flexicare
TOTAL QUALITY - TOTAL CARE

UK CA 0120



FL-10000
RESPIRATORY HUMIDIFIER
OPERATING MANUAL

FOR USE WITH FLEXICARE HEATED AND
NON-HEATED WIRE BREATHING SYSTEMS

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Conventions Used

CAUTION:
A CAUTION statement warns of possible damage to equipment if a procedure is not followed exactly.

WARNING:
A WARNING statement refers to conditions where a risk of personal injury exists if a procedure is not followed exactly.

Symbols Glossary

REF	SN							MR
Catalogue number	*Serial number*	Date of manufacture	*Manufacturer*	Refer to instruction manual/ booklet	Caution	Caution, hot surface	Warning; Electricity	(MR) Unsafe
			IPX1					UK CA 0120
Power Off	Power On	Protective Earth Terminal	IP rating	Alternating current	Type BF applied part	Separate collection	*Importer*	Product conforms with UK MDR 2002 SI 618
MD			-10 50 °C	500 hPa 1060 hPa	30% 95%		CH REP	UDI
Medical device	Keep dry	Keep away from sunlight	Temperature limit	Atmospheric pressure limitation	Humidity limitation	Do not use if package is damaged	Indicates the authorised representative in Switzerland	Unique device identifier
EC REP								
Authorised representative in the European Community / European Union								

Product Specifications

ELECTRICAL RATING	
SUPPLY VOLTAGE	230V ±23V (220W)
SUPPLY CURRENT	1.0A max at 230V
SUPPLY FREQUENCY	50/60 Hz
HEATER PLATE CAPACITY	150W
HEATED WIRE CAPACITY	60W Max
HEATED WIRE SUPPLY	22 +/-3 VAC
OVERCURRENT PROTECTION	230V/1.5A Fuse
PRODUCT SPECIFICATIONS	
MAXIMUM LIMITED (INSPIRATORY) PRESSURE (PLIM)	45cmH_2O
MAXIMUM START-UP TIME	≤ 30 minutes (Starting temperature 23±2°C)
DIMENSIONS	W135mm x D170mm x H156mm (without chamber fitted)
WEIGHT	2.9 kg (without chamber fitted)
DISPLAY	5.6" Touch Screen TFT LCD
RANGE	5.0°C to 80.0°C
ACCURACY	±0.5°C between 25 to 45°C
HEATER PLATE THERMAL CUTOUT	115±3°C
HUMIDITY OUTPUT	Invasive ≥ 33mg/l Non-invasive ≥ 12mg/l
FLOW RATE	Max 60 lpm
ALARM SPECIFICATIONS	
ALARM SOUND PRESSURE LEVEL	>50 dBA at 1m.
HIGH PRIORITY ALARM	Red visual indication and a High priority alarm.
MEDIUM PRIORITY ALARM	Yellow visual indication and a Medium priority alarm.
AUDITORY ALARM SIGNALS	High Priority - triple beep, pause, double beep Medium Priority - triple beep

NOTES:
FL-10000 does not have any applied parts. It is intended to be connected with type BF heated wire breathing circuit.
Maximum flow rate is dependant on selected mode and temperature settings.

Product Specifications

OPERATING, TRANSPORT AND STORAGE ENVIRONMENT			
	OPERATING	**TRANSPORT**	**STORAGE**
TEMPERATURE	18 to 26˚C (64.4 to 78.8˚F)	-10 to 50˚C (14 to 122˚F)	-10 to 50˚C (14 to 122˚F)
RELATIVE HUMIDITY	30 to 95%	30 to 95%	30 to 95%
ATMOSPHERIC PRESSURE	50kPa to 106kPa	50kPa to 106kPa	50kPa to 106kPa

