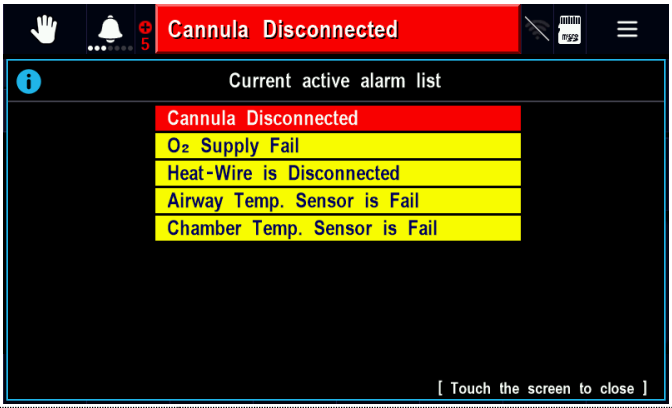
If you press a parameter in the monitoring display, the rapid setting function of the related setting item is activated.

If you adjust the set value and press the parameter again, the set value change is applied.

The rapid setting parameters linked to each monitoring parameter are found in the next section.



No.	Items	Symbols and descriptions	
A	Screen Lock/UnLock		Touch key is activated. (Screen UnLock is activated) Pressing this symbol activates the Screen Lock.
			Touch key is not activated. (Screen Lock is activated) Pressing this symbol inactivates the Screen Lock.
B	Alarm Sound Status		Displays the alarm sound level. Can control it in the System menu. For more details, see "6.2.6.2 Device settings."
			The alarm mute is activated. The alarm mute is maintained for 2 minutes and the remaining time is displayed.
C	Number of the alarm triggers	If there are more than two alarms, the number of the alarms currently being activated is displayed.	

No.	Items	Symbols and descriptions
D	Alarm display window	Displays an alarm message. If you press the alarm display window, you can check all alarms currently activated. 
		 In the case of an alarm related to Masimo SpO_2, an alarm message is displayed with the corresponding symbol.
E	Wi-Fi	 Wi-fi is connected.
		 Wi-fi is not connected.
F	microSD card	 microSD card is not inserted.
		 microSD is inserted successfully.
		 (Symbol flickering) The data access to the microSD card. (*CAUTION)
		 Displays the countdown before the data is stored to the microSD card. The countdown starts 10 seconds before the auto-save.

No.	Items	Symbols and descriptions
		(*CAUTION)
G	Main Menu	 Moves to the Main menu.
H	Therapy modes	Displays the currently-applied therapy mode. If the therapy is not in progress, you can change the therapy modes by pressing the corresponding area. (See "6.1 Setting therapy modes.")
II	Monitoring display type	Displays the currently-applied monitoring display. You can select the type of monitoring display by pressing the corresponding area. Simple / All / Trend monitoring displays
J	Therapy Start/Stop button	 Starts a therapy.
		 Stop a therapy.
K	Home button	 Activated in other menus which is not the monitoring display. Moves from the other menus to the monitoring screen.
L	Setting	 Moves to the settings menu related to the therapy. (Same as the "Settings" in the Main menu)
M	Humidifier	 Moves to Humidifier settings and Monitoring menu. (Same as the "Humidifier" in the Main menu)
N	Alarm	 Moves to the Alarm Settings menu. (Same as the "Alarm" in the Main menu)

No.	Items	Symbols and descriptions
O	Event	 Moves to the Event Check menu. (Same as the "Events" in the Main menu)
P	System	 Moves to the System Settings menu. (Same as the "System" in the Main menu)
Q	Set Point Change (Increase/Decrease)	It is activated when the set point is changeable. Tap: The set point changes by one. Press and hold: The set point changes continuously while pressing the button.

CAUTION



or or an icon flickering

Do not force the microSD card out if the status icon of the microSD in the display is shown as above. Doing so may cause data– or system errors.

7.2.2 Simple monitoring display

The Simple monitoring display consists of three areas, allowing the measured values to check and rapidly set.



7.2.2.1 Parameter Table (Simple monitoring)

HF function parameter table			
Type	Parameter 1	Parameter 2	Parameter 3
Monitoring	Flow	FiO_2	SpO_2
Rapid setting	Flow	FiO_2	–

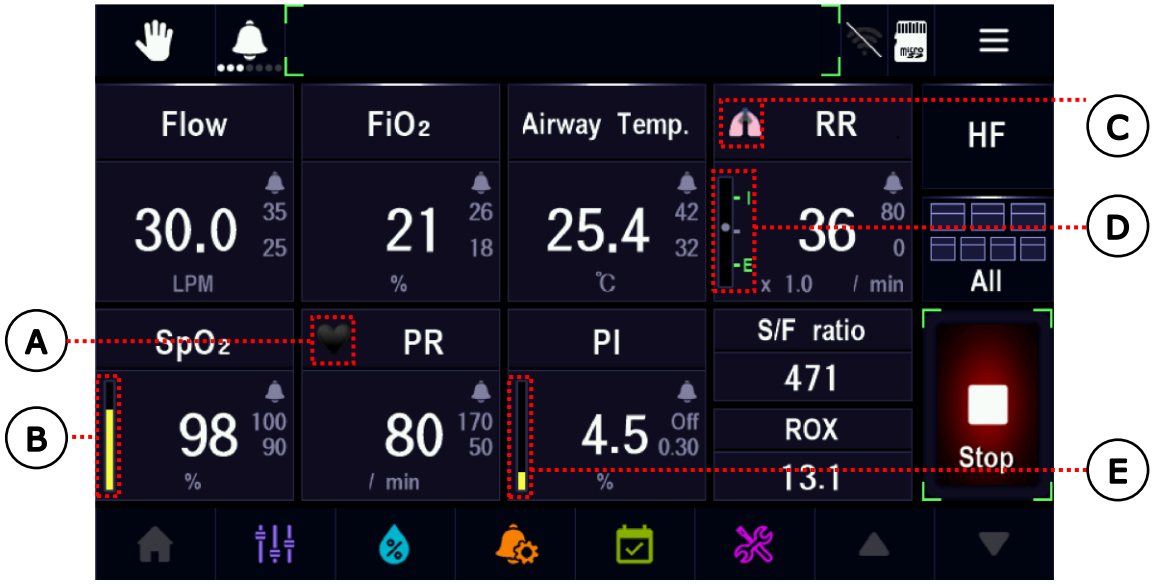
CPAP mode parameter table			
Type	Parameter 1	Parameter 2	Parameter 3
Monitoring	FiO_2	PEEP	PA (+) (−) set point
Rapid setting	FiO_2	CPAP	PA(+)(−)

bi-level mode (Volume Guarantee Off) parameter table			
Type	Parameter 1	Parameter 2	Parameter 3
Monitoring	FiO_2	PIP	PEEP
Rapid setting	FiO_2	IPAP	EPAP

bi-level mode (Volume Guarantee On) parameter table			
Type	Parameter 1	Parameter 2	Parameter 3
Monitoring	FiO_2	V delivery	PEEP
Rapid setting	FiO_2	Vi	EPAP

7.2.3 ALL monitoring display

ALL monitoring display shows every monitoring item of each respiratory mode.



No.	Items	Symbols and descriptions	
A	Pulse detection		This icon is displayed when a heart rate is detected.
B	SpO_2 bar	Shows plethysmography or signal IQ (for Masimo only) regarding the SpO_2 measuring. For more details about the signal IQ, see "9.2.1 SpO_2 monitoring parameter."	
C	Respiration detection		Respiration is not detected.
			Inhalation is detected.
			Exhalation is detected.
D	Respiration sensitivity indicator	The pointer of the respiration sensitivity indicator moves between I and E according to the patient's breathing in the HF function	
E	PI bar	Visually displays the PI values being measured currently.	

7.2.3.1 Parameter Table (All monitoring)

HF function parameter table				
Type	Parameter 1	Parameter 2	Parameter 3	Parameter 4
Monitoring	Flow	FiO_2	Airway temperature	RR
Rapid setting	Flow	FiO_2	Dew point	–
Type	Parameter 5	Parameter 6	Parameter 7	Parameter 8
Monitoring	SpO_2	PR	PI	S/F ratio, ROX
Rapid setting	–	–	–	–

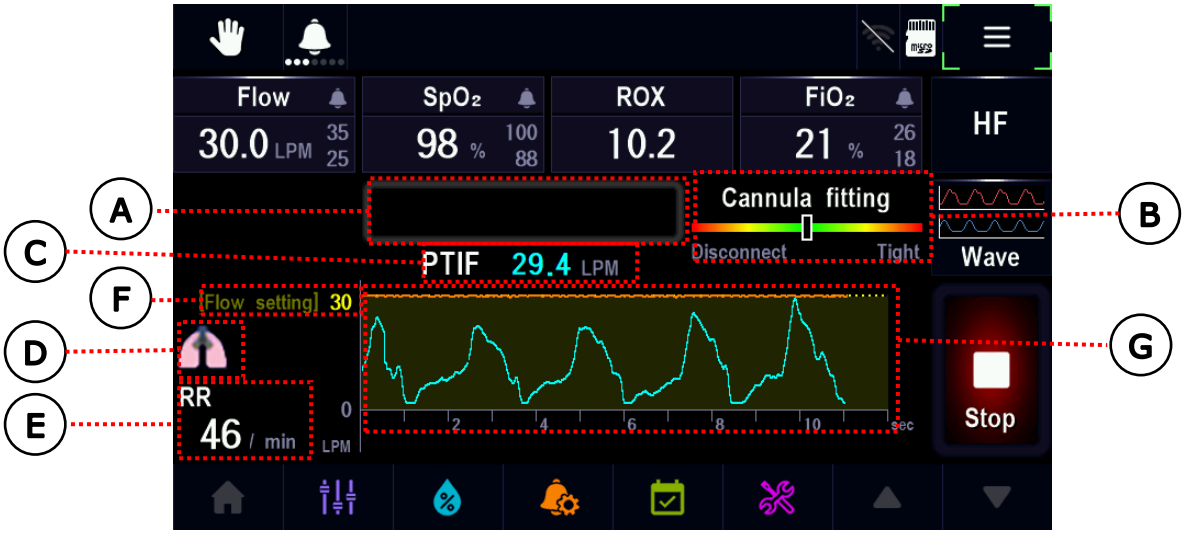
CPAP mode parameter table				
Type	Parameter 1	Parameter 2	Parameter 3	Parameter 4
Monitoring	FiO_2	PEEP	PA (+) (–) set point	RR
Rapid setting	FiO_2	CPAP	PA(+)(–)	–
Type	Parameter 5	Parameter 6	Parameter 7	Parameter 8
Monitoring	SpO_2	PR	PI	Vt est
Rapid setting	–	–	–	–

bi-level mode (Volume Guarantee Off) parameter table				
Type	Parameter 1	Parameter 2	Parameter 3	Parameter 4
Monitoring	FiO_2	PIP	PEEP	RR
Rapid setting	FiO_2	IPAP	EPAP	–
Type	Parameter 5	Parameter 6	Parameter 7	Parameter 8
Monitoring	SpO_2	PR	PI	Vt est
Rapid setting	–	–	–	–

bi-level mode (Volume Guarantee On) parameter table				
Type	Parameter 1	Parameter 2	Parameter 3	Parameter 4
Monitoring	FiO_2	V delivery	PEEP	RR
Rapid setting	FiO_2	Vi	EPAP	–
Type	Parameter 5	Parameter 6	Parameter 7	Parameter 8
Monitoring	SpO_2	PR	PI	PIP
Rapid setting	–	–	–	–

7.2.4 Wave monitoring display (HF function)

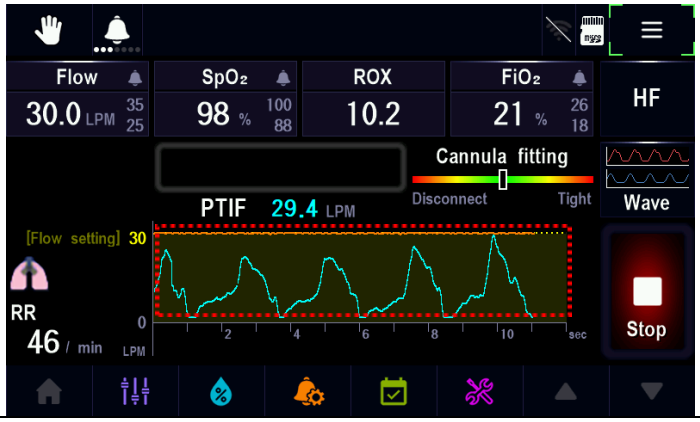
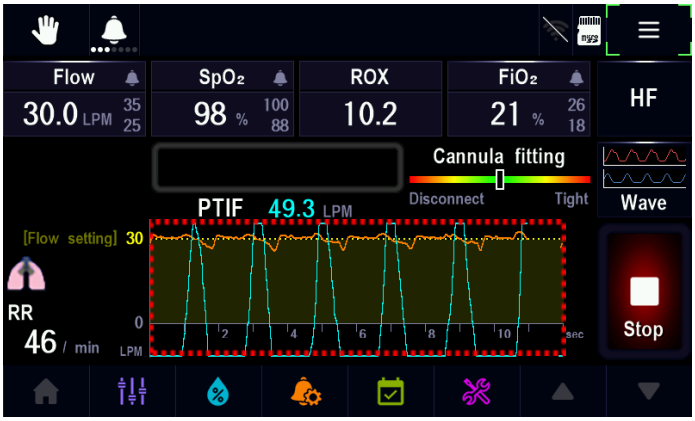
The wave monitoring display and displays the real-time graph of set flow rate and patient flow rate.



No.	Items	Symbols and descriptions	
A	Display window for cannula installation status	This window notifies the user with a message when the cannula is pulled out of the nostril or blocked to such an extent that the patient's breathing cannot be detected.	
		Cannula Tight	When the cannula is fitted too tight on the patient
		Unable to detect RR	When a patient breathing is not detected
		Cannula Wrong Type	When the cannula needs to be checked, such as if it is clogged or bent
B	Cannula fitting indication bar	This indicator bar shows the change in wearing condition during use from the initial condition when the cannula is worn on the patient.	
C	PTIF monitoring parameters	(PTIF: Peak Tidal Inspiratory Flow) Among the flow rates measured in the patient's respiration, the maximum flow value during inspiration is displayed.	
D	Respiration detection		Respiration is not detected.

No.	Items	Symbols and descriptions	
			Inhalation is detected.
			Exhalation is detected.
E	RR monitoring parameters	Patient respiration rate (Refer to 7.1 Measurement information.)	
F	Displays the set flow rate.	Displays the currently set flow rate.	
G	Set flow display line		Real-time waveform of the setting flow rate in the device
			Flow measured in the patient's respiration

7.2.4.1 Wave monitoring type

No.	Type	Description
1		[When the setting flow rate is appropriate compared to the patient's respiratory flow rate] In the waveform of respiration (cyan line) measured from the patient in the graph, the maximum flow waveform in the inspiratory section is appropriately positioned lower than the waveform of flow (orange line) supplied by the device.
2		[When the setting flow rate is not appropriate compared to the patient's respiratory flow rate] In the waveform of respiration (cyan line) measured from the patient in the graph, the maximum flow waveform in the inspiratory section exceeds the waveform of flow (orange line) supplied by the device. In this case, the flow of oxygen and humidification gas supplied to the patient may be insufficient for the patient, so the clinician must determine an appropriate therapy to increase the flow setting of the device.

7.2.4.2 Parameter Table (Wave monitoring)

HF function parameter table				
Type	Parameter 1	Parameter 2	Parameter 3	Parameter 4
Monitoring	Flow	SpO_2	ROX	FiO_2
Rapid setting	Flow	-	-	FiO_2

7.2.5 Wave monitoring display (bi-level mode)

The wave monitoring display is supported in the bi-level mode only and displays the real-time graph of pressure and flow.



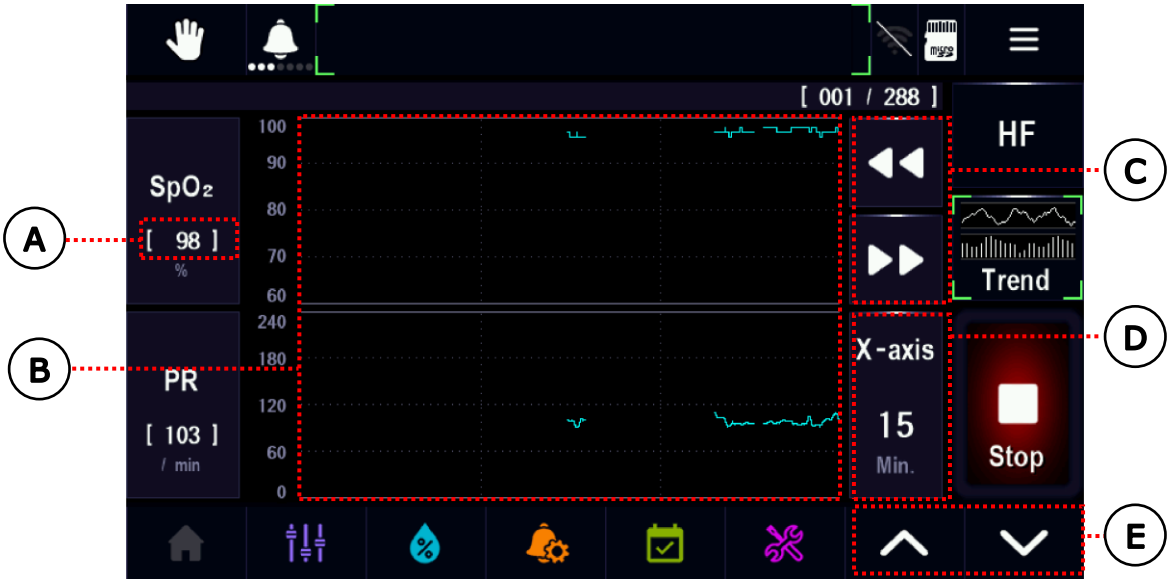
7.2.5.1 Parameter table (Wave monitoring)

bi-level mode (Volume Guarantee Off) parameter table				
Type	Parameter 1	Parameter 2	Parameter 3	Parameter 4
Monitoring	FiO_2	PIP	PEEP	Vt est
Rapid setting	FiO_2	IPAP	EPAP	-
Type	Parameter 5	Parameter 6	Parameter 7	
Monitoring	SpO	PR	RR	
Rapid setting	-	-	RR	

bi-level mode (Volume Guarantee On) parameter table				
Type	Parameter 1	Parameter 2	Parameter 3	Parameter 4
Monitoring	FiO_2	V delivery	PEEP	PIP
Rapid setting	FiO_2	Vi	EPAP	-
Type	Parameter 5	Parameter 6	Parameter 7	
Monitoring	SpO	PR	RR	
Rapid setting	-	-	RR	

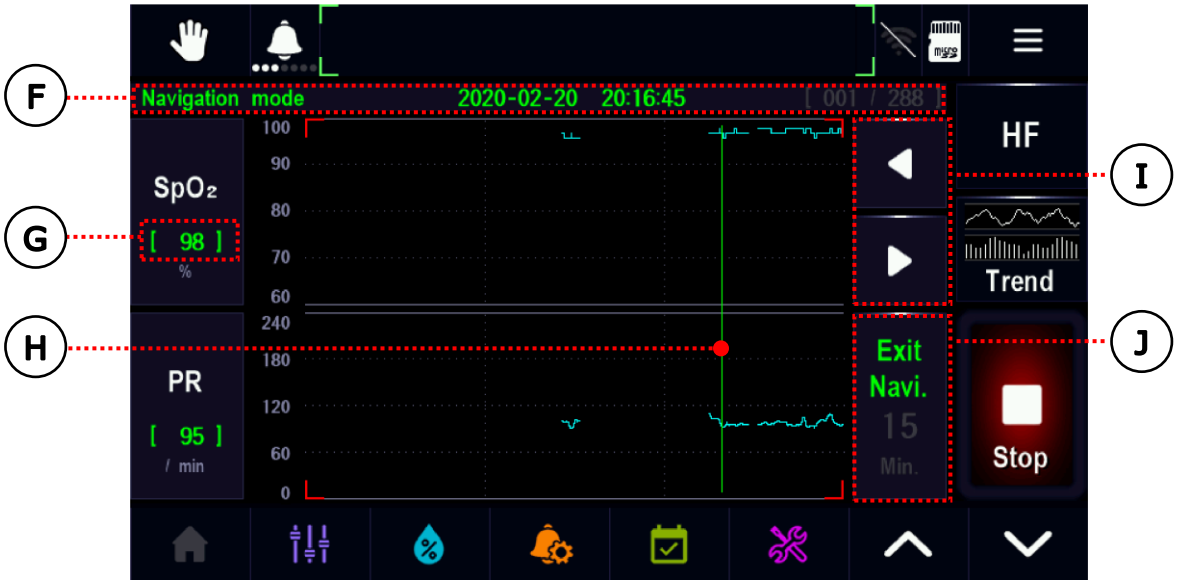
7.2.6 Trend monitoring display

The trend monitoring display shows the trend of the measurement parameters.



No.	Items	Symbols and descriptions
A	Measured value	Displays the real-time measured value of the parameter.
B	Navigation Mode Activation	Activate the Navigation mode by clicking the screen. ✓ When the Navigation mode is activated, you can see navigation bars (green vertical bars) and the navigation mode wording. - By turning the rotary knob in the activated state, you can see the stored values of the desired time point. You can also see them by clicking the screen of the desired time point or using the trend search arrow keys. - While the Navigation mode is activated, the other function keys are not working even though you press them. ✓ To exit the Navigation mode, press the rotary knob or click "Exit Navigation."
C	Page switching	Switches the pages of the Trend display.
D	Page time setting	Sets the display time per page. ✓ You can choose time among 15 min, 30 min, 1 hr., 3 hrs., 6 hrs., 12 hrs., 24 hrs., and 72 hrs. ✓ *The total hours stored in the device is 72 hours regardless of the setting.

No.	Items	Symbols and descriptions
E	Parameter switching key	Two parameters are displayed on one screen. If you press the key, the parameter displayed on the screen is switched. For the parameter entries of each page, see "7.2.5.1 Trend page configuration."



No.	Items	Symbols and descriptions
F	Trend Information Display	You can see the information at the time when the navigation bar is located and the page number in the Navigation mode.
G	Stored value	Displays the stored value at the time when the navigation bar is located in the navigation mode.
H	Navigation bar	A green vertical bar that is activated in the Navigation mode. You can see the stored values of the desired time point by moving the Navigation bar.
I	Trend search arrow keys	These buttons are activated only in the Navigation mode. You can see the stored values by fine tuning the desired time point.
J	Navigation mode Exit	If you press the [Exit Navigation] button, you exit the Navigation mode.

7.2.6.1 Trend page configuration

Page	Mode and function	Items
1 / 4	Common	SpO_2
		PR
2 / 4	HF Function	RR
		FiO_2
	CPAP mode	Vt est
		FiO_2
	bi-level mode	Vt est
		FiO_2
3 / 4	HF Function	Flow
		PI
	CPAP mode	PEEP
		PI
	bi-level mode	PEEP
		PIP
4 / 4	HF Function	ROX
		S/F ratio
	CPAP mode	ROX
		RR
	bi-level mode	PI
5/5	bi-level mode	ROX
		RR

8 Alarm

8.1 Alarm function

This device has an alarm system for the patient's safety.
The device displays an alarm message and triggers an alarm sound in case of:

- Changes in the patient's condition or an issue that can occur during the treatment (for example: Apnea)
- Power problem (for example: Abnormal termination of the system due to AS power failure or the power supply disconnected)
- Gas problem (for example: Gas supply pressure reduced)
- Hardware problem (for example: Overheating or the chamber)
- Software problem (for example: Memory error)

Alarm priority

Alarm priority (Priority Level)	Description	Tone	Color
[High] Immediate actions are necessary to secure the patient's life and safety.	High priority audible alarm (The 5-tone sequence repeats twice, pauses and repeats.)	CCC-CC CCC-CC	Red
[Medium] Immediate attention is necessary.	Medium priority audible alarm (The 3-tone sequence repeats.)	CCC	Yellow
[Low] Attention is necessary as changes to the patient and the system have occurred.	Low priority audible alarm (2-tone sequence. No repeat)	CC	Blue

WARNING

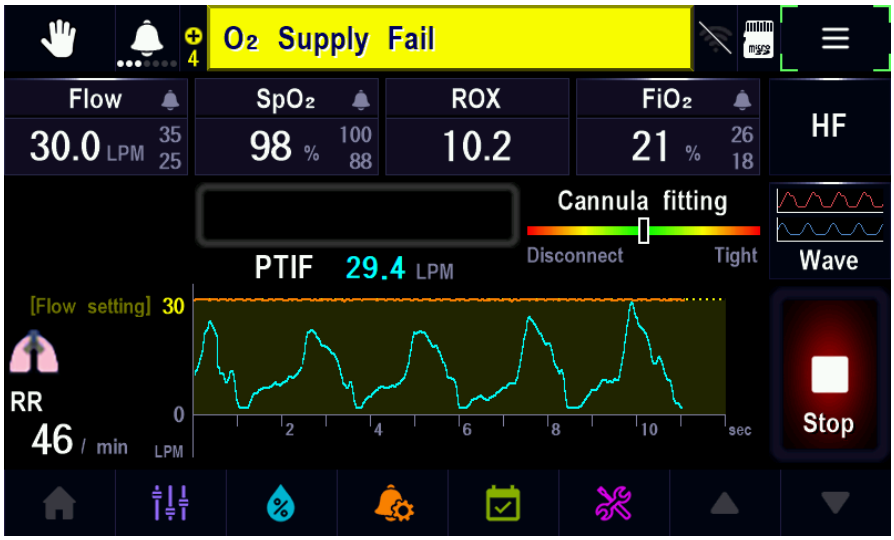
If another device used in the same location triggers an alarm at the same time, potential risks can increase because of the alarm recognition error.