TEMPERATURE RANGE	
AMBIENT AIR TEMPERATURE RECOMMENDED RANGE	18-26°C

TEMPERATURE CONTROL:			
	MODE	**SET POINT (AIRWAY)**	**SET POINT (CHAMBER)**
HEATED WIRE CIRCUIT	INVASIVE	Default 40°C Custom 38-40°C	Default 37°C Custom 36-37°C
HEATED WIRE CIRCUIT	NON-INVASIVE	Default 34°C Custom 31-35°C	Default 31°C Custom 31-35°C
NON-HEATED WIRE CIRCUIT	INVASIVE (DUAL LIMB)	Default 37°C Custom 36-38°C	
NON-HEATED WIRE CIRCUIT	NON-INVASIVE (DUAL LIMB)	Default 31°C Custom 31-35°C	
NON-HEATED WIRE CIRCUIT	INVASIVE (SINGLE LIMB)	Default 40°C Custom 36-40°C	
NON-HEATED WIRE CIRCUIT	NON-INVASIVE (SINGLE LIMB)	Default 34°C Custom 31-35°C	

NOTE:
Heated Wire Circuits are for both dual and single heated limbs.

Ordering Codes

Ordering code suffix denotes plug and power setting appropriate to the country of intended use.
All accessories are compatible with the FL10000 and patient breathing circuit.

FL10000	FL-10000 Respiratory Humidifier 230V with 3 pin plug	1
FL10000INDIA	FL-10000 Respiratory Humidifier with India plug	1
FL10000THA	FL-10000 Respiratory Humidifier with Thailand plug	1
FL10000CL	FL-10000 Respiratory Humidifier with Chile plug	1
FL10000CH	FL-10000 Respiratory Humidifier with China plug	1
FL10000 AUS	FL-10000 Respiratory Humidifier with 3 pin Australia plug	1
FL10000EU	FL-10000 Respiratory Humidifier 230V with 2 pin plug	1

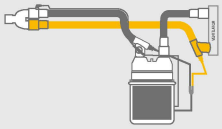
Accessories

FL10000-01	Single Heated Wire Humidifier Adapter Lead	1
FL10000-02	Dual Heated Wire Humidifier Adapter Lead	1
FL10000-03	Temperature Probe Lead (1.5m)	1
FL9000-04	Single Use Temperature Probe Lead (1.5m)	20
FL9000-04STR	Single Use Temperature Probe Lead (1.5m) - Sterile	20
FL2000-01	Mounting Accessory - Pole Clamp (30-50mm)	1
FL2000-02	Mounting Accessory - C-Clamp (19-40mm)	1
FL2000-03	Mounting Accessory - Wall Bracket	1
FL2000-04	Mounting Accessory - Rail Bracket	1
FL2000-05	Mounting Accessory - Offset Rail Bracket	1

Standards Compliance

ELECTRICAL SAFETY	EMC
IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012	IEC 60601-1-2:2014, EN 60601-1-2:2015 CISPR 11, IEC 61000-3-2:2005 A1:2008 A2:2009, IEC 61000-3-3:2013 IEC 61000-4-2:2008, IEC 61000-4-3:2006 A1:2007 A2:2010 IEC 61000-4-4:2012, IEC 61000-4-5:2005 IEC 61000-4-6:2013, IEC 61000-4-8:2009, IEC 61000-4-11:2004

Alarm Parameters

ALARM CATEGORY	INDICATOR		ALARM	PRIORITY
TEMPERATURE		AIRWAY	Temp too high	High
			Temp too low	High
		CHAMBER	Temp too high	High
			Temp too low	Medium
		HEATER PLATE	Temp too high	Medium
			Temp too low	Medium
I/O DETECT		TEMPERATURE PROBE CABLE	Not connected	High
		HEATED WIRE	Not connected	Medium
LIMB DETECT		EXPIRATORY HEATED WIRE	Incorrect Limb Setup	Medium
POWER OFF	N/A	POWER OFF	Not connected	Medium
ERROR SCREEN	ERROR 1	HEATED WIRE SHORT	ERROR 1	High
	ERROR 2	TEMPERATURE SENSOR OF HEATED PLATE OPEN /SHORT	ERROR 2	High
	ERROR 3	INTERNAL COMMUNICATION FAULT	ERROR 3	High
	ERROR 4	HEATER PLATE EXCEEDED TEMPERATURE LIMIT	ERROR 4	High
	ERROR 5	AIRWAY EXCEEDED TEMPERATURE LIMIT	ERROR 5	High

NOTES:
Please refer to the Troubleshooting guide if alarms are raised.
If the set temperatures are no reached within 30 minutes, the device will alarm.