CAUTION

If an alarm sound is activated, a medical team in charge or a medical practitioner who receives the device service training supplied by MEKICS must address the problem.

8.1.1 Displaying alarm

If an alarm sound is activated, an alarm message appears on the top of the screen while the alarm sound is generated.
If an alarm related to a measured value is activated, the measured value is displayed in red.
If an alarm sound is activated, the user must find the cause and react immediately.
For more details, see "8.2 Patient alarms", "8.3 System alarms," and "8.4 Information alarms."



WARNING

When you change or repair parts that may influence therapy such as the oxygen (O2) sensor, you must disconnect the device from the patient.

CAUTION

Do not lift or disconnect the chamber while the device is running, which may cause a burn or the device malfunction. Disconnect the chamber only in the System standby mode or when the device is not working.

NOTE

If the device malfunction alarm keeps ringing, contact a service representative of MEKICS.

8.1.2 Audio Paused

If you press the [Audio Paused] button on the front of the device, the alarm sound is turned off for 2 minutes.
If you press the [Audio Paused] button again during the sound-off, the Audio Paused will be cleared.
During the Audio Paused, the remaining time is displayed with the symbols below:



< Audio Paused button image>



<Audio Paused activated>

8.2 Patient alarms

8.2.1 Apnea

Items	Description
Alarm message	Apnea
Alarm priority	HIGH
Mode / Function	All modes and functions
Cause	The patient's breathing is not detected longer than the alarm set time.
Actions	1. Check the patient's breathing condition. 2. Check the connection status of the breathing circuit. 3. Contact the Service Center.
Alarm Settings Range	10 to 60 seconds, Off
Alarm Settings Resolution	1 second

8.2.2 Open Circuit

Items	Description
Alarm message	Open Circuit
Alarm priority	HIGH
Mode / Function	All modes and functions
Cause	The breathing circuit is disconnected from the device for more than 10 seconds.
Actions	1. Check the connection status of the breathing circuit including the nasal cannula. 2. Perform the nasal cannula calibration or the circuit cannula calibration again. 3. Contact the Service Center.

8.2.3 Check Cannula

Items	Description
Alarm message	Check Cannula
Alarm priority	HIGH
Mode / Function	All modes and functions
Cause	The resistance of the breathing circuit is significantly higher than the pre-therapy (cannula or circuit) calibration results due to a bend or plug of the breathing circuit.
Actions	1. Check if there is a plug in the breathing circuit including the nasal cannula. 2. Check the connection status of the breathing circuit. 3. Contact the Service Center.

8.2.4 Total Leakage High

Items	Description
Alarm message	Total Leakage High
Alarm priority	HIGH
Mode / Function	CPAP, bi-level mode
Cause	The sum of the base leakage of the mask and the additional leakage exceeds 80 l/min. -Base leakage: Leakage due to the vent holes of the mask -Additional leakage: Leakage because of the mask-wearing status
Actions	1. Check the mask-wearing status. 2. Check the connection status of the breathing circuit including the mask. 3. Contact the Service Center.

8.2.5 Leakage High

Items	Description
Alarm message	Leakage High
Alarm priority	HIGH
Mode / Function	CPAP, bi-level mode
Cause	The additional leak exceeds the alarm set point due to the loose mask wearing.
Actions	1. Check the patient's mask wearing status. 2. If the alarm set point is too low, adjust the set point.
Alarm Setting Range	10 to 70 l/min
Alarm Setting Resolution	1 l/min

8.2.6 Flow High

Items	Description
Alarm message	Flow High
Alarm priority	MEDIUM
Mode / Function	HF Function
Cause	The measured flow is maintained higher than the alarm upper limit set point for more than 10 seconds.
Actions	1. If the alarm set point is too close to the therapy set point, adjust the alarm set point. 2. Contact the Service Center.
Alarm Settings Range	• The maximum flow is ≤ 8 l/min. (The alarm lower limit set point + 0.5) to 30.0 l/min • The maximum flow is ≥ 40 l/min. (The alarm lower limit set point + 1) to 65 l/min
Alarm Settings Resolution	• The maximum flow is ≤ 8 l/min. 0.5 l/min • The maximum flow is ≥ 40 l/min. 1 l/min

8.2.7 Flow Low

Items	Description
Alarm message	Flow Low
Alarm priority	MEDIUM
Mode / Function	HF Function
Cause	The measured flow is maintained lower than the alarm lower limit set point for more than 10 seconds.
Actions	1. If the alarm set point is too close to the therapy set point, adjust the alarm set point. 2. Contact the Service Center.
Alarm Setting Range	• The maximum flow is ≤ 8 l/min. 0 to (The alarm lower limit set point – 0.5) l/min • The maximum flow is ≥ 40 l/min. 0 to (The lower limit of the alarm set point – 1) l/min
Alarm Setting Resolution	• The maximum flow is ≤ 8 l/min. 0.5 l/min • The maximum flow is ≥ 40 l/min. 1 l/min

8.2.8 PIP High

Items	Description
Alarm message	PIP High
Alarm priority	HIGH
Mode / Function	CPAP, bi-level mode
Cause	The measured PIP value is higher than the alarm upper limit set point
Actions	1. If the alarm set point is too close to the therapy set point, adjust the alarm set point. 2. Check if there is leakage in the breathing circuit including the mask. 3. Contact the Service Center.
Alarm Setting Range	• In the CPAP mode, (CPAP set point + 1) to 43 cmH_2O • In the bi-level mode(Volume guarantee Off), (IPAP set point + 1) to 50 cmH_2O • In the bi-level mode(Volume guarantee On), 5(Minimum IPAP set value +1) to 50 cmH_2O
Alarm Setting Resolution	1 cmH_2O

8.2.9 PIP Low

Items	Description
Alarm message	PIP Low
Alarm priority	HIGH
Mode / Function	CPAP, bi-level mode (Volume guarantee Off)
Cause	The measured PIP value is lower than the alarm lower limit set point
Actions	1. If the alarm set point is too close to the therapy set point, adjust the alarm set point. 2. Check if there is leakage in the breathing circuit including the mask. 3. Contact the Service Center.
Alarm Setting Range	• In the CPAP mode, 0 to (CPAP set point – 1) cmH_2O • In the bi-level mode(Volume guarantee Off), 0 to (IPAP set point – 1) cmH_2O • In the bi-level mode(Volume guarantee On), Inactive alarm
Alarm Setting Resolution	1 cmH_2O

8.2.10 PEEP High

Items	Description
Alarm message	PEEP High
Alarm priority	MEDIUM
Mode / Function	CPAP, bi-level mode
Cause	The measured PEEP value is higher than the upper limit of the alarm set point
Actions	1. If the alarm set point is too close to the therapy set point, adjust the alarm set point. 2. Check if the breathing circuit including the mask is plugged. 3. Contact the Service Center.
Alarm Setting Range	• In the CPAP mode, (CPAP set point + 1) to 22 cmH_2O • In the bi-level mode, (EPAP set point + 1) to 22 cmH_2O
Alarm Setting Resolution	1 cmH_2O

8.2.11 PEEP Low

Items	Description
Alarm message	PEEP Low
Alarm priority	MEDIUM
Mode / Function	CPAP, bi-level mode
Cause	The measured PEEP value is lower than the lower limit of the alarm set point
Actions	1. If the alarm set point is too close to the therapy set point, adjust the alarm set point. 2. Check if there is leakage in the breathing circuit including the mask. 3. Contact the Service Center.
Alarm Setting Range	• In the CPAP mode, 0 to (CPAP set point – 1) cmH_2O • In the bi-level mode, 0 to (EPAP set point – 1) cmH_2O
Alarm Setting Resolution	1 cmH_2O

8.2.12 FiO_2 High

Items	Description
Alarm message	FiO_2 High
Alarm priority	MEDIUM
Mode / Function	All modes and functions
Cause	The measured oxygen density is maintained higher than the alarm upper limit set point for more than 3 minutes.
Actions	1. If the alarm set point is too close to the therapy set point, adjust the alarm set point. 2. Check the replacement cycle of the oxygen (O_2) sensor. 3. Perform the oxygen (O_2) calibration again. 4. Contact the Service Center.
Alarm Setting Range	(The alarm lower limit set point + 1) to 100 %
Alarm Setting Resolution	1 %

8.2.13 FiO_2 Low

Items	Description
Alarm message	FiO_2 Low
Alarm priority	MEDIUM
Mode / Function	All modes and functions
Cause	The measured oxygen density is maintained lower than the alarm lower limit set point for more than 3 minutes.
Actions	1. If the alarm set point is too close to the therapy set point, adjust the alarm set point. 2. Check the replacement cycle of the oxygen (O_2) sensor. 3. Perform the oxygen (O_2) calibration again. 4. Contact the Service Center.
Alarm Setting Range	18 to (The alarm upper limit set point – 1) %
Alarm Setting Resolution	1 %

8.2.14 RR High

Items	Description
Alarm message	RR High
Alarm priority	MEDIUM
Mode / Function	All modes and functions
Cause	The measured RR value is maintained higher than the alarm upper limit set point for more than 5 seconds.
Actions	1. Check the patient's condition. 2. If the alarm set point is too low, adjust the alarm set point. 3. CPAP or bi-level mode: If the Trig. Level set point is too low, adjust the setting. 4. Contact the Service Center.
Alarm Setting Range	(The alarm lower limit set point + 1) to 150 /min
Alarm Setting Resolution	1 /min

8.2.15 RR Low

Items	Description
Alarm message	RR Low
Alarm priority	MEDIUM
Mode / Function	All modes and functions
Cause	The measured RR value is maintained lower than the alarm lower limit set point for more than 5 seconds.
Actions	1. Check the patient's condition. 2. If the alarm set point is too high, adjust the alarm set point. 3. CPAP or bi-level mode: If the Trig. Level set point is too high, adjust the setting. 4. Contact the Service Center.
Alarm Setting Range	0 to (The alarm upper limit set point – 1) /min
Alarm Setting Resolution	1 /min

8.2.17 V delivery High

Items	Description
Alarm message	V delivery High
Alarm priority	MEDIUM
Mode / Function	bi-level mode
Cause	The average measured V delivery value is higher than the upper limit of the alarm set point. - The average is performed from 1 minute after the start of treatment. - The average is calculated as the V delivery value of the last 3 breaths.
Actions	1. Check the patient's condition. 2. If the alarm set point is too low, adjust the alarm set point. 3. Contact the Service Center.
Alarm Setting Range	(The alarm lower limit set point + 1) to 2500 ml
Alarm Setting Resolution	1 ml

8.2.18 V delivery Low

Items	Description
Alarm message	V delivery Low
Alarm priority	MEDIUM
Mode / Function	bi-level mode
Cause	The average measured V delivery value is lower than the lower limit of the alarm set point. - The average is performed from 1 minute after the start of treatment. - The average is calculated as the V delivery value of the last 3 breaths.
Actions	1. Check the patient's condition. 2. If the alarm set point is too high, adjust the alarm set point. 3. Contact the Service Center.
Alarm Setting Range	50 to (The alarm upper limit set point - 1) ml
Alarm Setting Resolution	1 ml

8.2.19 SpO_2 High

Items	Description
Alarm message	SpO_2 High
Alarm priority	MEDIUM
Mode / Function	SpO_2 monitoring function
Cause	The measured SpO_2 value is maintained higher than the alarm upper limit set point for more than 7 seconds.
Actions	1. Check the patient's condition. 2. If the alarm set point is too low, adjust the alarm set point. 3. Check that the SpO_2 probe is well connected to the patient's finger. 4. Check that the FiO_2 settings are set properly to the patient's condition. 5. Change the SpO_2 probe and the probe extension cable. 6. Contact the Service Center.
Alarm Setting Range	(The alarm lower limit set point + 1) to 99 %, Off
Alarm Setting Resolution	1 %

8.2.20 SpO_2 Low

Items	Description
Alarm message	SpO_2 Low
Alarm priority	MEDIUM
Mode / Function	SpO_2 monitoring function
Cause	The measured SpO_2 value is maintained lower than the alarm lower limit set point for more than 7 seconds.
Actions	1. Check the patient's condition. 2. If the alarm set point is too high, adjust the alarm set point. 3. Check that the SpO_2 probe is well connected to the patient's finger. 4. Check that the FiO_2 settings are set properly to the patient's condition. 5. Change the SpO_2 probe and the probe extension cable. 6. Contact the Service Center.
Alarm Setting Range	1 to (The alarm upper limit set point – 1) %
Alarm Setting Resolution	1 %

8.2.21 PI High

Items	Description
Alarm message	PI High
Alarm priority	MEDIUM
Mode / Function	SpO_2 monitoring function
Cause	The measured PI value is maintained higher than the alarm upper limit set point for more than 7 seconds.
Actions	1. Check the patient's condition. 2. If the alarm set point is too low, adjust the alarm set point. 3. Check that the SpO_2 probe is well connected to the patient's finger. 4. Contact the Service Center.
Alarm Setting Range	• If PI < 0.1 %, (The alarm lower limit set point + 0.01) to 19 %, Off • If 0.1 % ≤ PI < 1 %, (The alarm lower limit set point + 0.1) to 19 %, Off • If 1 % ≤ PI, (The alarm lower limit set point + 1) to 19 %, Off
Alarm Setting Resolution	• If PI < 0.1 %, 0.01 % • If 0.1 % ≤ PI < 1 %, 0.1 % • If 1 % ≤ PI, 1 %

8.2.22 PI Low

Items	Description
Alarm message	PI Low
Alarm priority	MEDIUM
Mode / Function	SpO_2 monitoring function
Cause	The measured PI value is maintained lower than the alarm lower limit set point for more than 7 seconds.
Actions	1. Check the patient's condition. 2. If the alarm set point is too high, adjust the alarm set point. 3. Check that the SpO_2 probe is well connected to the patient's finger. 4. Contact the Service Center.
Alarm Setting Range	• If PI < 0.1 %, 0.03 to (The alarm upper limit set point – 0.01) %, Off • If 0.1 % ≤ PI < 1 %, 0.03 to (The alarm upper limit set point – 0.1) %, Off • If 1 % ≤ PI, 0.03 to (The alarm upper limit set point – 1) %, Off
Alarm Setting Resolution	• If PI < 0.1 %, 0.01 % • If 0.1 % ≤ PI < 1 %, 0.1 % • If 1 % ≤ PI, 1 %

8.2.23 PR High

Items	Description
Alarm message	PR High
Alarm priority	MEDIUM
Mode / Function	SpO_2 monitoring function
Cause	The measured PR value is maintained higher than the alarm upper limit set point for more than 7 seconds.
Actions	1. Check the patient's condition. 2. If the alarm set point is too low, adjust the alarm set point. 3. Check that the SpO_2 probe is well connected to the patient's finger. 4. Change the SpO_2 probe and the probe extension cable. 5. Contact the Service Center.
Alarm Setting Range	(The alarm lower limit set point + 5) to 235 /min, Off
Alarm Setting Resolution	5 /min

8.2.24 PR Low

Items	Description
Alarm message	PR Low
Alarm priority	MEDIUM
Mode / Function	SpO_2 monitoring function
Cause	The measured PR value is maintained lower than the alarm lower limit set point for more than 7 seconds.
Actions	1. Check the patient's condition. 2. If the alarm set point is too high, adjust the alarm set point. 3. Check that the SpO_2 probe is well connected to the patient's finger. 4. Change the SpO_2 probe and the probe extension cable. 5. Contact the Service Center.
Alarm Setting Range	30 to (The alarm upper limit set point – 5) /min, Off
Alarm Setting Resolution	5 /min

8.2.25 SpO_2 Probe off Patient

Items	Description
Alarm message	SpO_2 Probe off Patient
Alarm priority	LOW (Under treatment) or Information Alarm (In Standby)
Mode / Function	SpO_2 monitoring function
Cause	If the SpO_2 probe is disconnected from the patient's finger during the SpO_2 monitoring; or if the nothing is measured for more than 7 seconds during the SpO_2 monitoring
Actions	1. Check the patient's condition. 2. Check that the SpO_2 probe is well connected to the patient's finger. 3. Change the SpO_2 probe and the probe extension cable.

8.3 System alarms

8.3.1 Check Blower

Items	Description
Alarm message	Check Blower
Alarm priority	HIGH
Cause	The blower inside the device is not working normally.
Actions	1. Contact the Service Center.

8.3.2 Blower Temp. High

Items	Description
Alarm message	Blower Temp. High
Alarm priority	HIGH
Cause	The temperature of the blower inside the device is abnormally high
Actions	1. Check the indoor temperature. If the indoor temperature is too high, the temperature inside the device can rise abnormally. 2. Check if the ventilation openings on the bottom, each side, and back of the device are blocked or covered with other objects. 3. Contact the Service Center.

8.3.3 Airway Temp. High

Items	Description
Alarm message	Airway Temp. High
Alarm priority	HIGH
Cause	The measured airway temperature is maintained higher than the alarm upper limit set point for more than 20 minutes. If the dew point set point is set to Off in the CPAP or bi-level mode, this alarm is not activated.
Actions	1. Check the temperature sensor connection or the cable status (such as excessive bend or damage.) 2. If the alarm set point is too close to the monitoring value, adjust the alarm set point. 3. Check the indoor temperature. If the indoor temperature differs too much from the recommended indoor temperature (18 to 26 ℃), the exact control cannot be guaranteed. 4. Contact the Service Center.
Alarm Setting Range	(The alarm lower limit set point + 1) to 44 ℃
Alarm Setting Resolution	1 ℃

8.3.4 Airway Temp. Low

Items	Description
Alarm message	Airway Temp. Low
Alarm priority	HIGH
Cause	The measured airway temperature is maintained lower than the alarm lower limit set point for more than 20 minutes. If the dew point set point is set to Off in the CPAP or bi-level mode, this alarm is not activated.
Actions	1. Check the temperature sensor connection or the cable status (such as excessive bend or damage.) 2. If the alarm set point is too close to the monitoring value, adjust the alarm set point. 3. Check the indoor temperature. If the indoor temperature differs too much from the recommended indoor temperature (18 to 26 ℃), the exact control cannot be guaranteed. 4. Contact the Service Center.
Alarm Setting Range	0 to (The alarm upper limit set point – 1) ℃
Alarm Setting Resolution	1 ℃

8.3.5 O_2 Inlet Pressure High

Items	Description
Alarm message	O_2 Inlet Pressure High
Alarm priority	HIGH
Cause	The pressure of O_2 which is supplied to the high-pressure oxygen inlet is 655 kPa (95 psi) or higher.
Actions	1. Check the connection status and the pressure of the high-pressure oxygen hose. 2. Contact the Service Center.

8.3.6 O_2 Supply Fail

Items	Description
Alarm message	O_2 Supply Fail
Alarm priority	MEDIUM
Cause	The pressure of O_2 which is supplied to the high-pressure oxygen inlet is below 172.4 kPa (25 psi).
Actions	1. Check the connection status and the pressure of the high-pressure oxygen hose. 2. Contact the Service Center.

8.3.7 No chamber

Items	Description
Alarm message	No Chamber
Alarm priority	MEDIUM
Cause	The chamber is not installed or not fixed completely.
Actions	1. Check that the chamber is securely attached. 2. Check that the installed chamber is supplied or approved by MEKICS. Using a chamber from another manufacturer may cause the sensor to malfunction. 3. Contact the Service Center.

8.3.8 Refill the water

Items	Description
Alarm message	Refill the water
Alarm priority	MEDIUM
Cause	If the water shortage situation persists for approximately 30 seconds
Actions	1. Check that the water level within the chamber is lower than the appropriate level marked on the chamber. 2. Refill the water until it reaches the appropriate level marked on the chamber.



WARNING

1. Make sure there are no foreign substances such as dust.
2. The alarm may not sound if the product is placed on an uneven surface.
3. If the indoor lighting environment is too bright, the alarm may operate in accurately.

- Incandescent light: It may not operate properly above 500lx.
- Fluorescent/LED light: It may not operate properly above 15000lx.

8.3.9 Heat-Wire is Disconnected

Items	Description
Alarm message	Heat-Wire is Disconnected
Alarm priority	MEDIUM
Cause	The heated wire power cable of the breathing circuit is disconnected from the device or the cable is damaged. If the dew point set point is set to Off in the CPAP or bi-level mode, this alarm is not activated.
Actions	1. Check if the heated wire power cable is damaged or not. 2. Change the cable to a new one. 3. Contact the Service Center.

8.3.10 Heat-Plate Fail

Items	Description
Alarm message	Heat-Plate Fail
Alarm priority	MEDIUM
Cause	Although the heat plate is energized for humidification, the temperature of the heat plate does not change or reach the target. If the dew point set point is set to Off in the CPAP or bi-level mode, this alarm is not activated.
Actions	1. Contact the Service Center.

8.3.11 Heat-Plate Temp. Sensor is Fail

Items	Description
Alarm message	Heat-Plate Temp. Sensor is Fail
Alarm priority	MEDIUM
Cause	The heat-plate temperature sensor inside the device is disconnected or damaged If the dew point set point is set to Off in the CPAP or bi-level mode, this alarm is not activated.
Actions	1. Contact the Service Center.

8.3.12 Airway Temp. Sensor is Fail

Items	Description
Alarm message	Airway Temp. Sensor is Fail
Alarm priority	MEDIUM
Cause	The temperature sensor cable is disconnected from the device or the cable is damaged. If the dew point set point is set to Off in the CPAP or bi-level mode, this alarm is not activated.
Actions	1. Check if the temperature sensor cable is damaged or not. 2. Change the cable to a new one. 3. Contact the Service Center.

8.3.13 Chamber Temp. Sensor is Fail

Items	Description
Alarm message	Chamber Temp. Sensor is Fail
Alarm priority	MEDIUM
Cause	The temperature sensor cable is disconnected from the device or the cable is damaged. If the dew point set point is set to Off in the CPAP or bi-level mode, this alarm is not activated.
Actions	1. Check if the temperature sensor cable is damaged or not. 2. Change the cable to a new one. 3. Contact the Service Center.

8.3.14 AC loss

Items	Description
Alarm message	AC loss
Alarm priority	HIGH(Only sound)
Cause	This alarm occurs when the main power (AC power) is disconnected during normal operation or the power is turned off abnormally while the unit is in use. If an alarm does not occur at abnormal power-off or an alarm occurs at normal power-off, it is a system malfunction. This alarm will not be paused for approximately at least 2 minutes until the device is reconnected (powered on) and turned on again.
Actions	1. Check the AC power connection and AC power switch 2. Contact service center.

8.4 Information alarms

8.4.1 Check SpO_2 Probe

Items	Description
Alarm message	Check SpO_2 Probe
Alarm priority	Information alarms
Mode / Function	SpO_2 monitoring function
Cause	The SpO_2 probe is not connected to the device when the SpO_2 function is activated.
Actions	1. Connect the SpO_2 probe 2. If you don't use the SpO_2 function, go to "Menu->System-> SpO_2" and deactivate the SpO_2 function. 3. If the alarm is activated when the SpO2 probe is normally connected, replace the SpO2 probe and the probe extension cable. 4. Contact the Service Center.

NOTE

1. The update rate of the monitoring value is generally one second.
2. The display of the monitoring values, the data average of the transferred data values, and the other signal processes are controlled automatically by the device.
3. The trigger of the alarm is delayed for up to 5 seconds depending on the difference between the alarm set point and the measured values.
4. The delay of the alarm condition can be up to 1 second depending on the response rate of values.

8.5 Alarm test

To test if the alarm is activated correctly, the oxygen must be supplied normally and the AC power cord must be connected. Accessories listed below are also prepared.

Perform the test at least every 6 months by reviewing the alarm test method described here.

Things to prepare for the alarm test

- Nasal cannula
- Mask
- Breathing circuit
- SpO_2 probe
- SpO_2 extension cable
- Heated wire power cable & temperature probe Y cable
- etc.

Refer to "4 How to prepare" and install every accessory necessary for the therapy correctly.

If the alarm sound is not ringing even though the value is beyond the set alarm range, check the parameters of the device and perform the test again. Refer to the table below for how to trigger each alarm.