Introduction

Intended Use

The Flexicare FL-10000 Respiratory Humidifier is designed to warm water stored in a Humidification Chamber which adds heat and humidity to respiratory gases delivered to patients who require invasive or non-invasive ventilation via artificial airway or non-invasive interface. For use by trained personnel in a hospital environment only. It can be operated with either Flexicare heated wire breathing systems or non-heated breathing systems, and is suitable for any patient requiring active humidification.

Heated Wire Application

The fresh gas absorbs moisture and is warmed as it passes over the heated water in the humidification chamber and travels through the circuit. The temperature is monitored by the temperature probe at the chamber outlet and automatically adjusts the power to the heater plate. The chamber outlet temperature is automatically set to 37ºC in Invasive mode and 31ºC in Non-Invasive mode, with the actual temperature of the delivered gas displayed on the touch-screen display.

To avoid cooling of the respiratory gas and prevent condensation in the inspiratory limb, a second temperature probe is located at the patient end connector. This monitors the temperature of the gas received by the patient and automatically adjusts the power to the heated wire located in the circuit tubing. The patient end temperature is automatically set to 40ºC in Invasive mode and 34ºC in Non-Invasive mode.

Non-Heated Wire Application

The fresh gas absorbs moisture and is warmed as it passes over the heated water in the humidification chamber. The temperature is monitored by the temperature probe at the airway outlet and automatically adjusts the power to the heater plate. The airway temperature is automatically set to 37ºC in Invasive mode and 31ºC in Non-Invasive mode, with the actual temperature of the delivered gas displayed on the touch-screen display.

However, as the humidified gas cools as it travels along the unheated inspiratory limb condensation (“rain-out”) will form. A water trap must be included in the inspiratory limb to collect the rain-out.

Warnings

- Do not use breathing circuits, humidification chambers and other accessories which are not approved by Flexicare as it may result in sub-optimal performance and place the patient at risk.
- Do not add any attachments or accessories to the humidifier that are not listed in the instructions for the use of the humidifier or accessory or the humidifier might not function correctly affecting the quality of the therapy or injuring the patient.
- Ensure the invasive mode is selected for patients with by-passed airways.
- Ensure that temperature probe sensors are properly fitted. Incorrect fitting may result in the patient receiving excessively high temperature gas.
- Always position the humidifier lower than the head of the patient.
- High frequency, shortwave or microwave emissions may affect the function of the humidifier. If this occurs, move the humidifier away from the source of such emissions.
- Always disconnect from the power supply before servicing.
- Inspect the humidifier and all accessories for any deficiencies or damage prior to each use.
- Do not use as part of patient monitoring or life support systems. The patients supervision must be maintained properly and continuously by a clinician.
- Accessory equipment connected to the analogue and digital interfaces must be in compliance with the respective nationality harmonised IEC standards (i.e. IEC 60950 for data processing equipment, IEC 60065 for video equipment, IEC 61010-1 for laboratory equipment, and IEC 60601-1 for medical equipment.) Furthermore all configurations shall comply with the systems standard IEC 60601-1-1. Anyone who connects additional equipment to the signal input part or signal output part is configuring a medical system, and is therefore, responsible that the system complies with the requirements of the system standard IEC 60601-1-1. The unit is for exclusive interconnection with IEC 60601-1 certified equipment in the patient environment. If in doubt, consult the technical services department or your local representative.
- Do not modify this equipment without authorization from the manufacturer. HAZARDS can result from the unauthorised modification to the medical electrical equipment.
- Consistently monitor the water level in the humidification chamber to maintain adequate volume and avoid overheating.
- Plug used to isolate the Medical Equipment from the Mains Supply. Do not position the Medical Equipment so that it makes it difficult for the operator to isolate or disconnect the equipment from the Mains Supply.
- The device does not have a backup power supply. If power fails to device, there will be no alarms or indicators of this failure.
- The device does not have overfill water level alarms or indicators for the humidification chamber.
- Do not use the humidifier at an altitude or temperature above or below the rated range. Using the humidifier outside of the temperature and/or altitude range can affect the quality of the therapy or injure the patient.
- To prevent disconnection of the tubing or tubing system during use, especially during ambulatory use, only tubes in compliance with ISO 5367 or ISO 80601-2-74 should be used.