8.5.1 Patient alarm test

Alarm message [Priority]	Description
Apnea [HIGH]	• Select the HF function and perform the cannula calibration. • In the HF function, set the flow alarm to 30 l/min, FiO_2 to 21 %, the RR detection On and keep the default for other set points, and then press the [Therapy Start] button. • Check the RR value measured while breathing naturally. • Disconnect the nasal cannula from the nose after the RR value is measured, and wait until the alarm setting time. • Check if the alarm is activated.
Open Circuit [HIGH]	• Select the HF function and perform the cannula calibration. • In the HF function, set the flow alarm to 30 l/min and FiO_2 to 21 % and keep the default for other set points, and then press the [Therapy Start] button. • Verify that the device operates normally, and check that another alarm is not activated. • Disconnect the nasal cannula from the breathing circuit and wait for 10 seconds. • Check if the alarm is activated.
Check Cannula [HIGH]	• Select the HF function and perform the cannula calibration. • In the HF function, set the flow alarm to 30 l/min and FiO_2 to 21 % and keep the default for other set points, and then press the [Therapy Start] button. • Verify that the device operates normally, and check that another alarm is not activated. • Plug the nasal cannula outlet completely and wait for 10 seconds. • Check if the alarm is activated.
Total Leakage High [HIGH]	• Select the bi-level mode and perform the circuit calibration. • Set the FiO_2 to 21 % and keep the default for the other set points and start the therapy. • Wear the mask and breathe naturally. • Set the Leakage High alarm to 70 l/min and then loosen the mask slowly to increase the additional leak. • Check if the alarm is activated.
Leakage High [HIGH]	• Select the bi-level mode and perform the circuit calibration. • Set the FiO_2 to 21 % and keep the default for the other set points and start the therapy. • Wear the mask and breathe naturally. • Set the Leakage High alarm to 10 l/min and then loosen the mask slowly to increase the additional leak. • Check if the alarm is activated.

Alarm message [Priority]	Description
Flow High [MEDIUM]	• Select the HF function and perform the cannula calibration. • In the HF function, set the flow alarm to 30 l/min and FiO_2 to 21 % and keep the default for other set points, and then press the [Therapy Start] button. • In the Alarm Settings menu, set the alarm upper limit set point lower than the actual flow. • Check if the alarm is activated after waiting for about 10 seconds.
Flow Low [MEDIUM]	• Select the HF function and perform the cannula calibration. • In the HF function, set the flow alarm to 30 l/min and FiO_2 to 21 % and keep the default for other set points, and then press the [Therapy Start] button. • In the Alarm Settings menu, set the alarm lower limit set point higher than the actual flow. • Check if the alarm is activated after waiting for about 10 seconds.
PIP High [HIGH]	• Select the bi-level mode and perform the circuit calibration. • Set the IPAP to 20 cmH_2O, EPAP to 5 cmH_2O, FiO_2 to 21 % and Rise time to Fast, and keep the default for other set points, and then press the [Therapy Start] button. • In the Alarm Settings menu, set the alarm upper limit set point to the lowest value. • Inhale quickly to cause the PIP value to become higher than the alarm set point. • Check if the alarm is activated.
PIP Low [HIGH]	• Select the bi-level mode and perform the circuit calibration. • Set the IPAP to 40 cmH_2O, EPAP to 5 cmH_2O, and FiO_2 to 21 %, and keep the default for other set points, and then press the [Therapy Start] button. • In the Alarm Settings menu, set the alarm lower limit set point to the highest value. • Wearing the mask loosely causes the PIP value to become lower than the alarm set point. • Check if the alarm is activated.
PEEP High [MEDIUM]	• Select the bi-level mode and perform the circuit calibration. • Set the IPAP to 10 cmH_2O, EPAP to 5 cmH_2O, and FiO_2 to 21 %, and keep the default for other set points, and then press the [Therapy Start] button. • Exhale strongly to cause the measured PEEP value to become higher than the alarm set point. • Check if the alarm is activated.

Alarm message [Priority]	Description
PEEP Low [MEDIUM]	• Select the bi-level mode and perform the circuit calibration. • Set the IPAP to 40 cmH_2O, EPAP to 20 cmH_2O, and FiO_2 to 21 %, and keep the default for other set points, and then press the [Therapy Start] button. • Attempt to breathe naturally and check the PEEP value measured. • In the Alarm Settings menu, set the alarm lower limit set point to the highest value. • Wear the mask loosely to cause the PEEP value to become lower than the alarm set point. • Check if the alarm is activated.
FiO_2 High [MEDIUM]	• In the HF function, set the flow alarm to 30 l/min and FiO_2 to 21 % and keep the default for other set points, and then press the [Therapy Start] button. • Check if the FiO_2 monitoring value is displayed normally. • In the Alarm Settings menu, set the alarm upper limit set point lower than the measured FiO_2 value and wait for about 3 minutes. • Check if the alarm is activated.
FiO_2 Low [MEDIUM]	• In the HF function, set the flow alarm to 30 l/min and FiO_2 to 21 % and keep the default for other set points, and then press the [Therapy Start] button. • Check if FiO_2 monitoring value is displayed normally. • In the Alarm Settings menu, set the alarm lower limit set point higher than the measured FiO_2 value and wait for about 3 minutes. • Check if the alarm is activated.
RR High [MEDIUM]	• In the HF function, set the flow alarm to 30 l/min, FiO_2 to 21 %, the RR detection On and keep the default for other set points, and then press the [Therapy Start] button. • Check the RR value measured while breathing naturally. • In the Alarm Settings menu, set the alarm upper limit set point lower than the measured RR value and wait for about 7 seconds. • Check if the alarm is activated.
RR Low [MEDIUM]	• Select the HF function and perform the cannula calibration. • In the HF function, set the flow alarm to 30 l/min, FiO_2 to 21 %, the RR detection On and keep the default for other set points, and then press the [Therapy Start] button. • Check the RR value measured while breathing naturally. • In the Alarm Settings menu, set the alarm lower limit set point higher than the measured RR value and wait for about 7 seconds. • Check if the alarm is activated.

Alarm message [Priority]	Description
V delivery High [MEDIUM]	• Select the bi-level mode and perform the circuit calibration. • Set the IPAP to 10 cmH_2O, EPAP to 5 cmH_2O, and FiO_2 to 21 %, and keep the default for other set points, and then press the [Therapy Start] button. • Turn on the Volume Guarantee function. • Check the V delivery measured while breathing naturally. • In the Alarm Settings menu, set the alarm upper limit set point lower than the measured V delivery value and wait for about 60 seconds. • Check if the alarm is activated.
V delivery Low [MEDIUM]	• Select the bi-level mode and perform the circuit calibration. • Set the IPAP to 10 cmH_2O, EPAP to 5 cmH_2O, and FiO_2 to 21 %, and keep the default for other set points, and then press the [Therapy Start] button. • Turn on the Volume Guarantee function. • Check the V delivery measured while breathing naturally. • In the Alarm Settings menu, set the alarm lower limit set point higher than the measured V delivery value and wait for about 60 seconds. • Check if the alarm is activated.
SpO_2 High [MEDIUM]	• Wear the SpO_2 probe to a finger. • In the HF function, set the flow alarm to 30 l/min and FiO_2 to 21 % and keep the default for other set points, and then press the [Therapy Start] button. • Check if the SpO_2 value is measured normally. • In the Alarm Settings menu, set the alarm upper limit set point lower than the measured SpO_2 value and wait for about 7 seconds. • Check if the alarm is activated. • This alarm works only when the SpO_2function is activated.
SpO_2 Low [MEDIUM]	• Wear the SpO_2 probe to a finger. • In the HF function, set the flow alarm to 30 l/min and FiO_2 to 21 % and keep the default for other set points, and then press the [Therapy Start] button. • Check if the SpO_2 value is measured normally. • In the Alarm Settings menu, set the alarm lower limit set point higher than the measured SpO_2 value and wait for about 7 seconds. • Check if the alarm is activated. • This alarm works only when the SpO_2function is activated.
PI High [MEDIUM]	• Wear the SpO_2 probe to a finger. • In the HF function, set the flow alarm to 30 l/min and FiO_2 to 21 % and keep the default for other set points, and then press the [Therapy Start] button. • Check if the PI value is measured normally. • In the Alarm Settings menu, set the alarm upper limit set point lower than the measured PI value and wait for about 7 seconds. • Check if the alarm is activated.

Alarm message [Priority]	Description
	• This alarm works only when the SpO_2function is activated.
PI Low [MEDIUM]	• Wear the SpO_2 probe to a finger. • In the HF function, set the flow alarm to 30 l/min and FiO_2 to 21 % and keep the default for other set points, and then press the [Therapy Start] button. • Check if the PI value is measured normally. • In the Alarm Settings menu, set the alarm lower limit set point higher than the measured PI value and wait for about 7 seconds. • Check if the alarm is activated. • This alarm works only when the SpO_2function is activated.
PR High [MEDIUM]	• Wear the SpO_2 probe to a finger. • In the HF function, set the flow alarm to 30 l/min and FiO_2 to 21 % and keep the default for other set points, and then press the [Therapy Start] button. • Check if the PR value is measured normally. • In the Alarm Settings menu, set the alarm upper limit set point lower than the measured PR value and wait for about 7 seconds. • Check if the alarm is activated. • This alarm works only when the SpO_2function is activated.
PR Low [MEDIUM]	• Wear the SpO_2 probe to a finger. • In the HF function, set the flow alarm to 30 l/min and FiO_2 to 21 % and keep the default for other set points, and then press the [Therapy Start] button. • Check if the PR value is measured normally. • In the Alarm Settings menu, set the alarm lower limit set point higher than the measured PR value and wait for about 7 seconds. • Check if the alarm is activated. • This alarm works only when the SpO_2 function is activated.
SpO_2 Probe off Patient [LOW]	• Connect the SpO_2 probe to a finger. • In the HF function, set the flow alarm to 30 l/min and FiO_2 to 21 % and keep the default for other set points, and then press the [Therapy Start] button. • Check if the SpO_2 monitoring value is displayed normally. • Disconnect the SpO_2 probe from the finger. • Check if the alarm is activated. • This alarm works only when the SpO_2function is activated.
Check SpO_2 Probe [Info. Sound]	• Turn on the device without the SpO_2 probe connection. • Check if the alarm is activated. • This alarm works only when the SpO_2function is activated.

8.5.2 System alarm test

Alarm message [Priority]	Description
Airway Temp. High [HIGH]	• In the HF function, set the flow alarm to 30 l/min and FiO_2 to 21 % and keep the default for other set points, and then press the [Therapy Start] button. • Check if the airway temperature monitoring value is displayed normally. • In the Alarm Settings menu, set the alarm upper limit set point lower than the monitoring value. • Check if the alarm is activated after waiting for about 20 minutes.
Airway Temp. Low [HIGH]	• In the HF function, set the flow alarm to 30 l/min and FiO_2 to 21 % and keep the default for other set points, and then press the [Therapy Start] button. • Check if the airway temperature monitoring value is displayed normally. • In the Alarm Settings menu, set the alarm lower limit set point higher than the monitoring value. • Check if the alarm is activated after waiting for about 20 minutes.
O_2 Inlet Pressure High [MEDIUM]	• Do not connect the High Pressure O_2 to the device. • In the HF function, keep the default for all set points, and then press the [Therapy Start] button. • Check if the alarm is activated.
O_2 Inlet Pressure Low [HIGH]	• Connect the oxygen cylinder with a pneumatic regulator to the high-pressure oxygen inlet. At this time, fine-tune the pressure of the oxygen cylinder between 668.8 kPa and 689.5 kPa (between 97 psi and 100 psi, between 6.8 kg/cm^2 and 7 kg/cm^2). • Energize the device and check if the alarm is activated. • Take care that the maximum pressure of 689.5 kPa (100 psi, 7 kg/cm^2) is not exceeded. Supplying the high-pressure oxygen beyond the allowable range may cause a severe failure of the device.
No chamber [MEDIUM]	• In the HF function, set the flow alarm to 30 l/min and FiO_2 to 21 % and keep the default for other set points, and then press the [Therapy Start] button. • Remove the chamber from the device while it is working. • Check if the alarm is activated.
Refill the water	• Install all the necessary accessories for treatment correctly. Do not fill the chamber with water. • After 30 seconds, make sure to replenish the water and check if the alarm is triggered.

Alarm message [Priority]	Description
Heat-Wire is Disconnected [MEDIUM] Airway Temp. Sensor is Fail [MEDIUM] Chamber Temp. Sensor is Fail [MEDIUM]	• In the HF function, set the flow alarm to 30 l/min and FiO_2 to 21 % and keep the default for other set points, and then press the [Therapy Start] button. • Disconnect the heat wire & temp. probe cable from the device. • Check if the alarm is activated.
AC Loss [High]	• Turn on the device for this alarm test, and wait for more 10 seconds approximately. • Disconnect the power cord from the power outlet or device. • Verify this alarm occur. • Reconnect the power cord to power outlet or device. • Turn on the device and verify this alarm disappear after system booting
The other alarm tests	You cannot intentionally meet the alarm condition for the alarms below. For more details about the conditions that trigger alarms during the use of the device, see "8.3 System alarms." • Heat-Plate Temp. Sensor is Fail • Heat-Plate Fail • Check Blower • Blower Temp. High

9 Additional functions

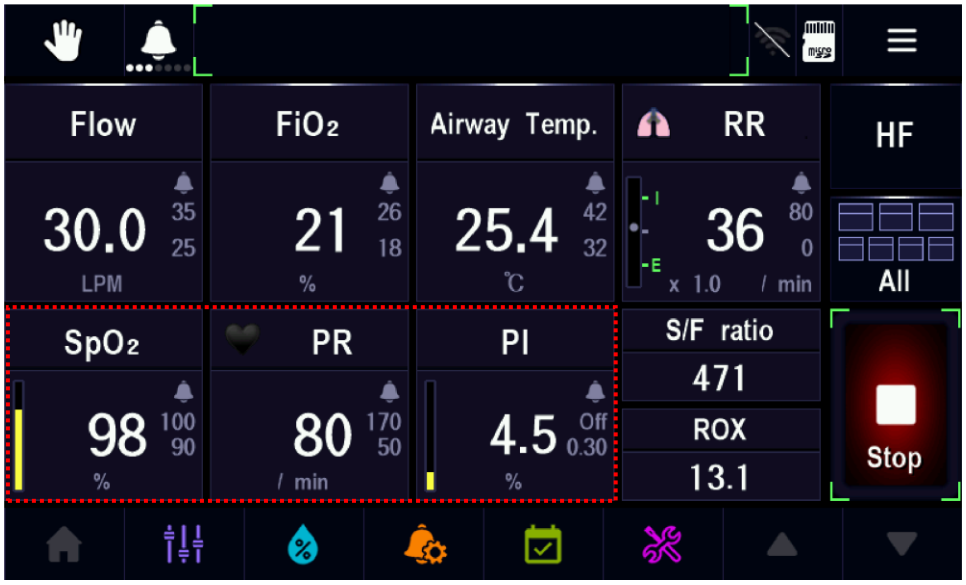
9.1 Masimo SpO_2

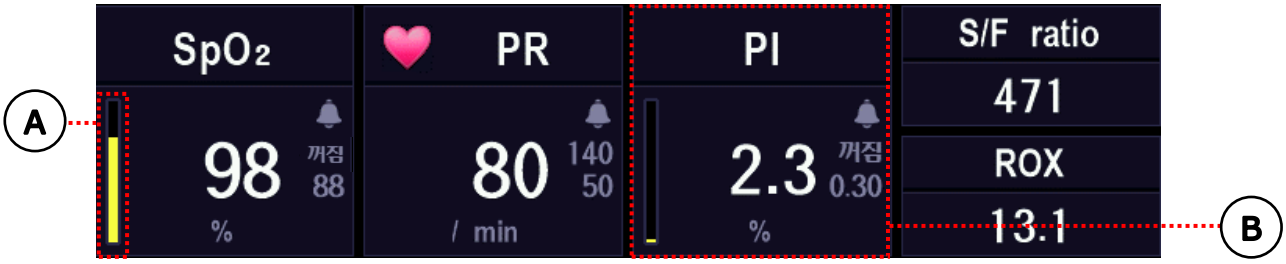
9.1.1 SpO_2 Monitoring display

Shows the SpO_2 value on the marked section of the Simple monitoring display.



Shows the SpO_2 value, Pulse rate (PR), signal IQ and Perfusion Index on the marked section of the All monitoring display.


Flow
30.0
35
25
LPM
FiO2
21
26
18
%
Airway Temp.
25.4
42
32
℃
RR
36
80
0
x 1.0
/ min
HF
All
SpO2
98
100
90
%
PR
80
170
50
/ min
PI
4.5
Off
0.30
%
S/F ratio
471
ROX
13.1
Stop

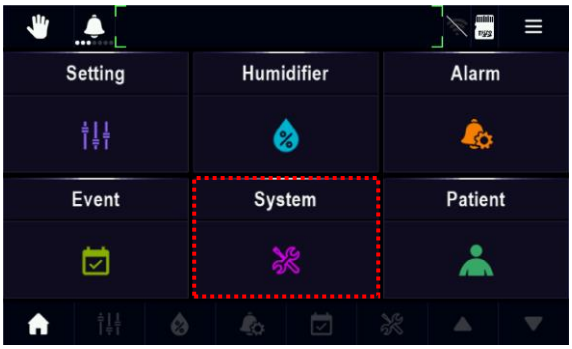


No.	Items	Description
A	Signal IQ	Signal IQ(SIQ) provides an indicator of the assessment of the confidence in the displayed SpO2 value. Over time, the SpO2 SIQ coincides with the peak of an arterial pulsation. Even when the plethysmograph waveform is obscured by artifact, the Signal IQ identifies the timing that the algorithms have determined for the arterial pulsation. The Audible pulse beep will coincide with the non-zero value of the SpO2 SIQ. Masimo SET will continue to report accurate arterial oxygen saturation and pulse rate readings during motion and low perfusion, even when the plethysmographic(pleth) waveform is sub-optimal. Masimo SET is able to read through these challenging yet rather common clinical conditions and provide good clinical data. Signal IQ is an indicator that our advanced signal processing algorithms are extracting and displaying reliable information. The magnitude of the SpO2 SIQ waveform provides an assessment of the confidence in the measurement displayed. A higher value indicates higher confidence in the measurement whereas a smaller value indicates lower confidence in the displayed measurement.
B	Perfusion Index (PI)	The perfusion index assists clinicians in determining optimal placement of the SpO_2 sensor. This parameter is also useful as a troubleshooting tool by helping a clinician rule out whether a questionable value may be due to low perfusion and/or a low signal to noise condition. Clinicians use Pi to quickly identify the optimal site to place the sensor. Higher Pi values reflect stronger pleth signals – which facilitate more consistent measurements. An added benefit is that changes in perfusion can be an indicator to the clinician of important changes in the patient's physiological status. The yellow bar graph on the left of the measured Perfusion Index value shows the currently measured PI value visually.

9.1.2 SpO_2 settings menu

[Step 1]

Enter the System settings menu (Main Menu or shortcuts)





[Step 2]

Go to "Masimo Setting" page in the System menu



9.1.2.1 Masimo Settings parameters

No.	Items	Description	
1	Average	The SpO_2 averaging feature allows the clinician to select the desired level of visibility to subtle variations in the measured value. 8-second averaging is generally considered the most common averaging interval and recommended for most patients since it is short enough to provide visibility to subtle desaturations while also being long enough to minimize major changes in SpO_2 due to quick, transitory desaturations.	
		Setting range	2 – 4, 4 – 6, 8, 10, 12, 14, 16
		Initial settings	8
2	Sensitivity	The sensitivity mode setting allows the clinician to adapt the SpO_2 measurement sensitivity to the patient's level of SpO_2 signal strength and quality at the measurement site. Patients who are experiencing some compromise in blood flow or perfusion. It is advisable for care areas where patients are observed frequently, such as an intensive care unit (ICU) Patients who have a high probability of the sensor becoming detached. It is also the suggested mode for care areas where patients are not visually monitored continuously. This mode delivers enhanced protection against erroneous pulse rate and arterial oxygen saturation readings when a sensor becomes inadvertently detached from a patient due to excessive movement. Max sensitivity is designed to interpret and display data at the measuring site when the signal may be weak due to decreased perfusion. When a sensor becomes detached from a patient, it will have compromised protection against erroneous pulse rate and arterial saturation readings.	
		Setting range	Normal, Maximum, APOD
		Initial settings	Normal
3	Fast SAT	FastSat enables rapid response to, and display of, fast changes in SpO_2 by giving priority to the most recent data. This aids the clinician in clinical settings requiring fast response time such as those seen with induction, intubation, sleep studies and resuscitation. As a result of the increased fidelity of this mode, FastSat is not recommended for routine use as there may be an increase of the frequency of alarms caused by rapid, transitory SpO_2 changes	
		Setting range	Off, On
		Initial settings	Off

No.	Items	Description	
4	Smart Tone	Enabling Smart Tone causes the Audible Pulse Beep to continue even when the pleth waveform is sporadic due to motion. This is useful in situations where clinicians cannot observe the monitor display (e.g. OR, during patient intubation, transport etc.). When enabled, Smart Tone supports seamless monitoring of changes in patient saturation and pulse rate in the presence of motion and low perfusion. Regardless of the Smart Tone configuration, the Signal IQ waveform shows the confidence value during motion.	
		Setting range	Off, On
		Initial settings	Off
5	Pulse sound	Can turn on or off the pulse sound.	
		Setting range	Off, On
		Initial settings	Off

9.1.3 SpO_2 alarm setting

Can set the SpO_2–related alarms on the Alarm menu.
For more details about the Alarm menu, see "6.2.4 Alarm menu."

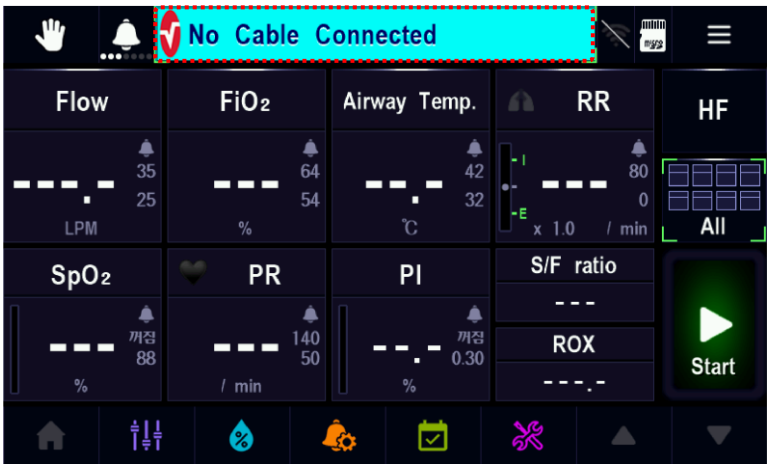
No.	Alarm entries	Setting range	Details	Default values
1	SpO_2	1 to 99 %, Off	The Technology Board is calibrated to measure and display functional oxygen saturation (SpO_2): the amount of oxyhemoglobin expressed as a percentage of the hemoglobin that is available to transport oxygen. The SpO_2 value from the board is encoded within a data range of 1 to 100.0 %.	Lower limit: 88 % Upper limit: Off
2	Pulse rate	30 to 240 /min Resolution: 5 /min	Pulse rate (PR), measured in beats per minute (BPM) is based on the optical detection of peripheral flow pulse. This value represents the number of time the heart beats per minute. The PR value from the board is encoded within a data range of 0 to 240.	Lower limit: 50 /min Upper limit: 140 /min

No.	Alarm entries	Setting range	Details	Default values
3	PI	Off, 0.03 to 19 %	The Perfusion Index (Pi) is the ratio of the pulsatile blood flow to the non-pulsatile or static blood in peripheral tissue. Pi thus represents a noninvasive measure of peripheral perfusion that can be continuously and noninvasively obtained from a pulse oximeter. The perfusion index assists clinicians in determining optimal placement of the SpO2 sensor. This parameter is also useful as a troubleshooting tool by helping a clinician rule out whether a questionable value may be due to low perfusion and/or a low signal to noise condition. Clinicians use Pi to quickly identify the optimal site to place the sensor. Higher Pi values reflect stronger pleth signals – which facilitate more consistent measurements. An added benefit is that changes in perfusion can be an indicator to the clinician of important changes in the patient's physiological status. The Pi value from the board is encoded within a data range of 0.000 % to 20.000 %. It is recommended to round the Pi value to the hundredths place digit for a value of 0.02 % to 0.99 %, round to the tenths place digit for values between 1 % and 9.9 % and use whole numbers for values between 10 % and 20 %	Lower limit: 0.3 % Upper limit: Off

No.	Alarm entries	Setting range	Details	Default values
4	Alarm Delay (Masimo SpO_2 only)	Off, 5, 10, 15 s	Many changes in Respiration Rate are real but transitory. In some cases, such transitory changes may not require clinical action / intervention ("non-actionable"). This setting allows the user to set an audible alarm delay of a certain number of seconds before sounding an RR audible alarm. This delay setting only affects RR audible alarm limits. This option allows a clinician to require that the RR value exceeds the alarm limit for a userselectable duration before an audible alarm, minimizing the risk that clinicians will be desensitized to audible alarms due to non-actionable events	15 s
5	Rapid Desat. (Masimo SpO_2 only)	Off, -5, -10 %	The Rapid Desat Alarm is a user-selectable setting to allow a clinician to tell the monitor to override the audible alarm delay (as described above) when the SpO_2 value exceeds the alarm limit threshold by a user-selectable % (i.e., 10 % below the alarm limit threshold), thereby generating an audible alarm before the alarm delay period has passed. This setting is intended to allow the clinician to feel comfortable setting longer alarm delay periods – to minimize nuisance alarms for real but transitory events – by overriding the alarm delay period when rapid desaturations exceed the alarm limit threshold by a larger, user-selectable percentage.	-10 %

9.1.4 Alarm message, fault code and troubleshooting

If an alarm event occurs, all messages and fault codes are displayed in the red dotted line quadrangle of the display.



Among event messages and error codes, a Masimo icon is additionally displayed for issues related to Masimo.



<Masimo icon>

If there is any problem in the Masimo, the user can check the alarm sound and the message and take action as below:

9.1.4.1 Device Messages

Messages Displayed	Possible Causes	Actions
No Cable Connected	Cable not attached or not fully inserted into the connector.	Disconnect and reconnect cable into connector.
Cable Expired	The patient cable is non-functional or the life of the cable has expired. Note: The patient cable will not stop working while the connected sensor is on a patient. Because of this, it is recommended to replace the sensor when it is not a hindrance to the clinician and/or patient, such as between patients	Replace the patient cable.
Incompatible Cable	The currently connected cable is not a proper cable. The currently connected cable is not a proper cable	Replace with a proper cable
Unrecognized Cable	The currently connected cable is not being recognized The currently connected cable is not being recognized	
Defective Cable	The currently connected cable is defective and unable to be used. The currently connected cable is defective and unable to be used.	
Cable Near Expiration	Patient cable has less than 10 % of active monitoring life remaining	Replace with new patient cable.
No Sensor Connected	Sensor not fully inserted into the connector. May be an incorrect sensor or a defective sensor or cable.	Disconnect and reconnect sensor. See the instructions for use provided with your sensor.
	Sensor is disconnected from patient cable. Sensor connected upside down into patient cable.	Check to see if the sensor LED is flashing. Disconnect and reconnect the sensor. If the LED fails to operate, replace the sensor.

Messages Displayed	Possible Causes	Actions
Sensor Expired	Sensor has used all its available monitoring time. Note: The sensor will not stop reporting physiological data due to the sensor expiring while on a patient (except if a power failure occurs). Because of this, it is recommended to replace the sensor when it is not a hindrance to the clinician and/or patient, such as between patients.	Replace Sensor
Incompatible Sensor	Not a proper Masimo sensor	Use a compatible sensor for the currently licensed parameters. Use a board licensed for the sensor parameters.
	Sensor is attached to a device without an appropriate parameter installed.	
Unrecognized Sensor	The currently connected sensor is not being recognized	Replace with new sensor
Defective Sensor	The currently connected sensor is defective and unable to be used.	
Check Cable and Sensor Fault	The cable and/or sensor connection is faulty	Disconnect and reconnect Patient cable and sensor. If fault does not clear, replace patient cable and/or sensor.
Sensor Near Expiration	Sensor has less than 10 % active monitoring life remaining	Replace with new sensor
No Adhesive Sensor Connected	When a single-patient-use sensor is used, the adhesive portion of the sensor is not connected.	Ensure the adhesive portion is firmly connected to the sensor.

Messages Displayed	Possible Causes	Actions
Adhesive Sensor Expired	When a single-patient-use sensor is used, the adhesive portion of the sensor is non-functional, or the life of the adhesive portion of the sensor has expired. Note: The adhesive sensor will not stop reporting physiological data due to the sensor expiring while on a patient (except if a power failure occurs). Because of this, it is recommended to replace the sensor when it is not a hindrance to the clinician and/or patient, such as between patients.	Replace the adhesive portion of the sensor.
Incompatible Adhesive Sensor	Not a proper Masimo disposable sensor.	Replace with a proper Masimo sensor.
	Disposable Sensor is attached to a device without an appropriate parameter installed.	Use a compatible sensor for the currently licensed parameters. Use a board licensed for the sensor parameters.
Unrecognized Adhesive Sensor	The currently connected disposable sensor is not being recognized	Replace the adhesive (disposable) portion of the sensor.
Defective Adhesive Sensor	The currently connected sensor is defective and unable to be used	
Sensor Initializing	Device is checking the sensor for proper functioning and performance	If values are not displayed within 30 seconds, disconnect and reconnect sensor. If values are still not displayed, replace with a new sensor.

Messages Displayed	Possible Causes	Actions
Sensor Off Patient	The Sensor is not on the patient	Verify that the sensor is not on the patient. Disconnect and reconnect the sensor.
	Sensor not connected to patient properly. Sensor is damaged	Properly reapply the sensor on the patient and reconnect the sensor to the device or patient cable. If the sensor is damaged, replace the sensor
Pulse Search	Device is searching for a pulse	If device fails to display parameter values within 30 seconds, disconnect and reconnect. If pulse search continues, move sensor to better perfused site.
Interference Detected	High intensity light such as pulsating strobe lights, excessive ambient light sources such as surgical lights or direct sunlight, or other monitor displays.	Place a Masimo Optical Light Shield over the sensor.
Low Perfusion Index	The signal from the sensor is too small.	Move sensor to better perfused site.
Demo Mode	A Demonstration tool is currently connected to the sensor port causing the board to send out prerecorded data.	Replace with a patient cable and sensor (if necessary)
Adhesive Sensor Near Expiration	Disposable sensor has less than 10 % active monitoring life remaining.	Replace with new disposable sensor
Check Sensor Connection	The cable and/or sensor connection is faulty	Disconnect and reconnect Patient cable and sensor. If fault does not clear, replace patient cable and/or sensor. Alarm Yes 0x2000 0000 SpO2 Only Mode Occurs during an unsuccessful sensor initialization/pulse search routine or during monitoring. (See section 0) See the accessory directions for us

Messages Displayed	Possible Causes	Actions
SpO_2 Only Mode	Occurs during an unsuccessful sensor initialization/pulse search routine or during monitoring. (See section 0	See the accessory directions for use. Use a Masimo light shield to cover the sensor and adjust the sensor.
Too Much Ambient Light	High intensity light such as pulsating strobe lights, excessive ambient light sources such as surgical lights or direct sunlight, or other monitor displays	Place a Masimo Optical Light Shield over the sensor.
Low SpO_2 Signal IQ	Low signal quality	Ensure proper sensor application. Move sensor to a better perfused site

9.1.4.2 Board failure codes

Message display	Description	Actions
Board Failure Code 32	DSP: Checksum Failed	Contact the Service Center.
Board Failure Code 33	DSP: Program Memory Test Failed	
Board Failure Code 34	DSP: Data Memory Test Failed	
Board Failure Code 35	DSP: Detector ADC Interrupt Test Failed	
Board Failure Code 37	DSP: Diagnosis Queue Overrun	
Board Failure Code 38	DSP: Hardware Status Error	
Board Failure Code 39	DSP: Raw Queue Overrun	
Board Failure Code 40	DSP: MCU Witness Device Error	
Board Failure Code 41	DSP: Invalid MC Status	

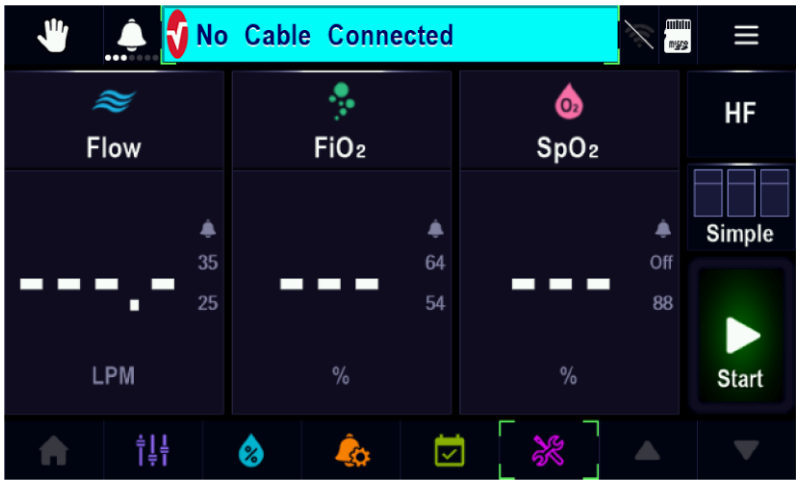
9.1.4.3 Diagnostic failure codes

Message display	Description	Actions
Diagnostic Failure Code 0001	LED Ground	Contact the Service Center.
Diagnostic Failure Code 0002	Base Voltage	
Diagnostic Failure Code 0004	Digital Voltage	
Diagnostic Failure Code 0008	DSP Voltage	
Diagnostic Failure Code 0010	Analog Voltage	
Diagnostic Failure Code 1000	LED Current	
Diagnostic Failure Code 2000	Analog Ground	
Diagnostic Failure Code 4000	LED Drive Voltage	
Diagnostic Failure Code 8000	Sensor ID	

9.1.4.4 Sensor failure codes

Message display	Description	Actions
Sensor Failure 1	LEDs Open	Contact the Service Center.
Sensor Failure 2	LEDs Short Circuit	
Sensor Failure 3	Shorted Detector	
Sensor Failure 4	Incorrect Sensor ID Offset	
Sensor Failure 5	ProCal Failed	
Sensor Failure 6	Memory Failure	

9.1.4.5 Loss of Communications



If the Masimo board is damaged or not recognized, an alarm is activated.

9.1.5 Event log

If an event occurs, all alarms and events are stored, and the stored events can be checked in the event menu. For more details about the event menu, see "6.2.5 Event menu."
All event messages and fault codes related to Masimo SpO2 are displayed with Masimo icons.



<Masimo icon>

9.1.6 Masimo Patents

For the patent information, contact the address below:
Masimo.com/company/Masimo/patents/

9.1.7 No Implied License

Possession of the Equipment does not convey any express or implied license to use the Equipment with unauthorized sensors or cables that would, alone, or in combination with the Equipment, fall within the scope of one or more of the patents relating to the Equipment.
(Source: Masimo – Terms and Conditions 364)

9.2 TSF(Target Saturation (SpO_2) Feedback) Control [HF function]

The clinician must consider the optimal FiO_2 and flow to keep the patient's SpO_2 that uses the HF function. This device has the SpO_2 module, which continuously measures the patient's oxygen saturation and pulse rate and displays them in real-time.

The TSF mode is an entire system feedback control function that operates only in the HF function, which compares the measured SpO_2 of the patients with the SpO_2 set point and sets the FiO_2 set point according to the patient's condition.

The TSF mode takes the SpO_2 and FiO_2 values measured every second, and changes the supplied FiO_2 value automatically to the set time interval (time constant) to reach the set SpO_2 values.

- SpO_2 (TSF) setting range: 85 to 99 %
- FiO_2 (TSF) setting range:
  - Upper limit (Backup FiO_2 to 100 %),
  - Lower limit (21 % to backup FiO_2),
  - Where the upper and lower limits can keep the range of at least 4 %.
- Backup FiO_2:
  - This is the same function as the existing FiO_2 settings. If the TSF feedback control error occurs, the target FiO_2 is changed to and kept as the set backup FiO_2.

If the TSF function is first activated, the existing FiO_2 set point becomes the initial set point of the backup FiO_2.

If the measured SpO_2 is lower than the target SpO_2, the concentration of the FiO_2 that is supplied to the patient increases by 1 % in 10 to 20 second-intervals. If the measured SpO_2 is higher than the target SpO_2, the concentration of the FiO_2 that is supplied to the patient decreases by 1 % in 30 to 120 second intervals.

The control range of the FiO_2 density that is adjusted automatically by the TSF algorithm is limited to the set FiO_2 upper or lower limit. If the measured SpO_2 value and the target SpO_2 value are identical, the FiO_2 density that is supplied to the patient is maintained the same.

9.2.1 How to activate the TSF function (supported only in the HF function)

[Step 1]

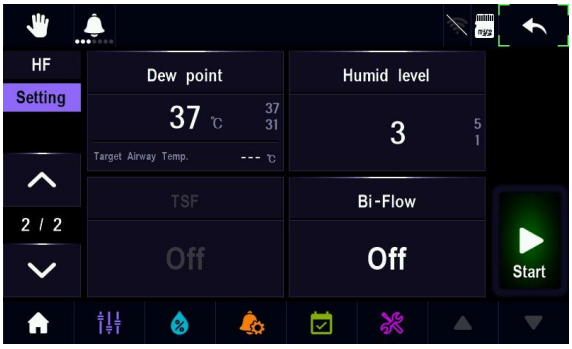
Enter the settings menu (Main Menu or shortcuts).





[Step 2]

Set the TSF to "On" on page 2 in the settings menu.



When turning on the TSF setting, the related parameters are added, so the settings menu increases to 4 pages.

[Step 3]

Set the parameters and start the therapy.

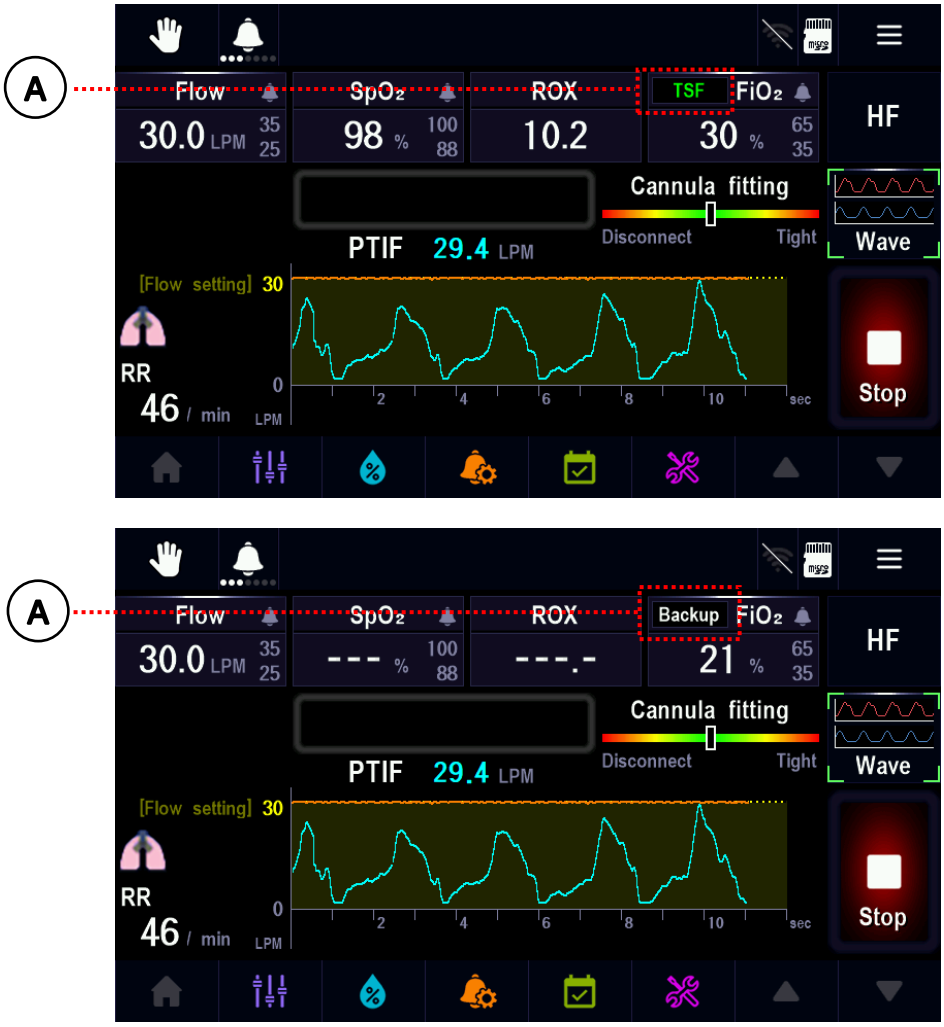


9.2.2 Setting parameters when the TSF function is activated

Settings menu page configuration		
Page	Items	
1 /3	Flow RR detection	
2 / 3	Backup FiO_2 Target SpO_2 FiO_2 Range Time constant	[TSF function-related setting items]
3 / 3	Dew point Humidity level TSF Bi-Flow	

Setting parameters to be added		
Items	Description	
Backup FiO_2	If the SpO_2 sensor cable or the probe is disconnected or damaged while the TSF function is working, so the SpO_2 cannot be measured, the device is run with the "Backup FiO_2" set point.	
	Setting range:	21 to 100 %
Target SpO_2	Sets the target SpO_2 value.	
	Setting range:	85 to 99 %
FiO_2 Range	Sets the upper- or the lower limit of the FiO_2 control range that is automatically adjusted while the TSF function is working.	
	Lowest Setting Range:	21 to 40 %
	Highest Setting Range:	40 to 100 %
Time constant	Sets the increase interval and the decrease interval of the FiO_2 control range that is automatically adjusted while the TSF function is working.	
	Increase Interval Setting range:	10 to 20 s/ %
	Decrease Interval Setting range:	30 to 120 s/ %

9.2.1 Monitoring display that the TSF function is set



No.	Items		Description
A	TSF Function Status	TSF	When the TSF function is working normally, "TSF" is displayed.
		Backup	If the sensor cable or the SpO_2 probe is disconnected or damaged while the TSF function is working, so the SpO_2 cannot be measured, the device is run with the "Backup FiO_2" set point, and "Backup FiO_2" is displayed.

9.3 Bi-Flow [HF function]



CAUTION

If the patient breathes with a mouth, the therapy performance may be degraded.

The High Flow Nasal Cannula (HFNC) therapy supplies the heated and humidified air containing high enough concentrations of oxygen to the patient.
The existing HFNC delivers the same high flow during the inhalation and exhalation. Therefore, it is used as an assist ventilator for the patient with acute hypoxemia. Given that on the respiratory physiological side, however, if the flow exhaled through the patient's airway during the exhalation phase meets the high flow of oxygen that is inhaled to the nasal cavity, respiratory resistance in the pharynx may occur, increasing the work of breathing.

The Bi-Flow, unlike the existing HFNC, detects the triggers during the exhalation and inhalation of the patient and supplies different flows depending on the respiratory condition. Based on the set Assist flow and Base flow, "Base flow + Assist flow" is supplied during inhalation and "Base flow" during exhalation.

The setting range of the Base flow and Assist flow are as below:

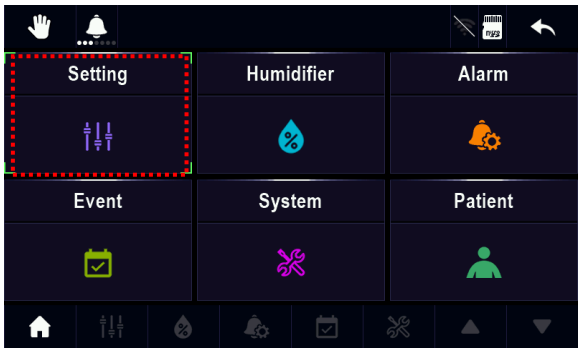
- Base flow setting range: 10 – 40 l/min
- Assist flow setting range: Off, 10 – 80 l/min (Base flow + Assist flow ≤ 90 l/min)

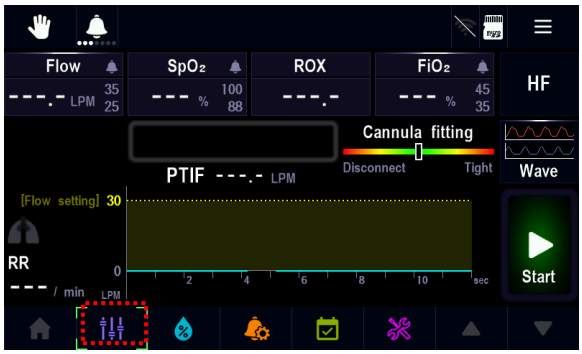
When the Bi-Flow function is first activated, "Base Flow" is 30 l/min and "Assist Flow" is 20 l/min.

9.3.1 How to activate the Bi-Flow function

[Step 1]

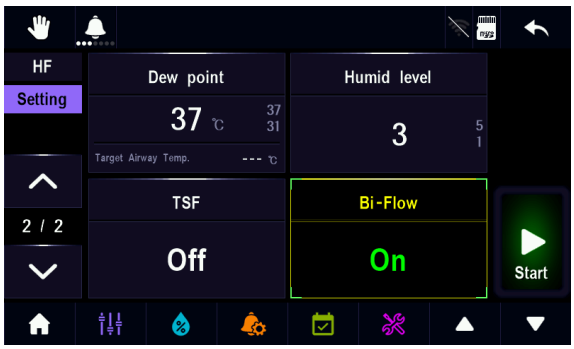
Enter the settings menu (Main Menu or shortcuts).





[Step 2]

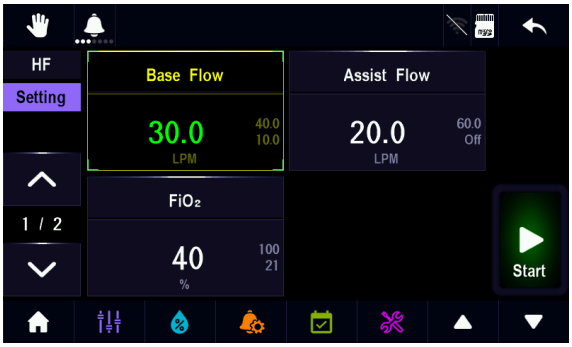
Set the Bi-Flow to "On" on page 2 in the settings menu.



When turning on the Bi-Flow setting, the related parameters are added to it, so the pages of the settings menu increase to 4 pages.

[Step 3]

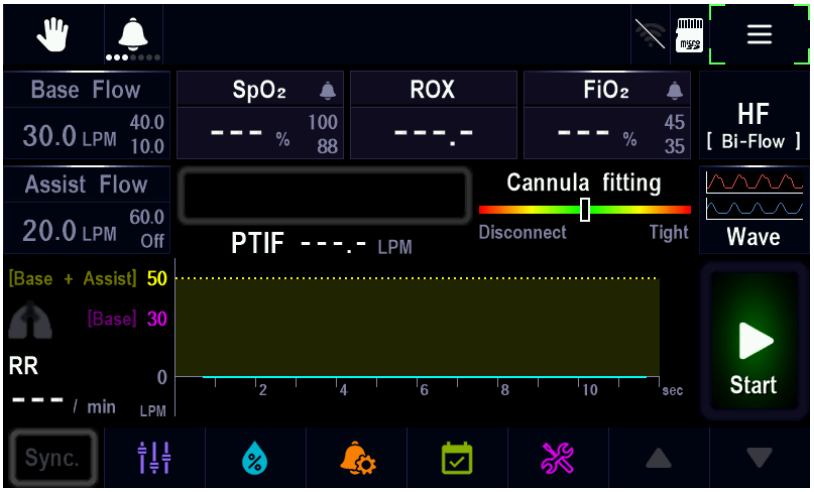
Set the parameters and start the therapy.



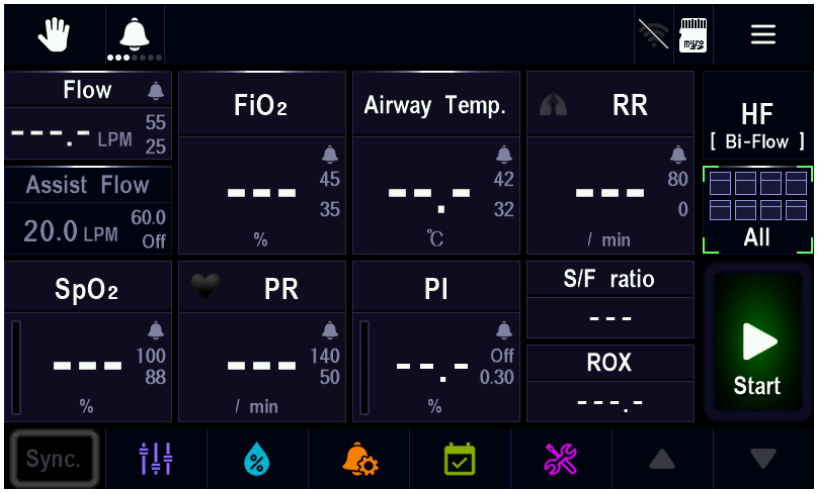
9.3.2 Setting parameters when the Bi-Flow function is activated

Settings menu page configuration		
Page	Items	
1 / 2	Base flow Assist flow	[Bi-Flow function-related setting items]
	FiO_2	
2 / 2	Dew point Humidity level Bi-Flow	

9.3.3 Monitoring display that the Bi-Flow function is set







10 Cleaning and maintenance

10.1 Cleaning

The device must be cleaned on a regular basis to prevent contamination and ensure normal function.



WARNING

1. If the device is used while it's contaminated or damaged, MEKICS is not responsible for the quality or performance of the device.
2. After each cleaning, check if there is any damage to the device or its accessories. If you find damage to a part, do not use that part.
3. Clean the surface of the device with a soft cloth dampened with lukewarm water or 70 % isopropyl alcohol once a month.
4. Do not clean the device or accessories with non-approved liquids or cleansers. (For example: lacquer, paint, thinner, ethylene or oxidizing agent.) The device can be damaged.
5. Take care that no liquid permeates the device or sensors during cleaning.
6. The anti-bacterial filter and the air intake filter, which are disposable products, cannot be reused even after being cleaned and sterilized.



WARNING

When disposing of disposable products, follow the hospital's regulations.

Exterior of the device

Clean the surface of the device with a lint-free, soft and moist cloth.
The following liquids are recommended cleansers:

- Lukewarm water
- Soapy water or a neutral detergent
- Chlorhexidine (0.5 %)
- Isopropyl alcohol (70 %)

Touchscreen

Wipe off the screen with a soft cloth dampened with nonabrasive glass cleaner.

- Do not use any cleaner other than a glass cleaner.
- Do not use a liquid containing vinegar ingredients.
- Do not use a coarse cloth and handle the screen with care.