- Covering breathing tubes 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.
- Ensure the mains supply connection is accessible during use. This is to allow the operator to easily isolate the equipment from the mains supply when required.
- Use default temperature settings to ensure optimum performance.
- Ensure the device is operated within the manufacturers specified Temperature and Altitude operating conditions.
- Ensure the water used in the humidification chamber is sterile. Using non-sterile water may have an adverse effects on the patient.
- Maladjustment and Intolerance are contraindications only.
- To maintain the safety, reliability and performance of this equipment it must be operated, maintained and repaired according to the manuals and instructions supplied.
- FL-10000 must be serviced, calibrated and repaired by a qualified service technician.
- FL-10000 must be properly earthed through connection to a “hospital grade” power cord. Always disconnect from supply before servicing.
- For use only by a qualified medical practitioner familiar with the use of the humidifier.

Cautions
- Use suitable mounting apparatus to avoid risk of injury.
- Unauthorised modification of the equipment may impair humidifier performance.
- Refer to the chamber and/or breathing circuit IFU's for gas leakage at the maximum rated pressure.

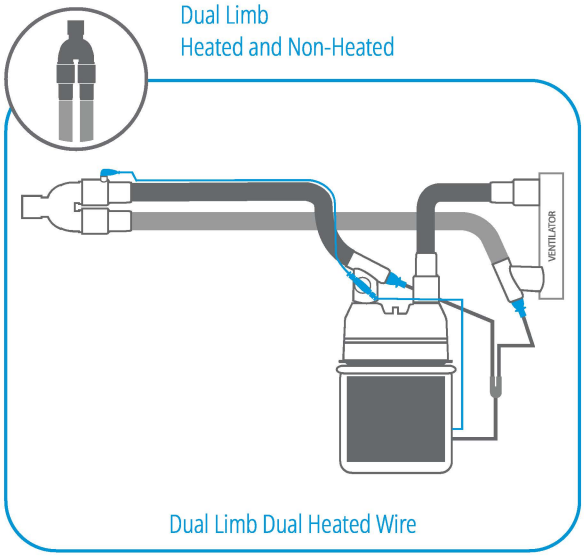
Contraindications
- No specific contraindications are declared. However, the user should be familiar with, and trained in the use and care of the product.

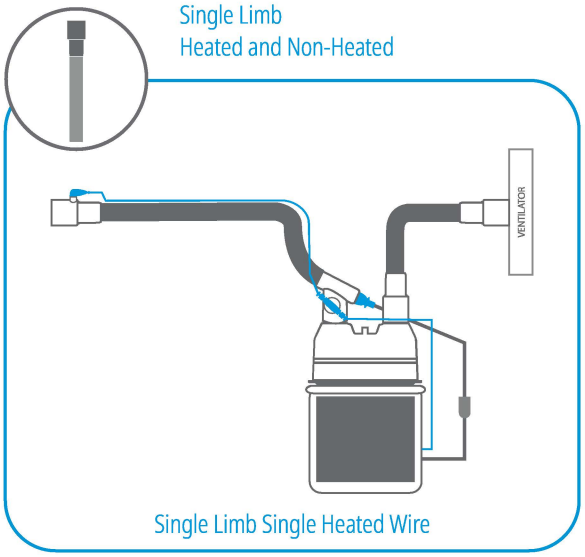
Clinical Benefits
- Heated humidification is recommended for patients receiving respiratory therapy support to preserve normal airway function, improve mucociliary clearance, reduce work of breathing and help improve patient outcomes.

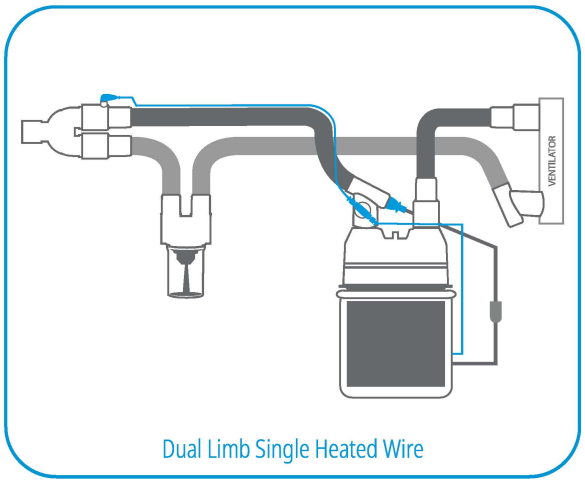
Any serious incident that occurs in relation to the device should be reported to the manufacturer and the competent authority of the Member State of the user and/or patient.

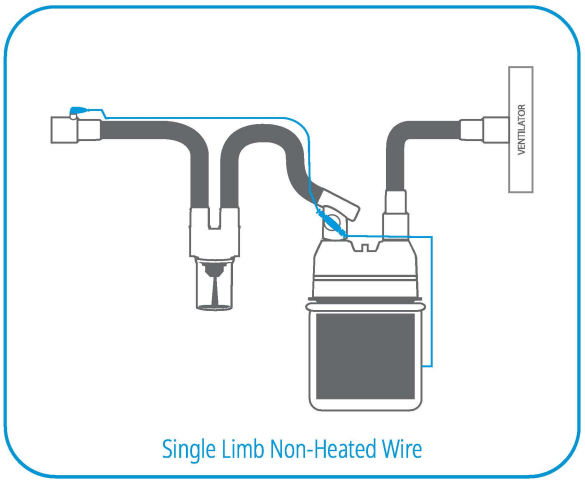
Circuit Types

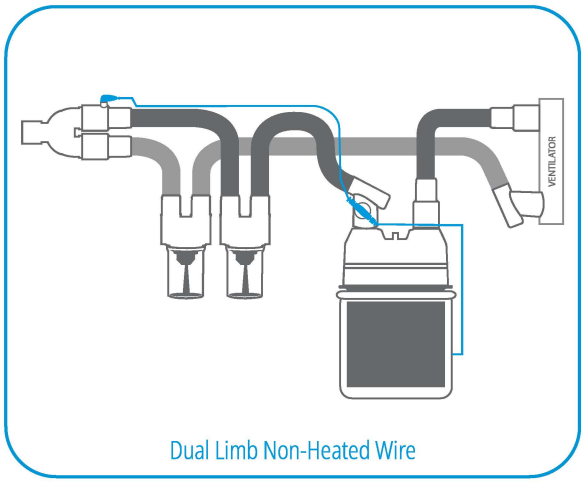
Choose the breathing system setup that matches how the patient is connected to the ventilator or respiratory device. When prompted, press the Left or Right arrows and then confirm your selection.





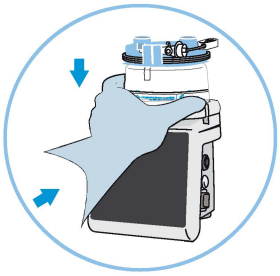






Humidifier Setup

The FL-10000 Respiratory Humidifier does not have any applied parts and is intended to be connected with Type BF breathing tubes.

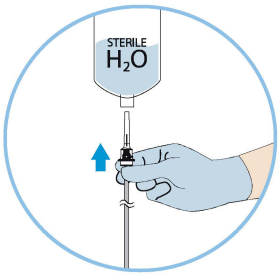


Mount the FL-10000 Respiratory Humidifier to the appropriate stand using the rear mount and/or mounting accessory (sold separately).
NOTE: When mounting a humidifier always ensure that the humidifier is positioned lower than the patient.

Select a suitable Flexicare humidification chamber. (Refer to chamber/circuit information and instructions).

NOTE: Check that the chamber base and heater plate are undamaged, clean and dry.

Press down the spring-loaded guard at the front of the heater plate and slide the humidification chamber on to the plate. Once located, the guard will automatically lock the chamber in place. Ensure the chamber is secure and level.



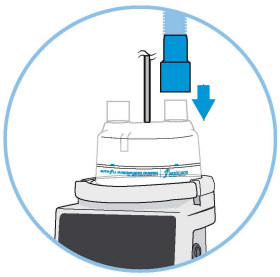
Unwind the delivery set and attach to the sterile water bag or bottle using the vented spike. The pinch clamp should be closed.

- If using an auto-fill chamber, connect the sterile water supply to the chamber.
- If using a manual chamber, fill with sterile water to the maximum water level line.