If you need to clean the touchscreen which is operative, activate the Screen Lock/Unlock function during the cleaning for convenience.

CAUTION

When cleaning the touchscreen, be careful not to damage the touchscreen. Do not drop water or soapy liquid on the touchscreen. After cleaning and rinsing it, dry off with a soft dry cloth. Do not use a polishing brush when cleaning the touchscreen. MEKICS is not responsible for the resulting damage.

Anti-bacterial filter, breathing circuit and the other accessories

Follow the manufacturer's instructions.

10.2 Maintenance

Below is the information about the regular maintenance of the device and the breathing circuit.

Interval	Item	Details
Every day	Filters - Anti-bacterial filter - Air intake filter	Verify that all filters are installed correctly.
	Breathing circuit / breathing circuit	Check the connection and verify if there is a leak or a plugging.
Every individual patient	Breathing circuit / breathing circuit, an anti-bacterial filter, the chamber, the mask, and the nasal cannula	These items must be checked more than once per 7 days. If there is contamination or damage, change it to a new one. Dispose of the discarded item according to the hospital's regulations.
Once every two weeks or as necessary	Air intake filter	An air intake filter must be checked more than once every two weeks. If there is contamination or damage, change it to a new one. Dispose of the discarded item according to the hospital's regulations.
Every year	The HFT700 ventilator	Check the overall performance and the operation of the alarms.
Every 3 years or when the battery fails	Battery	Change the battery. The battery's lifetime is depending on the storage and use environment.
Every 10,000 hours	Oxygen sensor (Max 250 or another product compatible with the device)	The oxygen sensor that passes the use time may have a negative impact on the accuracy of the oxygen control and the patient therapy.
Every 15,000 hours	Blower	The blower that passes the use time may have a negative impact on the accuracy of the flow or pressure control and the patient therapy.

WARNING

To prevent the contamination of the patient and the ventilator, check an anti-bacterial filter applied to the patient regularly and replace it if necessary.

CAUTION

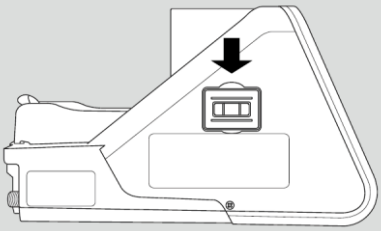
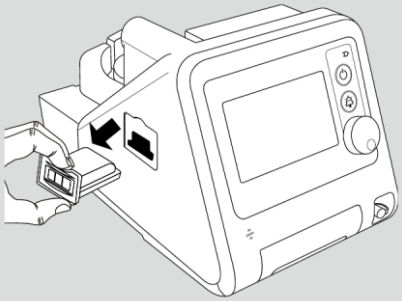
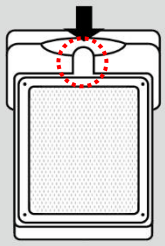
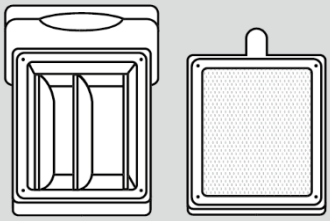
1. The user must visually check the anti-bacterial filter and breathing circuit. If any contamination or plugging is fund, change the item immediately.
2. Whenever the patient is changed, the breathing circuit and the anti-bacterial filter must be replaced with new ones. Dispose of the discarded item according to the hospital's regulations.
3. The anti-bacterial filter must be changed after treating each individual patient or after seven days of use.
4. If the oxygen sensor is used in a continuously high FiO_2 density or under a high temperature, its life may be shortened.
5. The lives of the oxygen sensor and the blower may vary depending on the use condition.
6. A rechargeable lithium-ion battery must be changed by a skilled technician.

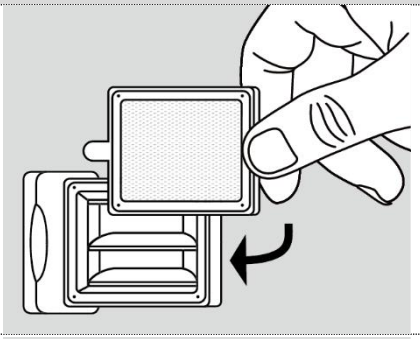
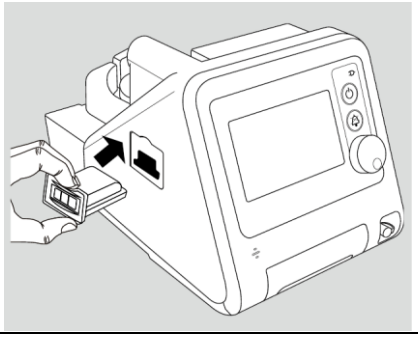
NOTE

1. A rechargeable lithium-ion battery is used when the device must keep operating but the AC power is not supplied.
2. The warranty period of a lithium-ion battery is 3 year.
3. The charging time of the battery of the HFT700 ventilator is about 5 hours.

10.2.1 Air intake filter change

Check the air intake filter regularly.
Check the filter once every two weeks and if you find contamination or damage, you must replace it with a new filter supplied by MEKICS.

No.	Procedure	Photo	Description
1	The air intake filter is located on the left of the device.		
2	Remove the air intake filter from the device.		Grab the groove on the air intake filter and pull it out to remove it from the device.
3	Remove the air filter from the case of the air intake filter.		Grab the handle of the air filter and pull it out to remove it from the case of the air intake filter.
4	Prepare the air intake filter to be replaced.		Be careful not to damage and contaminate the new air filter.

No.	Procedure	Photo	Description
5	Assemble the air filter to the case of the air intake filter.		Assemble so that the handle of the air filter toward the head of the case. Assemble by aligning the groove of the air filter with the groove of the case.
6	Install the air intake filter to the device.		Install the air intake filter into the device by pushing it all the way.

10.2.2 Changing an oxygen sensor

Change an oxygen sensor on a regular basis.
We recommend changing the sensor at least once every year, and, if any, you have to replace it with an oxygen sensor supplied by MEKICS.

WARNING



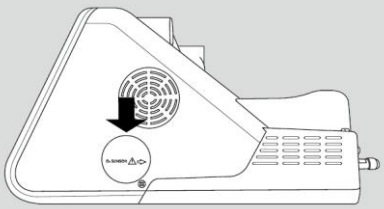
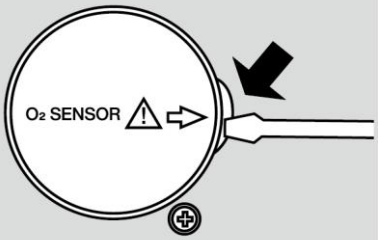
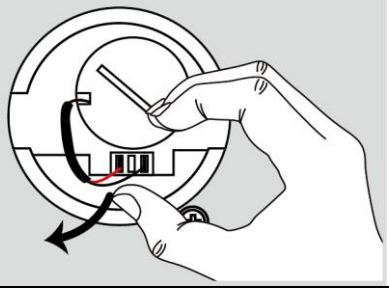
An oxygen sensor is sealed tight and contains corrosive substances that can cause severe burns to the skin or eyes. If these substances contact the skin or eyes, rinse them for 15 minutes with running water. If they enter the eyes, contact the doctor immediately.

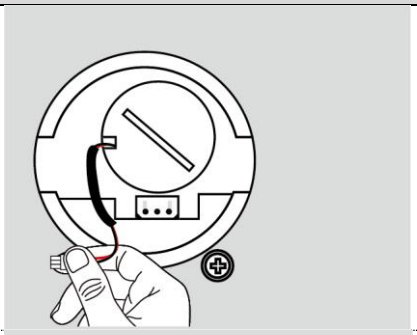
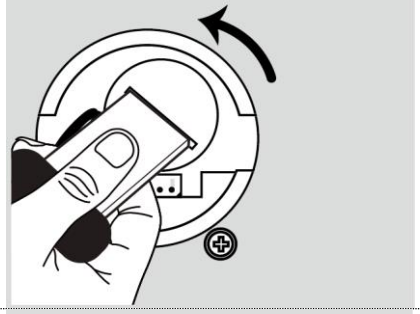
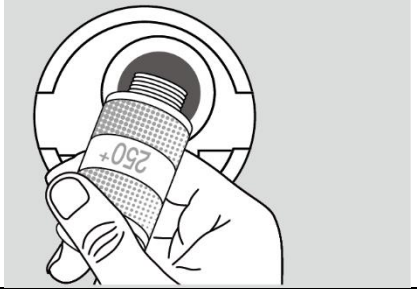
[Preparing and replacing an oxygen sensor]

Before replacing the oxygen sensor with a new one, disconnect the power cord and a high pressure oxygen hose from the device.

To change the oxygen sensor, a new oxygen sensor must be gotten out of the package and placed at room temperature for 15 minutes or more.

Do not turn on the device while installing the new oxygen sensor to the device.

No.	Procedure	Photo	Description
1	The oxygen (O_2) sensor cover is located on the right of the device.		On the round cover, "Oxygen (O_2) sensor" is marked as shown on the left.
2	Use a small flat-head screwdriver to open the cover.		Don't press excessively the driver into the small minor groove of the cover.
3	The oxygen (O_2) sensor with the cable is located inside and is visible.		Check the cable connector of the oxygen sensor that is connected to a terminal.
4	Disconnect the cable connector of the oxygen (O_2) sensor.		Disconnect the cable connector of the oxygen sensor from the connection terminal.

No.	Procedure	Photo	Description
5	Prepare to disconnect the oxygen sensor from the device.		Prepare a wide flat-head screwdriver to remove the oxygen sensor.
6	Disconnect the oxygen sensor by using the wide flat-head screwdriver.		Turn the screwdriver with care not to damage the groove of the oxygen sensor.
7	Remove the oxygen sensor from the mounting block.		To install a new oxygen sensor, perform the disconnection procedure in the reverse order.

10.3 Storage

Store the device in a dark room within the temperature range of −25 °C to 70 °C (−13 °F to 158 °F).
The atmospheric pressure range is from 70 kPa to 106 kPa (from 10.2 psi to 15.4 psi).



WARNING

Refer to "2.1 Precautions related to storage" and check that all requirements are met and considered.

10.4 Disposal

Disposing of the device, accessories, and parts that were discarded from the device must be performed according to local environmental regulations on secondhand goods and waste disposal. Ask local suppliers for disposal procedures.



NOTE

You must recycle the battery attached to the device according to local environmental regulations.

Annex A Specifications

A.1 General characteristics

- Easy-to-use touchscreen menu
- Easy interface with the rotary knob and a touchscreen
- Real-time display of the monitoring data and the device status
- Easy and convenient operation
- Two types of alarm function (speaker and buzzer)
- Heating and humidifying function using a battery

A.2 Table of functions

Table of functions		Remarks
Hardware functions	Humidifier	Basic
	FiO_2 density measurement	Basic
	Electronic oxygen density control unit	Basic
	Wi-Fi communication module	Basic
	Masimo SpO_2 sensor kit	Basic
	MEKICS SpO_2 sensor kit	Optional
	Cart	Optional
	External power supply	Optional
Therapy modes/functions	HF	Basic
	CPAP	Basic
	bi-level	Basic
	TSF	Optional
	Bi-Flow	Optional

A.3 Useful functions

FunctionsScreen Lock/UnLock	Activates or inactivates the screen touch key function.
Audio Paused (2 minutes)	Inactivates the alarm sound for 2 minutes.
Sound volume	Adjusts the volume of the alarm sound. (Over MAX. 70dB(A))
Brightness	Controls the brightness in 5 levels.
Screen off	If there is no keystroke during the set time, the LCD screen is switched off automatically.

A.4 Power supply

Input power source	100 – 240 VAC, 50/60 Hz
Fuse capacity	250 V / 2.5 A (Mounted on the power board)
Power Consumption	350 VA Max.
Battery	Li-ion Battery (DC: 10.89 V, 10,400 mAh)
Communication	Main and Pneumatic Boards
Display	5" TFT Touch LCD (Resolution: 800 x 480)

A.5 Setting parameter specification

Mode		Items	Setting Range	Accuracy	Default value
HF		Flow	1 to 60 l/min	±10 % (11 to 60 l/min) ±1 l/min(1 to 10 l/min)	–
		RR detection	1. Off 2. On	–	Off
	TSF only	TSF	Off / On	–	Off
		Backup FiO_2	21, 25 to 100 %	–	40 %
		Target SpO_2	85 to 99 %	–	95 %
		FiO_2 range	Low: 21, 25 % to Backup FiO_2 setting value	±5 %(digit)	40%
			High: Backup FiO_2 setting value to 100 %	±5 %(digit)	60%
		Time constant	Rising interval: 10 to 20 s	–	20 s
			Falling interval: 30 to 120 s	–	60 s
	Bi-Flow only	Base flow	10 to 40 l/min	± 10 % (10 – 40 l/min)	30 l/min
		Assist flow	Off, 10 to 80 l/min (Base flow + Assist flow) ≤ 90 l/min	± 10 % (10 – 80 l/min)	20 l/min

Mode	Items	Setting Range	Accuracy	Default value
CPAP	PA(+) (+Pressure Assist)	Off, 1 to 3 cmH_2O	±(1.7 + 4 % of the set value) cmH_2O	Off
	CPAP	4 to 20 cmH_2O	±(1.7 + 4 % of the set value) cmH_2O	5 cmH_2O
	PA(–) (–Pressure Assist)	Off, –3 to –1 cmH_2O	±(1.7 + 4 % of the set value) cmH_2O	Off
	Trig. Level (Trigger level)	3 to 20 l/min	±1.5 l/min	5.0 l/min
	Rise Time	Fast (0.2 s) Medium (0.3 s) Slow (0.4 s)	± 0.1 s	Medium
	Auto Start	Off / On	–	Off

Mode	Items	Setting Range	Accuracy	Default value
bi-level	IPAP	4 to 40 cmH_2O	±(1.7 + 4 % of the set value) cmH_2O	8 cmH_2O
	EPAP	4 to 20 cmH_2O	±(1.7 + 4 % of the set value) cmH_2O	5 cmH_2O
	PA (-) (- Pressure Assist)	Off, -3 to -1 cmH_2O	±(1.7 + 4 % of the set value) cmH_2O	Off
	RR (Respiration Rate)	2 to 60 /min	±10 %	10 /min
	Ti (Inspiratory Time)	0.3 to 3.0 s	± 0.1 s (at (IPAP–EPAP) < 15) ± 0.3 s (at 15 ≤ (IPAP–EPAP) < 30) ± 0.5 s [at 30 ≤ (IPAP–EPAP)]	1.2 s
	Trig. Type	S/T, S, T	-	S/T
	Trig. Level (Trigger level)	3 to 20 l/min	±1.5 l/min	7.0 l/min
	Rise Time	Fast (0.2 s) Medium (0.3 s) Slow (0.4 s)	± 0.1 s (at (IPAP–EPAP) < 10) ± 0.2 s (at 10 ≤ (IPAP–EPAP) < 20) ± 0.3 s (at 20 ≤ (IPAP–EPAP) < 30) ± 0.5 s (at 30 ≤ (IPAP–EPAP))	Medium
	Volume guarantee	Off / On	-	Off
	Vi	100 to 2000 ml	-	400 ml
	Pressure limit	10 to 45 cmH_2O	±(1.7 + 4 % of the set value) cmH_2O	25 cmH_2O
	Auto Start	Off / On	-	Off
	Ti (Backup ventilation)	0.3 to 3.0 s	± 0.1 s (at (IPAP–EPAP) < 15) ± 0.3 s (at 15 ≤ (IPAP–EPAP) < 30) ± 0.5 s [at 30 ≤ (IPAP–EPAP)]	1.2 s
	RR (Backup ventilation)	4 to 60 /min	±10 %	10 /min

Mode	Items	Setting Range	Accuracy	Default value

Common	FiO_2 %		21 %, 25 to 100 %	– ±5 %(digit)	40 %
	Dew point	HF	31 ℃ to 37 ℃	±3 ℃	37 ℃
		CPAP& bi-level	Off, 31 ℃ to 37 ℃		34 ℃
	Humidity level		1 to 5	–	3

CAUTION

1. The flow setting range and default value for each nasal cannula vary depending on the nasal cannula calibration results. For information on how to calibrate the nasal cannula, see "6.3.3 Nasal cannula calibration."
2. "RR Detection" is a function to select the measuring method to detect the patient's breath. For more details, see "6.2.2 Settings menu."
3. The control accuracy according to the FiO_2 setting may depend on the flow setting. If the flow setting is under 3 l/min and the FiO_2 set point is under 40 % or not less than 80 %, the accuracy of "± 5 (digit)" is not guaranteed.
4. If you use the Volume guarantee function in the bi-level mode, the set tidal volume is delivered to the inspired air. The HFT700 ventilator satisfies the set tidal volume by adjusting the inspiration pressure whenever the patient breathes. This is applied only to the Volume Guarantee function.

A.6 Technical specifications

Measurement parameters		Description
When the FiO_2 is set to 21 % to 90 %, response time for measuring the Fraction of Inspired Oxygen		Less than 3 minutes
BF insulation application		Breathing circuit, Nasal cannula, Mask, SpO_2 probe, and Temperature sensor
Maximum flow	HF function	60 l/min
	CPAP, bi-level mode	200 l/min
Maximum Limited pressure	HF function	70 cmH_2O
	CPAP mode	40 cmH_2O
	bi-level mode	70 cmH_2O
Inspiratory pressure drops after the device failure: Measured at the connection to the patient when using the recommended respiratory system.		Less than 2.0 cmH_2O (@ 60 l/min) Less than 1.0 cmH_2O (@ 30 l/min)

Uncertainty of the measurement items	Measurement error
Measuring the water weight of the humidifier	0.01 % of the entire range
Measuring the flow	3.0 % of 0.1 l/min
Measuring the pressure	0.2 % of 0.1 cmH_2O
Measuring the oxygen concentration	0.1 % of 0.1 % O_2
Measuring the temperature	0.2 % of 0.1 ℃

A.7 Display parameter specifications

1) Common display specifications

Items	Contents	Display range	Resolution	Accuracy
FiO_2	Fraction of Inspired Oxygen	18 to 100 %	1 %	±5 digit
SpO_2	Saturation of Percutaneous Oxygen	0 to 100 %	1 %	See "Annex E SpO_2 monitoring."
PR	Pulse rate	0 to 300 /min	1 /min	30 to 250 ±2 /min The other area is not guaranteed.
RR	Respiratory Rate	0 to 300 /min	1 /min	± 2 /min
Airway Temp.	Airway temperature	0 to 60℃	0.1℃	± 3.0 ℃ (Range: 10 to 50 ℃) The other area is not guaranteed.
Chamber Temp.	Chamber temperature	0 to 60℃	0.1℃	± 3.0 ℃ (Range: 10 to 50 ℃) The other area is not guaranteed.
Heat-Plate Temp.	Heat-plate temperature	10 to 115℃	0.1℃	± 3.0 ℃ (Range: 10 to 110 ℃) The other area is not guaranteed.
PI	Perfusion Index	0.02 to 20 % (At Masimo SpO_2)	0.01 (if PI < 1 %) 0.1 (if PI ≥ 1 %)	See "Annex E SpO_2 monitoring."
		0 to 20 % (At MEKICS SpO_2)	0.01 (if PI < 1 %) 0.1 % (If PI ≥ 1 %)	See "Annex E SpO_2 monitoring."

2) **HF** function

Items	Contents	Display range	Resolution	Accuracy
Flow	Supply flow rate	0 to 240 l/min	0.1 l/min	±10 % or ±1 l/min
S/F ratio	SpO_2/FiO_2 ratio	0 to 499	1	(*Note 1)
ROX	S/F ratio for the RR	0 to 499	1	(*Note 2)

3) CPAP mode

Items	Contents	Display range	Resolution	Accuracy
PEEP	Positive End Expiratory Pressure	0 to 100 cmH_2O	0.1 cmH_2O	±0.5 cmH2O or ± 2 %
Vt est	Estimated Tidal Volume	0 to 2500 ml	1 ml	(*Note 3)

4) bi-level mode

Items	Contents	Display range	Resolution	Accuracy
PIP	Peak Inspiratory Pressure	0 to 100 cmH_2O	0.1 cmH_2O	±0.5 cmH_2O or ± 2 %
PEEP	Positive End Expiratory Pressure	0 to 100 cmH_2O	0.1 cmH_2O	±0.5 cmH_2O or ± 2 %
Vt est	Estimated Tidal Volume	0 to 2500 ml	1 ml	(*Note 3)

NOTE

1. The accuracy of the S / F ratio depends on the accuracy of the FiO_2 and SpO_2 monitoring.
2. The accuracy of the ROX depends on the accuracy of the FiO_2, SpO_2 and RR monitoring.
3. The 'Vt est' value displayed in the bi-level mode is calculated by the leak flow calibration algorithm using the measured flow value. If the patient's respiratory condition and the leak flow rate are not stable, the accuracy cannot be guaranteed.

A.8 Alarm specifications

Patient alarms			
Items (Therapy mode)		Initial settings	Setting Range
Apnea		Off	10 to 60 seconds, Off
Open Circuit		–	–
Check Cannula (HF)		–	–
Total Leakage High		(Default is over 80 LPM) in CPAP & bi-level mode	Over 80 l/min
Leakage High (CPAP & bi-level)		50 l/min	10 to 70 l/min
Flow High (HF)		• Maximum flow is 40 l/min or more, the set flow rate is +5 l/min	• The maximum flow is 40 l/min or more, • (The alarm lower limit set point + 1) to 65 l/min
Flow High (HF) (cannula type : neonate)		• Maximum flow is 8 l/min or less, the set flow rate is +2.0 l/min	• If the maximum flow is 8 l/min or less, (The alarm lower limit set point + 0.5) to 30.0 l/min
Flow Low (HF)		• Maximum flow is 40 l/min or more, the set flow rate is −5 l/min	• The maximum flow is 40 l/min or more, 0 to (The alarm lower limit set point − 1) l/min
Flow Low (HF) (cannula type : neonate)		• Maximum flow is 8 l/min or less, the set flow rate is −2.0 l/min	• If the maximum flow is 8 l/min or less, 0 to (The alarm lower limit set point − 0.5) l/min
PIP High	CPAP	CPAP set point + 5 cmH_2O	CPAP set point +1 to 43 cmH_2O
	bi-level (Volume guarantee Off)	IPAP set point + 5 cmH2O	IPAP set point +1 to 50 cmH_2O
	bi-level (Volume guarantee On)	P limit set point + 3 cmH2O	5(Minimum IPAP set value +1) to 50 cmH_2O
PIP Low	CPAP	CPAP set point − 5 cmH_2O	0 to CPAP set point −1 cmH_2O
	bi-level (Volume guarantee Off)	IPAP set point − 5 cmH2O	0 to IPAP set point −1 cmH_2O
	bi-level (Volume guarantee On)	Inactive alarm	Inactive alarm

Patient alarms			
Items (Therapy mode)		Initial settings	Setting Range
PEEP High	CPAP	CPAP set point + 2 cmH_2O	CPAP set point +1 to 22 cmH_2O
	bi-level	EPAP set point + 2 cmH_2O	EPAP set point +1 to 22 cmH_2O
PEEP Low	CPAP	CPAP set point − 2 cmH_2O	0 to CPAP set point −1 cmH_2O
	bi-level	EPAP set point − 2 cmH_2O	0 to EPAP set point −1 cmH_2O
FiO_2 High		FiO_2 set point + 5 %	The alarm lower limit set point +1 to 100 %
FiO_2 Low		FiO_2 set point − 5 %	18 % to the alarm upper limit set point −1
RR High		80 /min	The alarm lower limit set point +1 to 150 /min
RR Low		0 /min	0 /min to the alarm upper limit set point −1
V delivery High		1000 ml in bi-level, volume guarantee on	The alarm lower limit set point + 1 to 2500 ml
V delivery Low		100 ml in bi-level, Volume guarantee on	50 ml to the alarm upper limit set point −1
SpO_2 High		Off	The alarm lower limit set point +1 to 99 %, Off
SpO_2 Low		88 %	1 % to the alarm upper limit set point −1
PI High		Off	The alarm lower limit set point +1 (or +0.01) to 19 % Off
PI Low		0.3 %	0.03 % to the alarm upper limit set point −1 (or −0.01), Off
PR High		140 /min	The alarm lower limit set point +5 to 235 /min, Off
PR Low		50 /min	30 /min to the alarm upper limit set point −5, Off
SpO_2 Probe off Patient		–	–

System alarms		
Items	Initial settings	Setting Range
Airway Temp. High	–	The alarm lower limit set point +1 to 44 ℃
Airway Temp. Low	–	0 ℃ to the alarm upper limit set point -1
O_2 Supply Fail	172.4 kPa (25 psi) or less	–
Heat-Wire is Disconnected	–	–
Airway Temp. Sensor is Fail	–	–
Chamber Temp. Sensor is Fail	–	–
No Chamber	–	–
Refill the water	On	On/Off
AC loss	–	–
Blower Temp. High	–	–
Heat-Plate Temp. Sensor is Fail	–	–
Heat-Plate Fail	–	–
Check Blower	–	–
O_2 Inlet Pressure High	655 kPa (95 psi) or more	–

System alarms		
Items	Items	Items
Check SpO_2 Probe	–	–

NOTE

For more details on each alarm, see "8 Alarms."

A.9 Device specifications

Total size	: 20.4 x 33.8 x 25.4 (Width x Depth x Height) cm
Total weight	: 7.5 kg
Main Unit Size	: 20.4 x 33.8 x 20.4 (Width x Depth x Height) cm
Main Unit Weight	: 4.5 kg
External power supply Size	: 20.4 x 31.3 x 5.0 (Width x Depth x Height) cm
External power supply Weight	: 3.0 kg
Material (External case)	: Fire-retardant thermoplastic resin
Gas outlet port	: ISO 22 mm conical male
High pressure oxygen inlet	: DISS male / female
Cart size	: 60 x 60 x 185 (Width x Depth x Height) cm
Cart weight	: 11 kg
Total weight	: 24 kg (Including safe working load)

A.10 Humidifier specifications

Humidification capacity	Humidification capacity is 20 mg/L to 40 mg/L depending on the operating environment, flow rate settings, and humidification settings.
Maximum temperature of the output gas	40 ℃ (104 °F)
Maximum temperature of the humidifier heat-plate	90 ℃ (194 °F) Maximum temperature of the chamber surface: 74 ℃ (165.2 °F)
Maximum flow range	CPAP and bi-level mode: 200 l/min HF function: 60 l/min
Setting Range	Level 1 to Level 5, Default: Level 3 (Humidity control in 5 levels) Dew Point temperature setting, HF function: 31 ℃ to 37 ℃ CPAP & bi-level mode: Off, 31 ℃ to 37 ℃
Preheating time	20 minutes (Flow rate 40 l/min, initial temperature 23 ℃ condition)
Recommended temperature range	18 to 26 ℃

WARNING

If the total leakage is more than 50 l/min in the bi-level mode, the humidification function is not guaranteed.

CAUTION

If the device has been stored at a low temperature, adapt it to room temperature before use. The time required to be warmed from the lowest storage temperature of -25°C to room temperature of 18℃ is at least 20 minutes.

CAUTION

Outside the recommended temperature range, the set humidity level may not be maintained.

A.11 Accessory requirements

Items	Specifications
Bacteria filter	Dead Space: 66 ml Bacterial/Viral Filter Efficiency: > 99.999 % Resistance: 1.2 cmH_2O Male Connector: 15 mm I.D./22 mm O.D Female Connector: 22 mm I.D.

A.12 Use environment

Operative temperature range	5 ℃ to 40 ℃ (41 ℉ to 104 ℉)
Operative atmospheric pressure range	700 hPa to 1060 hPa (10.2 psi to 15.4 psi)
Operative altitude range	−500 m to 3000 m
Operative humidity range	10 % to 90 % R.H.
Shipping/storage temperature range	−25 ℃ to 70 ℃
Shipping/storage atmospheric pressure range	700 hPa to 1060 hPa (10.2 psi to 15.4 psi)
Shipping/storage altitude range	Air transport from at least −500 m to at most 3000 m is based on the atmospheric pressure inside the airplane regardless of the altitude.
Shipping/storage humidity range	0 % to 95 % R.H.
High Pressure Oxygen Inlet pressure range	241.3 kPa to 620.5 kPa (35 psi to 90 psi)
Low flow O_2 input pressure Range	< 60 kPa (8.7 psi)
Pressure range of respiratory detection port	−12.5 cmH_2O to +12.5 cmH_2O
Recommended ambient light	500 lx
A-weighted sound pressure level (ISO 3744:2010)	About 55 dB(A)
A-weighted sound power level (ISO 3744:2010)	About 60 dB(A)

Annex B Operation Principle

The portable ventilator assists the patient's breathing by using the surrounding air and high-pressure oxygen. Air comes into the device through the air intake filter of the device. Oxygen flows into the device through the high-pressure oxygen inlet, and the mixed gas at the user-set oxygen density is supplied through a proportional valve.

The system mixes air and oxygen at an appropriate ratio, pressurizes the mixed gas in a blower, and delivers it to the user at the set pressure.

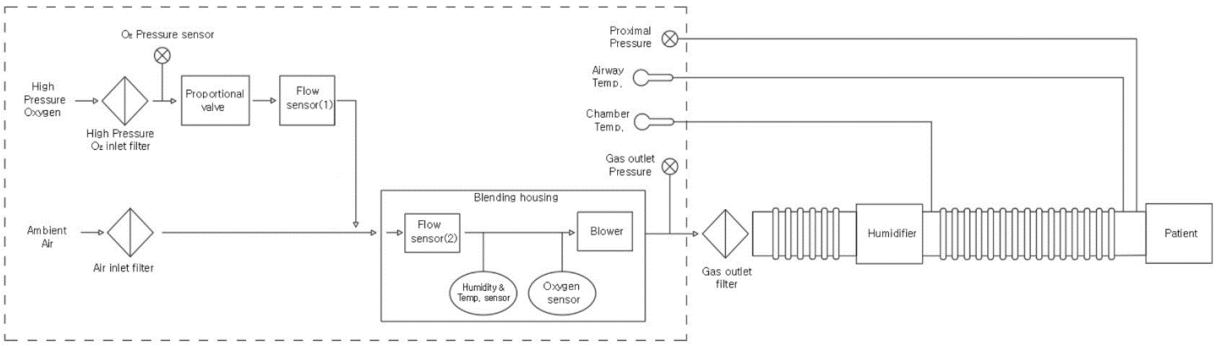


Figure B.1 Gas Delivery System in the HF function of the HFT700 ventilator

The portable ventilator delivers the mixed gas in proper air and oxygen levels to the patient through the patient interface such as an anti-bacterial filter, Single Limb breathing circuit, a humidifier, and the nasal cannula.
In the HF function, the respiratory rate is monitored with the respiratory detection port adjacent to the patient.

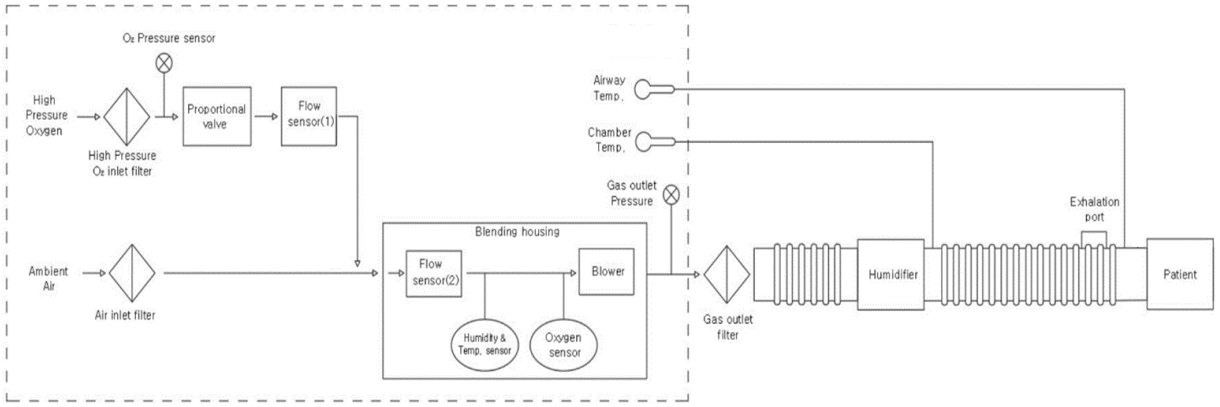


Figure B.2 Gas Delivery System in the CPAP and the bi-level mode of the HTF700 ventilator

An exhaust port ensures to eliminate carbon dioxide (CO_2) in the CPAP and bi-level mode, by continuously exhausting the mixed gas of air and oxygen from the breathing circuit during the inhalation and exhalation to minimize the patient's rebreathing.

Humidification control system

The electronic heat-plate system is operated to reliably control the heat plate and to maintain the temperature of the gas delivered to the patient. The target temperature delivered to the patient is calculated by the thermal energy required by the "dew point," "flow" and "chamber temperature." In addition, it is also possible to calculate the thermal energy by excluding the heat generated by the blower compression system which can interfere with the humidification control system.

As a result, the heat-plate control system can be controlled by setting the flow/pressure delivered to the patient, the humidity level, and the dew point.

Annex C Therapy Modes and Functions

The HFT700 ventilator operates in:

- HF (High Flow Nasal Cannula) function
- CPAP (Continuous positive airway pressure) mode
- bi-level (bilevel positive airway pressure) mode

Table C.1 outlines the characteristics of the therapy modes and functions. Mandatory breathing of the portable ventilator means the breathing by the portable ventilator, and spontaneous breathing means that the ventilator is operating by the voluntary breathing of the patient.

Mode/function	Mandatory breath			Spontaneous breath		
	Trigger	Limit	Cycle	Trigger	Limit	Cycle
HF	N/A	N/A	N/A	Flow	Pressure	Flow
CPAP	N/A	N/A	N/A	Flow	Pressure	Flow
bi-level(T)	Time	Pressure	Time	N/A	N/A	N/A
bi-level(S/T)	Time	Pressure	Time	Flow	Pressure	Flow
bi-level (Volume Guaranteed)	Time	Pressure	Time	Flow	Pressure	Flow

Table C.1 the HFT700 ventilation and the function characteristics

C.1 HF (High Flow) function

This is a high flow function. If the patient inhales the dry air and/or the oxygen gas directly, the patient's nasal cavity can be injured. For that reason, make sure to use the humidifier.



WARNING

When the system is changed from the HF function interface to the NIV mask, verify that the exhaust port is installed inside the patient's breathing circuit to reduce the risk of CO_2 rebreathing.

C.2 CPAP (Continuous Positive Airway Pressure) mode

The CPAP mode maintains the airway at a positive pressure. The proper PEEP setting prevents the patient's tracheal collapse.
Adjust the apnea time properly according to the patient's condition.
The CPAP helps the patient to breathe (inhale and exhale) more comfortably.

C.3 bi-level (bilevel positive airway pressure) mode

The bi-level mode is applied to the patient who has a Spontaneous breathing response to initiate the inhalation but has apnea or lacks ventilation.

The bi-level mode provides three respiratory modes of S (Spontaneous breathing mode), S/T (Spontaneous breathing/Time mode), and T (Time mode). These respiratory therapies are classified according to how they allow the patient to initiate breathing.

The S mode initiates breathing only when the set trigger level is exceeded by the patient's spontaneous breathing effort. In other words, do not use the device for a patient who doesn't have spontaneous breathing.

In the S/T mode, when the set RR and the patient's spontaneous breathing effort exceed the trigger level, the ventilator initiates the breath if the pressure of the patient's spontaneous breath is not detected between the previous breath and the next breath.

In the T mode, the breathing is not triggered by the patient's spontaneous breathing effort, but it is performed according to the breathing cycle set by the ventilator.

As the bi-level mode operates with the goal of the PIP, a lot of flow can be supplied to reach the inspiratory pressure if the patient interfaces, e.g., a mask, do not adhere to the patient's face. In this case, the patient may feel uncomfortable when wearing the mask. Therefore, the Auto Start function initiates the patient's treatment from the time point that the patient's spontaneous breath is detected after the Therapy Start button is activated.
It is not applied in the T mode.

The Volume Guarantee function is to change the inspiratory target from pressure to volume. This function can be applied to the S, S/T, and T modes of the bi-level, and replace the inspiratory target set point with the tidal volume of the inspiratory positive airway pressure. The tidal volume supply is limited by the set pressure upper limit.

T (Timed) mode

In the T (Timed, Pressure control ventilation) mode, the pressure control breath is supplied according to the time interval. The control setting parameters activated in the Timed mode are shown in Figure 8.1. The IPAP setting defines the PIP applied to every breath. The inspiratory time (Ti) and the RR settings are based on the interval for every breath.

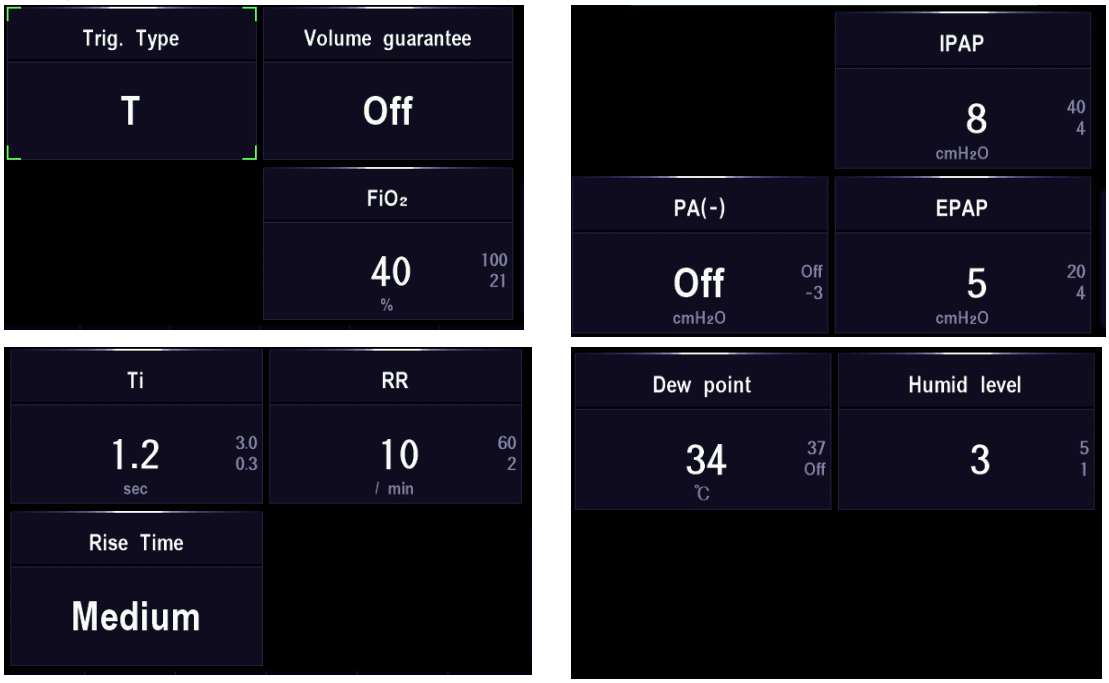


Figure C.1 Timed Controls

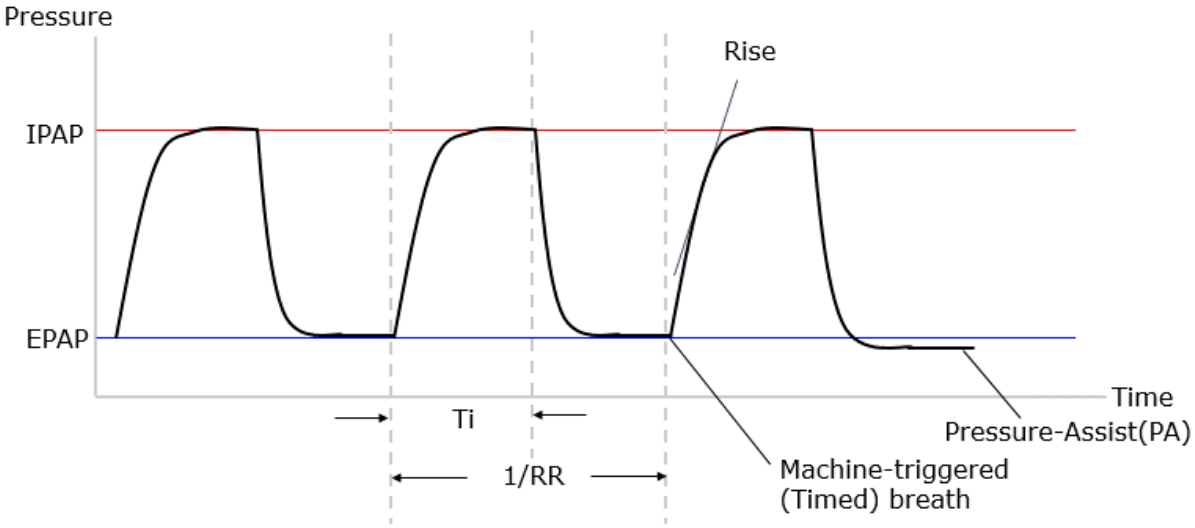


Figure C.2 Time pressure waveform

S/T (Spontaneous/Timed) mode

The S/T (Spontaneous/Timed) mode ensures the target volume for the patient by using the user-set RR. In every IPAP pressure level, it provides the pressure control, timed mandatory breathing, and pressure-controlled spontaneous breathing. If the patient does not breathe according to the breathing cycle determined based on the RR, the ventilator initiates a mandatory breath at the set inspiratory time. The respiratory is triggered and achieved based on the ventilator's flow trigger level sensitivity algorithm. The control setting parameters activated in the S/T mode are shown in Figure 8.3.

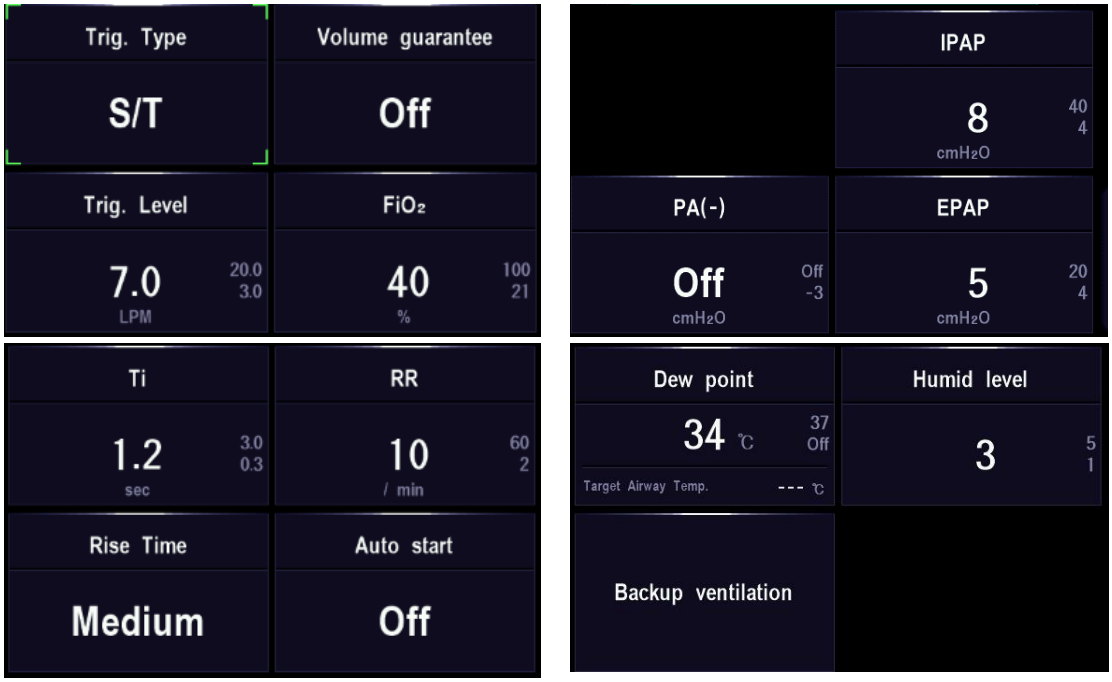


Figure C.3 S/T Controls

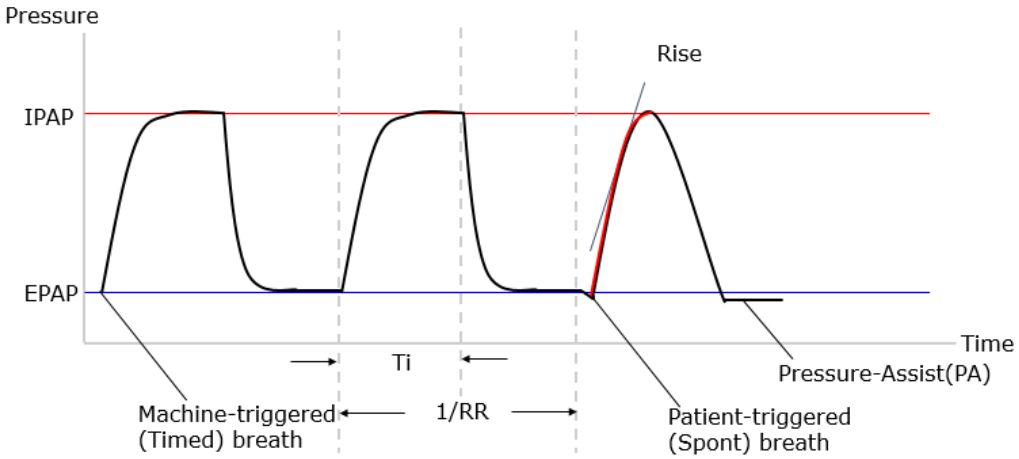


Figure C.4 S/T Pressure waveform

※ Respiration triggered by the patient is marked in red on the display.

S (Spontaneous) mode

The S(Spontaneous) mode supports the pressure-controlled spontaneous breath.

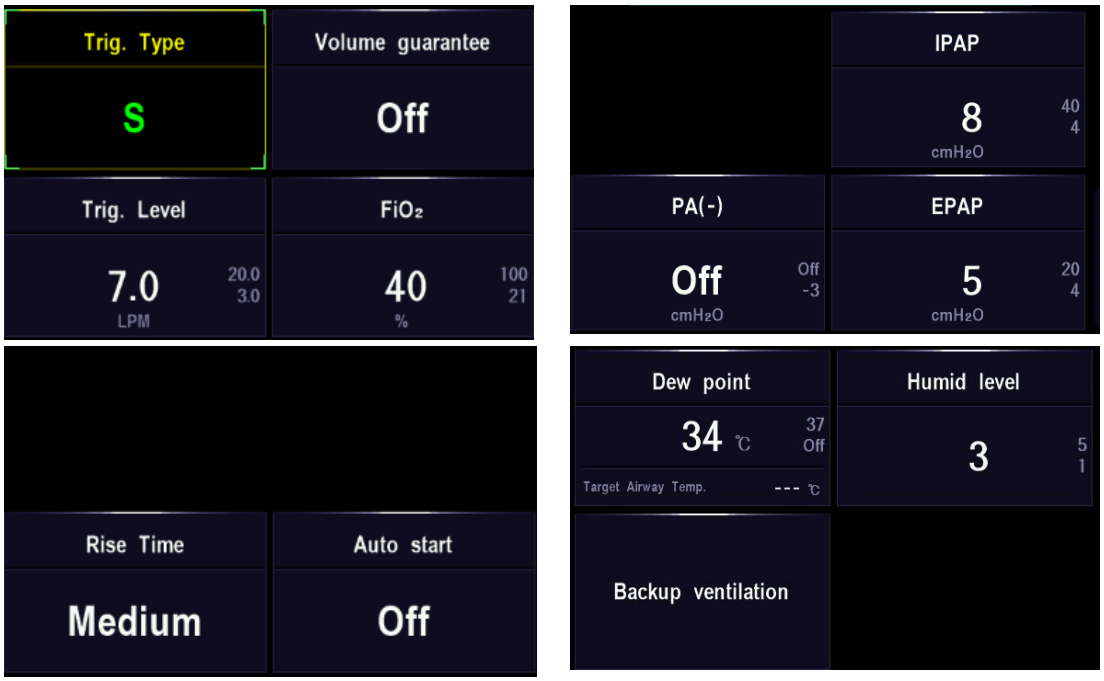


Figure C.5 S Control parameters

Volume Guarantee (VG)

The Volume Guarantee function in the bi-level is to deliver the target tidal volume to the patient. It delivers the target volume to the patient by controlling the pressure applied according to the initial pressure rise. Options of the Volume Guarantee support timed mandatory breathing and display the pressure-controlled spontaneous breathing.

As the mandatory breathing and spontaneous breathing are continuously delivered at the controlled pressure for a certain time, the target volume is achieved. The Pressure Limit sets the maximum pressure applied to the Volume Guarantee mode, and the patient breathes according to the flow trigger levels.

In the first level, the Volume Guarantee applies the PIP as below to operate the ventilator:
EPAP + 10 cmH_2O



[Volume Guarantee OFF] [Volume Guarantee ON]

Figure C.6 Volume Guarantee options in the bi-level mode

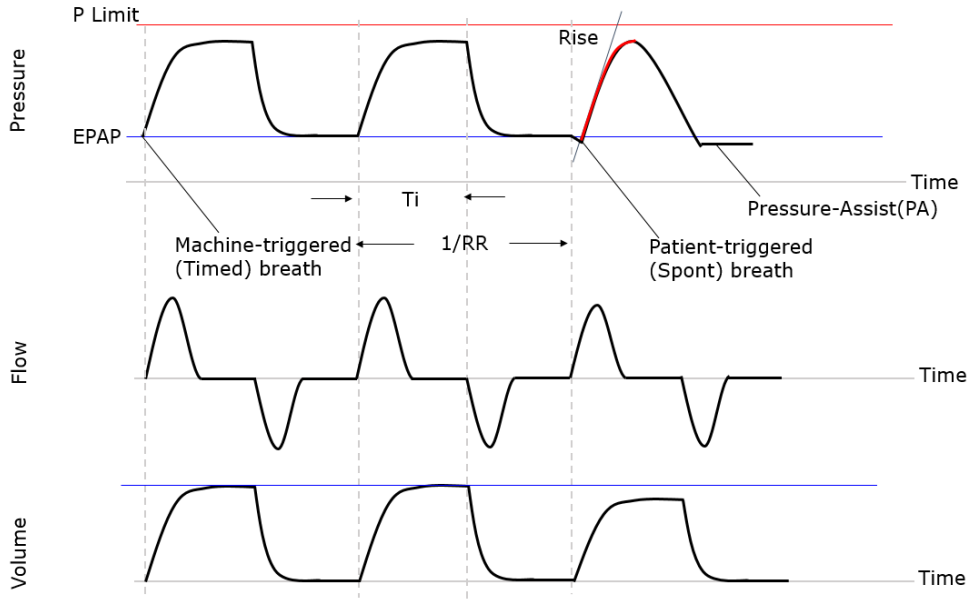


Figure C.7 Volume Guarantee Waveform

WARNING

To avoid excessive pressure or volume delivery, set the pressure limit of the HFT700 ventilator appropriately. Excessive pressure or volume may be delivered to the patient because of a sudden increase in mask leakage or inappropriate variable settings. Conversely, insufficient treatment may result in the patient if pressure limits are set too low.

NOTE

Do not forget to check that the IPAP value is adjusted to the target value when adjusting the pressure limit. If the calculated target pressure is outside the pressure limit range, the target volume may not be achieved.

Guide for the Volume Guarantee

To guarantee the optimal volume to enhance the comfort of the patient who uses the ventilator, follow the process below:

V_target: User-set target volume

P_target: Target control pressure to achieve the V_target

P_limit: User-set maximum pressure

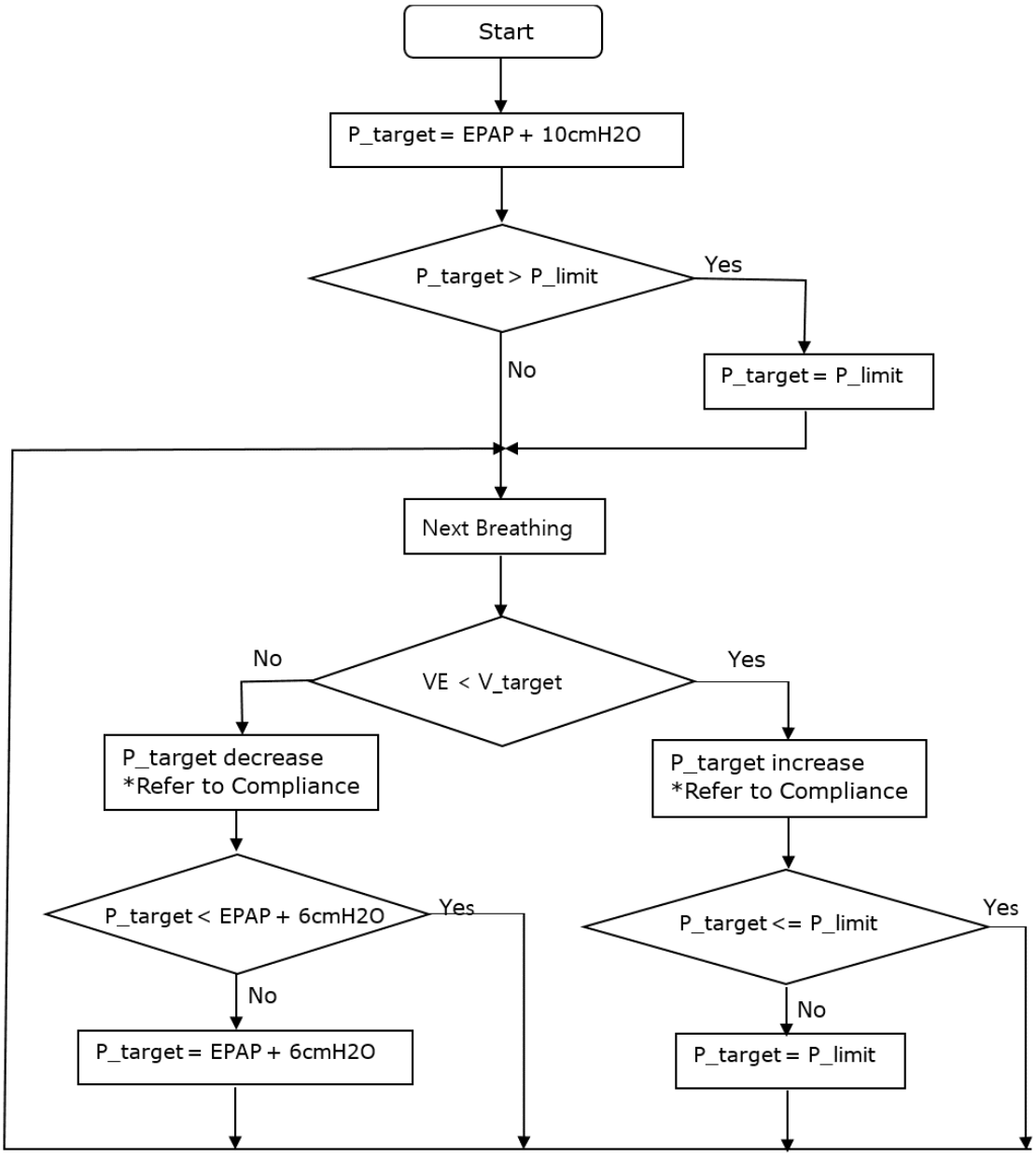


Figure C.8 Volume Guarantee Initialization Process

WARNING

MEKICS does not recommend the VG option to a patient who needs fast and frequent IPAP controls to maintain a consistent tidal volume. Using the VG option may take a longer time to achieve the target tidal volume.

IPAP Trigger

It is a set point to be set for the ventilator to deliver the mandatory breath or spontaneous breath to the patient.

The flow sensor for the breath delivery of the ventilator measures the flow delivered to the breathing circuit. The ventilator monitors the flow to the patient by measuring the differences between the measured inspiration flow and the trigger set point. If the patient's inspiration flow is above the trigger set point according to the set trigger levels, the IPAP Trigger of the patient occurs.

In addition, if the measured pressure is lower than the EPAP pressure value, the IPAP Trigger occurs. If the measured pressure is −5 cmH2O for 30 seconds, the IPAP Trigger occurs with no exception for the patient's safety.

Cycling

The set inspiratory time (Ti) defines the duration of the inspiratory phase.
The respiratory circulates between the inhalation and exhalation according to:

- Flow trigger level (Transition from exhalation to inhalation)
  - The flow trigger level can be controlled between 3 l/min and 20 l/min by 0.5 l/min. The flow trigger occurs when the patient's inspiratory effort is the same as or above the flow trigger level.
- Flow cycle (Transition from Inhalation to Exhalation) determination
  - The flow starts to decrease during the inspiratory. If the flow delivered to the patient is less than a certain ratio of the maximum flow, the respiratory level of the ventilator will be changed to exhalation.
- The patient's flow reaches the spontaneous exhalation threshold.
- It will occur after 3 seconds in the IPAP level (Timed backup safety algorithm).

Backup ventilation

The backup ventilation is activated only in the S/T or S mode, and if the patient is in apnea, it triggers the breath according to the mechanical trigger, pressure limit, and time cycle. If the breath is not triggered by the patient during the adjustable apnea time, the function will be performed according to the backup ventilation set points (IPAP, Ti, RR). If the patient's spontaneous breath is triggered while the backup ventilation function is run, the backup ventilation function is stopped and automatically converted to the S/T or S mode which is the previous set point.

Leak Compensation

This function is to compensate for the leak between the patient and the mask in the CPAP and bi-level modes. The important characteristics of the ventilator are to recognize or compensate for an unintended leak in the system, and if there is a leak in the system, to control the trigger and time cycle algorithm automatically to operate the ventilator.

It continuously monitors the flow, and compensates for a leak by calculating the patient's flow whenever a leak in the breathing circuit occurs or the mask changes. The leak compensation is provided by referring to the flow-based parameters such as the patient's flow and exhaled tidal volume according to the patient's breathing pattern.

When the leakage changes, the ventilator resets the base flow by considering the leakage, so it can keep the trigger level consistent. The maximum leak compensation is 60 l/min.

Functional target

- During the flow leak, the leak compensation function is intended to minimize the asynchronous trigger of the ventilator by detecting the stable patient's trigger.
- During the flow leak, the leak compensation function supports the accuracy of the volume measurement of the patient, the flow, and the patient treatment.

NOTE

MEKICS provides the information on the available masks and exhaust port ranges.
Choose the right device by considering those characteristics.

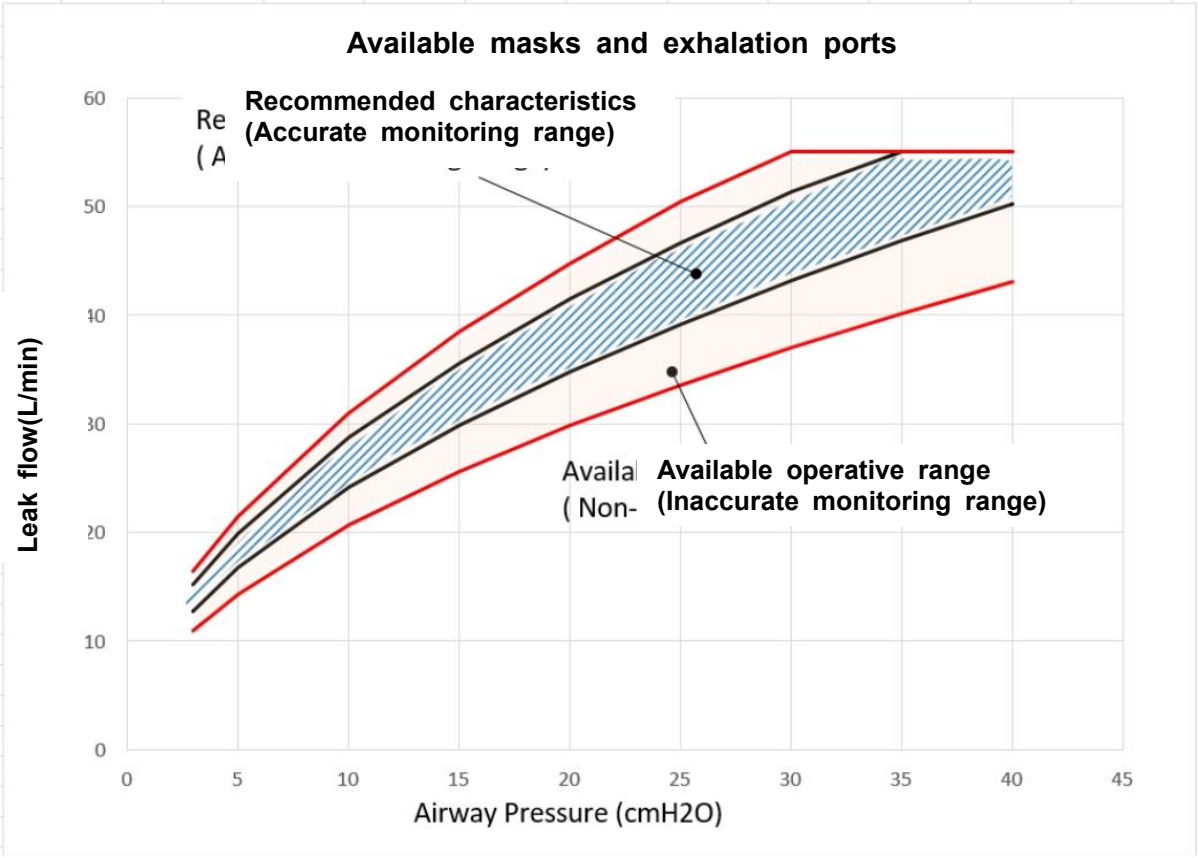
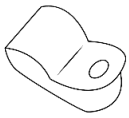
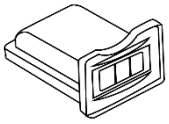
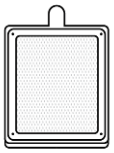
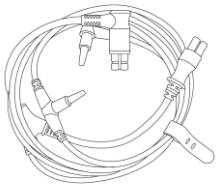
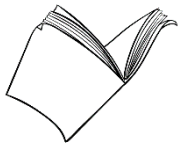
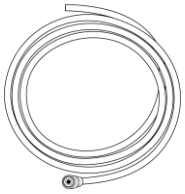


Figure C.9 Characteristic range of the masks and the exhaust port

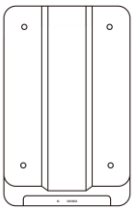
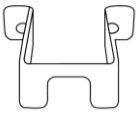
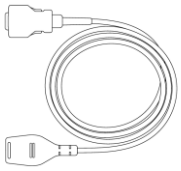
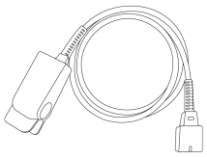
Annex D Basic Configuration /Optional Accessories

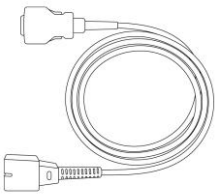
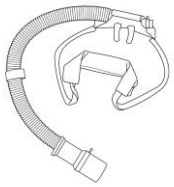
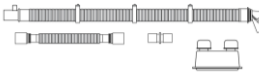
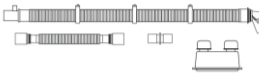
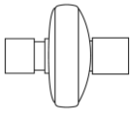
D.1 Basic composition

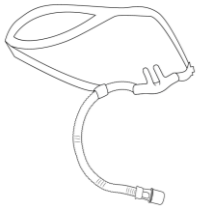
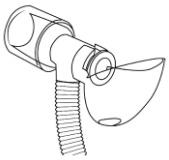
Items	Image	Part number	Quantity	Description
AC power cord		AC0006_01	1	AC power cord (Type Class II)
AC power cord clamp		AS0330_01	1	Clamp Power Cord, 4N
Air intake filter		MA0343_00	1	It is installed on the device with the air filter.
Air filter		AR0110_00	4	A replacement filter for the air intake filter. Thickness :2.5mm Resistance :16.5 Pa (28 l/min on 40 ㎠) Filtration efficiency: 99.99 %
Y cable		MA0342_00	1	Heated wire cable and Temperature sensor cable (1.5m, F&P connector Type)

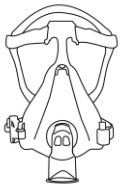
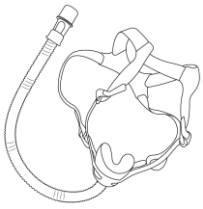
Items	Image	Part number	Quantity	Description
User manual		AS0474_00	1	English user manual
High pressure oxygen hose		AR0039_01	1	High pressure oxygen hose (3.5m / one side DISS and other side open)
Oxygen sensor		AB0024_02	1	The life cycle is generally more than 1 year but varies according to the use environment and the oxygen density. (Installed inside the device.) The manufacturer and the shape and color of the device may differ from the photo.

D.2 Optional accessories

Items	Photo	Part number	Quantity	Description
External Power Supply (MPS100)		MA0358_00	1	HFT700 dedicated external power supply.
DC OUTPUT CABLE		AC0266_00	1	Connecting DC Output Connector of external power supply and DC Cable Connector of HFT700, 0.17M
AC locking bracket(1)		AF0151_00	1	When using an external power supply, fix the AC output cable.
AC locking bracket(2)		AF0150_00	1	When using an external power supply, fix the AC power cord.
SpO_2 probe sensor (MASIMO)		PG0173_02	1	For adult. It can be only used on the device equipped with the MASIMO SpO_2 module (MASIMO SpO_2 sensor kit).
Patient cable (MASIMO, SpO_2 probe extension cable)		PG0173_01	1	
SpO_2 probe sensor (MEKICS)		PG0141_00	1	It can be only used on the device equipped with the MEKICS SpO_2 module (MEKICS SpO_2 sensor kit).

Items	Photo	Part number	Quantity	Description
SpO_2 probe extension cable (MEKICS)		AC0145_0q	1	
Cart		PG0086_15	1	Mobile cart dedicated to the HFT700 ventilator.
Nasal cannula for adult		L: PG0174_00 M: PG0174_01 S: PG0174_02	1	The nasal cannula is designed to deliver air with or without mixed oxygen at a flow rate of up to 60 l/min.
Breathing circuit		PG0064_05	1	The high flow circuit delivers the warmed and humidified breathing gas.
Breathing circuit (Pediatric)		PG0064_06	1	The high flow circuit delivers the warmed and humidified breathing gas.
Anti-bacterial filter		PG0186_00	1	An anti-bacterial filter is intended to reduce the bacteria and virus counts delivered to the patient.

Items	Photo	Part number	Quantity	Description
Veoflo High flow nasal cannula		L: PG0184_00 M: PG0183_00 S: PG0182_00	1	High flow nasal cannula supplies the high flow oxygen enrichment by using the warmed and humidified breathing gas.
Veoflo High Flow Tracheostomy Interface		PG0185_00	1	Veoflo High Flow Tracheostomy Interface is ideal for spontaneously breathing patients weaning from ventilation and requiring high O2.
Nioflo Paediatric Cannula		L: PG0187_02 M: PG0187_01 S: PG0187_00	1	High Flow Nasal Cannula delivers High Air Flow Oxygen Enrichment using warmed and humidified gas. - L Color : Black - M Color : Mint - S Color : Yellow
Nioflo Micro-Premature Cannula		PG0187_03	1	High Flow Nasal Cannula delivers High Air Flow Oxygen Enrichment using warmed and humidified gas. - Color : White
Nioflo Premature Cannula		PG0187_04	1	High Flow Nasal Cannula delivers High Air Flow Oxygen Enrichment using warmed and humidified gas. - Color : Green
Nioflo Neonate Cannula		PG0187_05	1	High Flow Nasal Cannula delivers High Air Flow Oxygen Enrichment using warmed and humidified gas. - Color : Blue

Items	Photo	Part number	Quantity	Description
Nioflo Infant Cannula		PG0187_06	1	High Flow Nasal Cannula delivers High Air Flow Oxygen Enrichment using warmed and humidified gas. - Color : Orange
Full Face Mask		L: PG0213_02 M: PG0213_01 S: PG0213_00	1	A mask delivers the warmed and humidified breathing gas to the patient in a non-invasive way at positive airway pressure.
Nasal Mask		L: PG0214_02 M: PG0214_01 S: PG0214_00	1	A mask delivers the warmed and humidified breathing gas to the patient in a non-invasive way at positive airway pressure.

CAUTION

The SpO_2 probe and the probe extension cable from the same manufacturer as the SpO_2 module must be used. If using a SpO_2 probe or a probe extension cable from a different manufacturer from the SpO_2 module in the device, a severe system error may occur or an incorrect monitoring value may be displayed on the screen.
Make sure to configure and use the device as below.

- MEKICS SpO_2 module: Use the MEKICS SpO_2 probe and the extension cable dedicated to the HFT700 ventilator.
- MASIMO SpO_2 module: Use the MASIMO SpO_2 probe and the extension cable.

NOTE

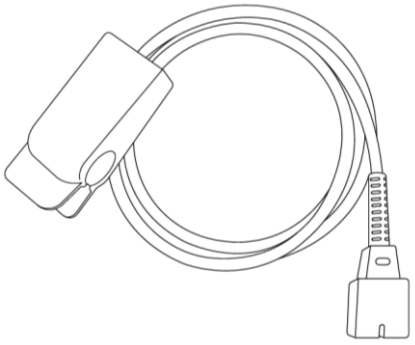
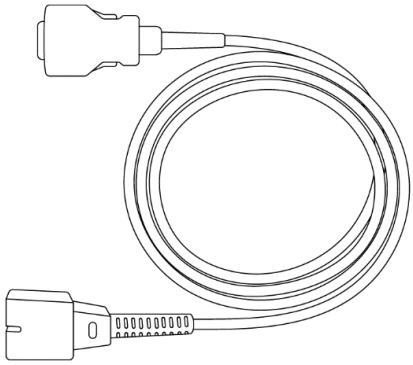
The HFT700 device can be bought with the accessories (IEC certified items) below:

- High Flow Nasal Cannula
- Vented Mask

Annex E SpO_2 Monitoring

The SpO_2 module can be equipped to measure the patient's SpO_2.

E.1 MEKICS SpO_2 Module Configuration

No.	Photo	Description
1		SpO_2 probe sensor
2		Probe extension cable dedicated to the HFT700 ventilator

E.2 MEKICS SpO_2 Monitoring

The oxygen saturation shows the degree of saturation of hemoglobin that can carry oxygen in the artery. In other words, it represents the amount of oxygen that hemoglobin is currently carrying against the amount of oxygen it can carry in percentage.

SpO_2 Measurement range	0 to 100 %
Resolution	1 %
Measurement error	Adult: ±2 %p for readings from 100 to 70 %, ±3 %p for readings from 69 to 51 %, Unspecified: from 50 to 0 % Neonate: ±3 %p for readings from 100 to 70 %, ±3 %p for readings from 69 to 51 %, Unspecified: from 50 to 0 %
Measurement condition	Measurements are possible only when the patient's perfusion index is higher than 0.1 %.
Pulse rate	0, 20 to 250 / min (based on electric pulse simulator)
Resolution	1 /min
Measurement error	±2 / min
Data average update	Displays the average of the last 4 measurements
Alarm delay	No delay, Immediately

Sentences below are displayed according to the SpO_2 measurement status.

SpO_2 Probe off Patient	The SpO_2 probe and the probe extension cable are connected to the device and on stand-by. (Applied to the patient of the previous level)
Check SpO_2 Probe	The SpO_2 probe and the probe extension cable are not connected to the device, or the connection is not stable.

WARNING



- Use only the MEKICS certified SpO_2 probe. Using other items may cause a performance problem.
- If it is on the measurement stand-by, "Stand-by" or "---" appears in the measurement display area.
- The responsible organization and the user need to verify the compatibility of the monitoring device or parts, probes and the cables before use.
- Wrong applications such as fixing the sensor with adhesive tape may cause a dermal tissue injury to the patient.
- Never use a sensor or a probe to a part of arterial catheters or intravenous injectors.
- Do not use a damaged SpO_2 probe on the patient.
- The sensor is not waterproof, so do not soak it in water or solvent or clean it excessively.
- Do not sterilize the sensor with ultraviolet rays, direct sunlight, steam, or hydrogen peroxide.
- As the self-test function that performs a test automatically in case of alarm is not provided, a test to connect the SpO_2 probe and the SpO_2 simulator is necessary if the user wants to test if an alarm triggers or not.
- The accuracy of the blood oxygen saturation measuring probe or blood oxygen saturation measuring device cannot be evaluated by using a performance tester.

CAUTION



Do not use the SpO_2 probe on a patient with a known allergy to the probe. Do not use the SpO_2 probe sensor during MRI scanning. The patient can be burned because of induced currents. If the patient feels uncomfortable after attaching the SpO_2 probe, remove the SpO_2 probe immediately.

CAUTION

In the following cases, if using the SpO2 probe incorrectly, the measured values may not be accurate and abnormal signals can appear:

- A SpO_2 probe is not approved by MEKICS or is used incorrectly.
- Hemoglobin dysfunctions
- The SpO_2 probe is exposed excessively to medical lighting (in particular, Xenon lighting), bilirubin lighting, fluorescent light, infrared heating device or direct sunlight.
- The patient's excessive movement
- Using the high frequency electrosurgical unit or cardiac ventilator
- Intravenous Pulse
- The measurement is performed on the location where the pulse rate is measured, a compress is applied, an arterial catheter is used, or the other sensor is used inside the blood vessel.
- There are artery blockages near the sensor used.
- If the patient is in cardiac arrest or in defibrillation.

In the following cases, the pulse rate may not be accurate:

- The SpO_2 probe is fastened too tightly.
- An excessive medical light or bilirubin light enters to the SpO_2 probe.
- The measurement is performed on the location pressed by a compress, a tourniquet, or a wrist.

NOTE

- You can verify that the MEKICS monitoring system, sensors, and cables are functioning properly by using a function tester in the market or some models of the patient simulators. For the process for each tester model, refer to the user manual of each tester.
- This equipment can be useful to verify that sensors, cables, and monitoring systems are functioning, but it can't provide the data necessary to correctly evaluate the SpO_2 measurement accuracy of a monitoring system.
- The SpO_2 module calibrates the measured values and displays the functional saturation (SpO_2). The amount of oxyhemoglobin is displayed as the percentage of hemoglobin that can carry oxygen.
- The SpO_2 module is proven to have the low perfusion accuracy in the benchtop test for the Biotek Index 2 simulator. This deviation is equal to ± standard deviation.
- The MEKICS SpO_2 probe is proven to have a pulse rate accuracy in the range of 30–250 /min in the benchtop test for the Biotek Index 2 simulator.

NOTE

- The update rate of the SpO_2 value and the pulse rate is generally one second. The display of the SpO_2 value and the pulse rate and the data average of the transferred data values, and the other signal processes are controlled automatically.
- Depending on the size of the difference between the alarm limits and the displayed values, the alarm signal generation delay can be the response time + 5 seconds. The delay of the alarm condition can be the response time + 1 second. If the SpO_2 update technical alarm ("alarm error") occurs, physiological alarm response time increases proportionally. If the system is configured with the SpO_2 alarm delay, the alarm trigger time is delayed by the configured time.

To avoid the excessive light, follow the guidelines. Use an opaque substance for the sensor not to be exposed to an external source of light. If the surrounding environment is too bright, the measured values can be inaccurate.
As the patient's movement can cause a problem, check if the sensor is functioning safely. Using an adhesive sensor may reduce measurement errors caused by the patient's movement.

1) Clinical studies

A. Introduction

This section contains data on the clinical studies performed on the MEKICS sensors used with the MEKICS SpO_2 monitoring system.
This device is used to monitor oxygenation consistently, whose result is important for hypoxia early detection. Therefore, verifying the SpO_2 accuracy is mandatory for the patient's safety.

B. Methodology

This study was performed in the normal environment of an intensive clinical laboratory of a medical center to the clinical test guidelines (of the Korean Ministry of Food and Drug Safety) for a pulse oximeter complying with ISO 14155:2011 guidelines and other ISO standards. ISO 80601-2-61:2011 (E). To evaluate the SpO_2 accuracy in a stationary state and movement-free condition, we placed pulse oximeters with MDNA disposable finger probes on each volunteer. Each volunteer is in the semi-Fowler position and connected to the breathing circuit to inject the post anoxic gas containing medical air, oxygen, nitrogen, and carbon dioxide, and another breathing circuit. For frequent blood collection, we injected local anesthetics and placed a radial artery nasal cannula on the left or right wrist of the volunteer. We sprayed warm air on the hand by using the finger probes to prevent hypoperfusion caused by the cold temperature. The mixed air was controlled to induce various levels of hypoxia and to keep the safe oxygen saturation of 70 % to 100 % SaO_2. While collecting the data from the device being tested, we collected arterial blood. We measured the functional SaO_2 by analyzing the blood sample with CO-Oximetry immediately, and made use of it as a benchmark to compare SpO_2 accuracy. As the pulse oximeter's measurement values are distributed statistically, we can expect that about two-thirds of the pulse oximeter's measurement values would be within ± Arms measured by the CO-oximeter.

We aligned the selected SaO_2 values to the corresponding SpO_2 values and analyzed the data according to the following statistics: • The accuracy of the SpO_2 was evaluated at the Arms for the entire range for 10 years.

$$A_{rms} = \sqrt{\frac{\sum_{i=1}^{n} (SpO_{2i} - S_{Ri})^2}{n}}$$

-SpO_2i: measured SpO_2
-SRi: reference SaO_2

C. Results

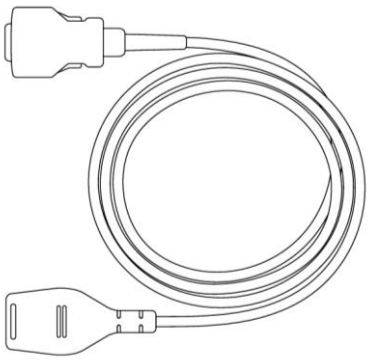
Accuracy was calculated using the root mean square difference (RMSD)

SpO_2 Range	WA-100	
	Data Points	Arms
70-100 %	275	2.83 %

D. Conclusion

Our results provide evidence that the SpO_2 accuracy of the SpO_2 pulse oximeter with the MDNA disposable and WA-100 reusable finger probes passes the Arms standards of ≤ 4 % within 70-100 % SaO_2 range in a stationary state or a nonstationary state.

E.3 MASIMO SpO_2 Module Configuration

No.	Image	Description
1		MASIMO SpO_2 probe sensor
2		MASIMO patient cable (SpO_2 probe extension cable)

E.4 MASIMO SpO_2 Monitoring

The MASIMO SpO_2 modules and accessories must be operated directly by a qualified medical staff or the person concerned or under his/her supervision. Users must read the manual, guidelines and all the precautions and specification requirements before use.

SpO_2 Measurement range	1 to 100 %		
Resolution	1 %		
Accuracy - During No Motion Conditions	Adults, Pediatrics:	±2 digits	70 % to 100 %
		Unspecified	0 %to 69 %
	Neonates:	±3 digits	70 % to 100 %
		Unspecified	0 % to 69 %
- During Motion Conditions	Adults, Pediatrics:	±3 digits	70 % to 100 %
		Unspecified	0 %to 69 %
	Neonates:	±3 digits	70 % to 100 %
		Unspecified	0 %to 69 %
Pulse rate			
- Movement-free condition	Adults, Pediatrics, Neonates: 25 to 240 ±3 digits		
- Moving condition	Adults, Pediatrics, Neonates: 25 to 240 ±5 digits		
Resolution	1 /min		
Low perfusion performance	>0.02 % Pulse Amplitude and %Transmission > 5 % Saturation ±2 digits, Pulse Rate ±3 digits		
Alarm delay	User Selection. (SpO_2 High, Low Alarm Only)		

NOTE

1. The Masimo sensors have been validated for no motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies in the range of 70–100 % SpO2 against a laboratory CO-Oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68 % of the population.
2. The Masimo sensors have been validated for motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70–100 % SpO2 against a laboratory CO-Oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68 % of the population.
3. Masimo SET has been validated for low perfusion accuracy in bench-top testing against a Biotek Index 2* simulator and Masimo's simulator with signal strengths of greater than 0.02 % and transmission of greater than 5 % for saturations ranging from 70–100 %. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68 % of the population.
4. The Masimo SET technology equipped with the Masimo Neo sensor is proven to have the neonatal motion accuracy in the human blood research to the healthy adult male and female volunteers with minor skin pigmentation in the hypoxia induction study while performing friction and tapping motions in 2 Hz to 4 Hz. Non-repetitive exercise between 1 and 5 Hz in 1 – 2 cm amplitude and 2 – 3 cm amplitude in the hypoxia induction study in the range of 70 – 100 % SpO_2 for the CO-Oximeter and the ECG monitor of the laboratory. This deviation is equal to ± standard deviation. The ± standard deviation includes 68 % of the population. 1 % is included in the result to explain the effect of fetal hemoglobin (HbF) existing in newborn babies. The Masimo SET technology including the Masimo sensor is proven to have a pulse rate accuracy in the range of 25–240 /min in the benchtop test for the Biotek Index 2™ simulator. This deviation is equal to ± standard deviation. The ± standard deviation includes 68 % of the population.

NOTE

5. See sensor directions for use (DFU) for complete application information. Unless otherwise indicated, reposition reusable sensors at least every 4 hours and adhesive sensors at least every 8 hours.
6. Sensor accuracy specified when used with Masimo technology using a Masimo patient cable for LNOP sensors, RD SET sensors, the LNCS sensors, or the M-LNCS sensors. Numbers represent Arms (RMS error compared to the reference). Because pulse oximeter measurements are statistically distributed, only about two-thirds of the measurements can be expected to fall within a range of ± Arms compared to the reference value

WARNING

1. As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.
2. Do not place the Oxygen Assist Module or accessories in any position that might cause it to fall on the patient.
3. Do not start or operate the Oxygen Assist Module unless the setup was verified to be correct.
4. Do not use the Oxygen Assist Module during magnetic resonance imaging (MRI) or in an MRI environment.
5. If you find or have a doubt about damage to the pulse oximeter, do not use it.
6. Explosion hazard: Do not use the Oxygen Assist Module in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide
7. To ensure safety, avoid stacking multiple devices or placing anything on the device during operation.
8. To protect against injury, follow the directions below:
   - Avoid placing the device on surfaces with visible liquid spills
   - Do not soak or immerse the device in liquids.
   - Do not attempt to sterilize the device.
   - Use cleaning solutions only as instructed in this Instructions for Use.
   - Do not attempt to clean the device while attached to a patient
9. To protect from electric shock, always remove the SpO2 sensor and completely disconnect the Oxygen Assist Module from the patient before bathing the patient.
10. If there is a measurement problem, check the patient's vital signs with another method first and test the pulse oximeter to verify it is operating correctly.
11. Inaccurate SpO2 readings may be caused by:
    - Improper sensor application and placement

◦ Elevated levels of COHb or MetHb: High levels of COHb or MetHb may occur with a seemingly normal SpO2. When elevated levels of COHb or MetHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed.
◦ Elevated levels of bilirubin ◦ Elevated levels of dyshemoglobin
◦ Vasospastic disease, such as Raynaud's, and peripheral vascular disease
◦ Hemoglobinopathies and synthesis disorders such as thalassemias, Hb s, Hb c, sickle cell, etc. ◦ Hypocapnic or hypercapnic conditions
◦ Severe anemia Page 6 3101126-EN Rev D Vapotherm Oxygen Assist Module Instructions for Use Section 1 Indications, Warnings and Cautions
◦ Very low arterial perfusion ◦ Extreme motion artifact
◦ Abnormal venous pulsation or venous constriction
◦ Severe vasoconstriction or hypothermia
◦ Arterial catheters and intra-aortic balloon
◦ Intravascular dyes, such as indocyanine green or methylene blue
◦ Externally applied coloring and texture, such as nail polish, acrylic nails, glitter, etc.
◦ Birthmark(s), tattoos, skin discolorations, moisture on skin, deformed or abnormal fingers. etc.
◦ Skin color disorders

12. Interfering Substances: Dyes or any substance containing dyes that change usual blood pigmentation may cause erroneous readings.
13. The Oxygen Assist Module should not be used as the sole basis for medical decisions. It must be used in conjunction with clinical signs and symptoms
14. The SpO2 measurement on the Oxygen Assist Module is not a measure of apnea
15. The Oxygen Assist Module may be used during defibrillation but this may affect the accuracy or availability of the SpO2 measurement.
16. The Oxygen Assist Module may be used during electrocautery, but this may affect the accuracy or availability of the SpO2 measurement.
17. The SpO2 measurement on the Oxygen Assist Module should not be used for arrhythmia analysis.
18. SpO2 is empirically calibrated in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb)
19. Do not adjust, repair, open, disassemble, or modify the Oxygen Assist Module or accessories. Injury to personnel or equipment damage could occur. Return the Oxygen Assist Module for servicing if necessary
20. Optical, pleth-based measurements (e.g. SpO2 and RRp) can be affected by the following:
    • Improper sensor application or use of use of incorrect sensor.
    • Blood pressure cuff applied to the same arm as the sensor site.
    • Intravascular dyes such as indocyanine green or methylene blue.
    • Venous congestion.
    • Abnormal venous pulsations (e.g. tricuspid value regurgitation, Trendelenburg

position).

• Abnormal pulse rhythms due to physiological conditions or induced through external factors (e.g. cardiac arrhythmias, intra-aortic balloon, etc.).

• Externally applied coloring and texture such as nail polish, acrylic nails, glitter, etc.

• Moisture, birthmarks, skin discoloration, nail aberration, deformed fingers, or foreign objects in the light path.

• Elevated levels of bilirubin.

• Physiological conditions that can significantly shift the oxygen disassociation curve.

• A physiological condition that may affect vasomotor tone or changes in vasomotor tone

21. Incorrect Ori reading may be caused by the following:
    - Low arterial perfusion
    - Artificial movement induction results
    - High COHb and/or MetHb level
    - Hemoglobinopathy (Qualitative defects including sickle cell) and hemoglobin synthesis disorders (Quantitative defects such as Thalassemias).
    - Hypotension, severe vasoconstriction, severe anemia, or hypothermia.
22. ORI is intended to supplement, not replace, SpO_2 monitoring and PaO_2 measurements.

CAUTION

1. Do not place the Root where the controls can be changed by the patient
2. Electrical shock and flammability hazard: Before cleaning, always turn off the device and disconnect from any power source.
3. When patients are undergoing photodynamic therapy they may be sensitive to light sources. Pulse oximetry may be used only under careful clinical supervision for short time periods to minimize interference with photodynamic therapy
4. Do not place the Oxygen Assist Module on electrical equipment that may affect the device, preventing it from working properly.
5. If SpO_2 values indicate hypoxemia, a laboratory blood sample should be taken to confirm the patient's condition
6. If the Low Perfusion message is frequently displayed, find a better perfused monitoring site. In the interim, assess the patient and, if indicated, verify oxygenation status through other means.
7. Change the application site or replace the SpO_2 sensor and/or patient cable when a "Replace sensor" and/or "Replace patient cable", or a persistent poor signal quality message (such as "Low SIQ") is displayed. These messages may indicate that patient monitoring time is exhausted on the patient cable or sensor.
8. If using the Oxygen Assist Module during full body irradiation, keep the SpO_2 sensor out of the radiation field. If the sensor is exposed to the radiation, the reading might be inaccurate or the device might read zero for the duration of the active irradiation period
9. In order to see if the alarm settings are suitable for the monitored patient, check the alarm settings whenever you use the device.
10. Variation in measurements may be profound and may be affected by sampling technique as well as the patient's physiological conditions. Any results exhibiting inconsistency with the patient's clinical status should be repeated and/or supplemented with additional test data. Blood samples should be analyzed by laboratory instruments prior to clinical decision making to completely understand the patient's condition.
11. Do not submerge the Oxygen Assist Module or any associated accessories in any cleaning solution or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage the device
12. Electrical Shock Hazard: Carry out periodic tests to verify that leakage currents of patientapplied circuits and the system are within acceptable limits as specified by the applicable safety standards. The summation of leakage currents must be checked and in compliance with IEC 60601-1 and UL60601-1. The system leakage current must be checked when connecting external equipment to the system. When an event such as a component drop of approximately 1 meter or greater or a spillage of blood or other liquids occurs, retest before further use. Injury to personnel could occur
13. Disposal of product – Comply with local laws in the disposal of the device and/or its accessories

14. To minimize radio interference, other electrical equipment that emits radio frequency transmissions should not be in close proximity to the Oxygen Assist Module.
15. Replace the SpO_2 cable or sensor when a replace sensor or when a low SIQ message is consistently displayed while monitoring consecutive patients after completing troubleshooting steps listed in this manual.

NOTE

1. A functional tester cannot be used to assess the accuracy of the SpO2 measurement on the Oxygen Assist Module
2. High-intensity extreme lights (such as pulsating strobe lights) directed on the SpO2 sensor, may not allow the Oxygen Assist Module to obtain an accurate reading.
3. If using the maximum sensitivity setting, "Sensor Off" sensitivity performance may be degraded. If the device has this setting, and the sensor is disconnected from the patient, incorrect reading can occur because of environmental noises such as light, vibration, or excessive movement of air.
4. Do not loop the SpO2 patient cabling into a tight coil or wrap around the device, as this can damage the patient cabling.
5. Additional information specific to the Masimo sensors compatible with the Oxygen Assist Module, including information about parameter/measurement performance during motion and low perfusion, may be found in the sensor's directions for use (DFU)
6. SpO2 cables and sensors are provided with X-Cal™ technology to minimize the risk of inaccurate readings and unanticipated loss of patient monitoring. Refer to the Cable or Sensor DFU for the specified duration of the patient monitoring time
7. A physiological condition that causes pulsating signal loss may result in the illegibility of the SpO_2, RRp, and ORi readings.

Annex F Standards

This device is approved by the following international standards:

Standards	International standards
EN 60601-1:2006+A1:2013	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests
EN 60601-1-6:2010+A1:2015	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard : Usability
EN 60601-1-8:2007+A1:2013 +A11:2017	Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
EN 60601-1-10:2008/A1:2015	Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers
EN 60601-1-11:2015	Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
EN ISO 80601-2-12:2020	Medical electrical equipment – Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
EN ISO 80601-2-61:2019	Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
EN ISO 80601-2-72:2015	Medical electrical equipment – Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients
ISO 80601-2-74:2017	Respiratory tract humidifiers for medical use – Particular requirements for respiratory humidification systems
EN ISO 80601-2-79:2019	Medical electrical equipment – Part 2-79: Particular requirements for basic safety and essential performance of ventilator support equipment for ventilator

Standards	International standards
	impairment.
EN ISO 80601-2-80:2019	Medical electrical equipment – Part 2-80: Particular requirements for basic safety and essential performance of ventilator support equipment for ventilator insufficiency.
EN ISO 15223-1:2021	Symbols for use in the labeling of medical devices
EN 780:2015	Graphical symbols for handling and storage of packages
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 20417:2021	Information to be supplied by the manufacturer
EN ISO 14971:2019	Medical devices – Application of risk management to medical devices
EN ISO/TR 24971:2020	Medical devices — Guidance on the application of ISO 14971
EN ISO 10993-1:2020	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
EN ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-10:2013	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
EN ISO 18562-1:2020	Biocompatibility evaluation of breathing gas pathways in healthcare application – Part 1: Evaluation and testing within a risk management process
EN ISO 18562-2:2020	Biocompatibility evaluation of breathing gas pathways in healthcare application – Part 2: Tests for emissions of particulate matter
EN ISO 18562-3:2020	Biocompatibility evaluation of breathing gas pathways in healthcare application – Part 3: Tests for emissions of volatile organic compounds(VOCs)
EN 62304:2006+A1:2015	Medical device software – software life cycle process
EN 62366-1:2015+A1:2020	Medical devices – Application of usability engineering to medical devices

Annex G TEST Summary

The table below contains the manufacturer's declaration about the electromagnetic emission and electromagnetic susceptibility of the ventilator, the distance between the ventilator and the portable and mobile radio frequency communication equipment, and the compliant cable lists.

WARNING

Mobile radio frequency communication equipment can affect the performance of the ventilator. Install and use this device according to the information included in this manual.

WARNING

The HFT700 ventilator must not be used adjacent to or together with other devices, except as specified in another section of the user manual. When the device should be used in adjacent or stacked conditions, you must verify that the configuration works well by trying to use the device.

WARNING

The portable and mobile radio frequency communication equipment must not be more than 30 cm away from any part of the ventilator including the cables designated by the manufacturer. Otherwise, the performance of the device may be degraded.

NOTE

The emission characteristics of this device are suitable for use in a hospital (CISPR 11 Class B).

G.1 Guidance and manufacturer's declaration – electromagnetic emissions

The HFT700 ventilator is designed for use in the following specified electromagnetic environment. A customer or user of the HFT700 ventilator must verify that it is used in that environment.

Emissions test	Compliance	Electromagnetic environment – guidance
Radiated RF emissions CISPR	Group 1 Class B	The HFT700 uses 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.
Harmonic emissions IEC 61000-3-2	Class A	The HFT700 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 public mains network.
Voltage Fluctuations and Flicker IEC 61000-3-3	Complies	

G.2 Guidance and manufacturer's declaration – electromagnetic immunity

The HFT700 ventilator is designed for use in the following specified electromagnetic environment.
A customer or user of the HFT700 ventilator must verify that it is used in that environment.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV Contact discharge ±2 kV , ±4 kV , ±8 kV ±15 kV air discharge	±8 kV Contact ±2 kV , ±4 kV , ±8 kV ±15 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 IEC 61000-4-4	±2 kV AC, 100 kHz PRR	±2 kV AC, 100 kHz PRR	Mains power quality should be that of a typical hospital environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV L1 to L2	±0.5 kV, ±1 kV L1 to L2	Mains power quality should be that of a typical hospital and home healthcare environment.
Voltage dips, interruptions and variations IEC 61000-4-11	0 % U_T for 0.5 cycle 0 % U_T for 1 cycle 50 Hz: 70 % U_T for 25 cycles 60 Hz: 70 % U_T for 30 cycles 50 Hz: 0 % U_T for 250 cycles 60 Hz: 0 % U_T for 300 cycles	0 % U_T for 0.5 cycle 0 % U_T for 1 cycle 50 Hz: 70 % U_T for 25 cycles 60 Hz: 70 % U_T for 30 cycles 50 Hz: 0 % U_T for 250 cycles 60 Hz: 0 % U_T for 300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of this product requires continued operation during power mains interruptions, it is recommended that this product be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field 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 or home healthcare environment.

NOTE U_T is the AC mains voltage prior to application of the test level.

G.3 Guidance and manufacturer's declaration – electromagnetic immunity

The HFT700 ventilator is designed for use in the following specified electromagnetic environment.
A customer or user of the HFT700 ventilator must verify that it is used in that environment.

Guidance and manufacturer's declaration – electromagnetic immunity			
The HFT700 is intended for use in the electromagnetic environment specified below. The customer or the user of the HFT700 should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment– guidance
			Except as indicated in 8.6.5, Portable and mobile RF communications equipment should not be used closer to any part of the ventilator system, including cables, than the recommended separation distance. This is calculated using the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz – 80 MHz Outside ISM bands[c] amateur radio bands[d]	3 Vrms	Recommended Separation Distance d = 1.2√P
	6 Vrms 150 kHz – 80 MHz In ISM bands[c] amateur radio bands[d]	6 V/m	
Radiated RF IEC61000-4-3	10 V/m 80 MHz to 2.7 GHz		IEC 60601-1-2:2007 d = 1.2√P 80 MHz to 800 MHz d = 2.3√P 80 MHz to 2.5 GHz IEC 60601-1-2:2014 $d=2.0\sqrt{p}$ 80 MHz to 2.7 GHz 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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with following symbol: 
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.
a 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 HFT700 is used exceeds the applicable RF compliance level above, the HFT700 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the HFT700. b In the frequency range exceeds 150 kHz – 80 MHz, the electric field strength should be not higher than 3 V/m. c The ISM (Industrial, Scientific and Medical) bands between 150 kHz and 80 MHz are 6.765 MHz to6.795MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. d The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

G.4 Recommended separation distances between portable and mobile RF communications equipment and the HFT700

The HFT700 ventilator is designed for use in an electromagnetic environment where the radial radio frequency interference is controlled. A customer or user of the HFT700 ventilator can prevent electromagnetic Interference by maintaining the minimum distance between the portable and mobile radio frequency communication equipment (transmitter) and the HFT700 ventilator according to the following recommendations depending on the maximum output power of the communication equipment.

Rated maximum output power of transmitter [W]	Separation distance according to frequency of transmitter [m]	
	IEC 60601-1-2: 2014	
	150 kHz to 80 MHz d = 1.2√P	80 MHz to 2.7 GHz d = 2.0√P
0.01	0.12	0.20
0.1	0.38	0.63
1	1.2	2.0
10	3.8	6.3
100	12	20

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated 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.

G.5 Guidance and Manufacturer's Declaration–Electromagnetic Immunity

Guidance and manufacturer's declaration – electromagnetic immunity					
The HGN1 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Portable RF communications equipment should be used no closer than 30cm (12 inches) to any part of the HGN1. Otherwise, degradation of the performance of this equipment could result.					
Immunity test	Band [a]	Service [a]	Modulation	IEC60601 test level	Compliance level
Proximity fields from RF wireless Communications IEC61000-4-3	380 – 390 MHz	TETRA 400	Pulse modulation 18Hz	27 V/m	27 V/m
	430 – 470 MHz	GMRS 460 FRS 460	FM ±5 kHz deviation 1 kHz sine	28 V/m	28 V/m
	704 – 787 MHz	LTE Band13, 17	Pulse modulation 217 Hz	9 V/m	9 V/m
	800 – 960 MHz	GSM800:900 TETRA 800 iDEN 820 CDMA 850 LTE Band 5	Pulse modulation 18 Hz	28 V/m	28V/m
	1700 – 1990 MHz	GSM 1800 CDMA 1900 GSM 1900 DECT LTE Band 1,2,4,25 UMTS	Pulse modulation 217 Hz	28 V/m	28V/m
	2400 – 2570 MHz	Bluetooth WLAN 802.11b/g/n RFID 2450 LTE Band 7	Pulse modulation 217 Hz	28V/m	28V/m
	5100 – 5800 MHz	WLAN 802.11a/n	Pulse modulation 217 Hz	9 V/m	9 V/m
NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1m. The 1m test distance is permitted by IEC 61000-4-3.					
a For some services, only the uplink frequences are included. b The carrier shall be modulated using a 50 % duty cycle square wave signal. c As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.					

Annex H Training and Service manual

Training on the device is available. If you need help, contact the local MEKICS distributor or the MEKICS Customer Service Center. For the service, contact +82-70-7119-2520.

The separate service manual includes the below information:

- Revision history
- Introduction
- Device overview
- Service information
  - Service procedures
  - Service records
  - Troubleshooting
  - Service required alarm list
  - Service not required alarm list
  - Troubleshooting without alarms
  - Alarm test
  - Factory view mode guide
  - Disassemble guide
  - LabView program guide
  - Calibration guide
  - Service item list
  - Test sheet
- Software upgrade
- Appendix
  - Service announcement index
  - Change announcement index

Annex I Warranty policy

A. This device is manufactured according to the strict quality management and tests of MEKICS.
B. The criteria for repair and exchange of the device follow the "Compensation regulations for consumer's damage" of the Economy Planning Commission.
C. The warranty period for the device is 2 years after the installation, except for the following items.
   : LCD(6 months), battery(1 year), oxygen sensor(10,000 hours) and blower(15,000 hours).
D. If damage occurs during the warranty period even though the device is used correctly, the MEKICS Customer Service Center will repair the device free of charge.
E. In case of the following situations, a service fee of a certain amount will be charged separately.
   - ▣ A defect caused by natural disaster such as fire, earthquake or lightning
   - ▣ A defect caused by using the device for a purpose other than listed in this user manual
   - ▣ A defect caused by the user's negligence
   - ▣ A defect caused by repair or modification by an unauthorized person (not service personnel designated by MEKICS)
F. Repair request preparation
   - ▣ If any defect is found in the device, stop using it immediately and check the related chapter of the user manual.
   - ▣ To request a repair, check the model's name, serial number, purchase date, and defects before contacting the MEKICS Customer Service Center.



CAUTION

The company and the person in charge are not responsible for any loss or damage due to careless use or users' negligence.

Contact Us

You can obtain more information about our services and products by contacting us at:

Part No. : WK102



[Manufacturer / Customer Service Center]

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