NOTE: Only use sterile water with the Humidifier. Adding additional substances can have an adverse effect. e.g. a nebulizer located between the ventilator and the gas inlet port.



Remove the protective cover from the humidification chamber and discard.
NOTE: Check the the chamber is clear from damage (dents etc) before use.



Attach the blue ventilator limb to one chamber port and to the ventilator.



Connect the inspiratory limb to the other port of the chamber.

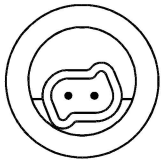
Note: Either chamber port can be used as the inspiratory or ventilator connection, i.e. the gas flow through the chamber can be in either direction.

To remove the chamber, press down on the front guard and pull the chamber forward. Take care to avoid contact with the hot chamber base and heater plate.

Humidifier Setup

Heated and Non-Heated Wire Circuit Setup

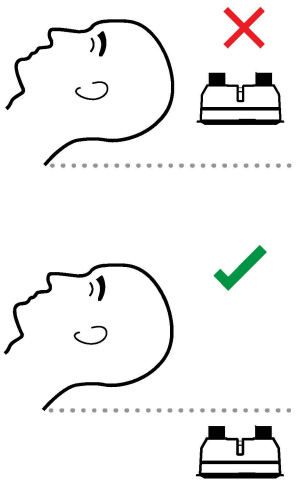
1. Connect the fresh gas supply limb to one port of the chamber.
2. Connect the inspiratory limb of the circuit to the other port of the chamber.
3. If using a Heated Wire Breathing System connect the heated wire adapter lead to the heater base unit, ensuring the arrows are pointing upwards.
   a. Single Heated Wire Breathing System – plug the heated wire adapter into the inspiratory limb (clover leaf) connector port.
   b. Dual Heated Wire Breathing System - plug the heated wire adapter into the inspiratory limb (clover leaf) connector and expiratory limb (S-shape) connector ports.
4. Connect the temperature probe lead to the heater base unit to the labeled port.
5. Insert the Chamber outlet temperature probe sensor into the sensor port on the circuit. Push in firmly to ensure the tip of the sensor is in the center of the gas flow.
6. Insert the Airway temperature probe sensor into the port at the patient end of the inspiratory limb. Push in firmly to ensure the tip of the sensor is in the center of the gas flow.
7. The humidifier is now ready for use.



S-shape Connector
(Expiratory Limb)



Clover Leaf Connector
(Inspiratory Limb)



WARNING:

- When mounting a humidifier always ensure that the humidifier is positioned lower than the patient.
- Use suitable mounting apparatus to avoid risk of injury.
- DO NOT fill the chamber above the maximum fill level line as liquid could enter the breathing circuit if the chamber is overfilled.
- DO NOT fill the chamber with water in excess of 37°C.
- Ensure that both temperature probe sensors are correctly and securely fitted. Failure to do so may result in temperatures in excess of 41°C being delivered to the patient.
- To avoid risk of electric shock, this equipment must only be connected to a mains supply with protective ground.
- Ensure the water used with the Humidifier is sterile. Other substances can have adverse effects.
- Perform a leakage test using the ventilators Short Shelf Test (SST) to ensure the probes are fitted correctly.
- Ensure to use manufacturers temperature probe cable. Using non-compatible temperature probes may introduce a risk to the patient.

Humidifier Operation

1. Connect the humidifier power lead to the approved power supply, ensuring it matches the ratings label on the unit.
2. Check the humidification chamber, breathing circuit and all cables are correctly installed and connected (See Humidifier Setup).
3. Switch on the ventilator and carry out flow and pressure checks in line with the ventilator manufacturer's instructions.
4. Switch on the FL-10000 humidifier, soon the Flexicare logo and software version number will be displayed.
5. Press the arrow button to start. The Intended Use, Contraindications and Instructions For Use screen will display for 3 seconds.
6. Follow the on-screen Patient Setup instructions (see page 13) to select and confirm your setup.

Language Setup

The first time that FL-10000 is used, or after a Factory Reset, you will be prompted to select a language. Select your preferred language press the Tick button to confirm your selection.

You can change your Language by using the Settings Menu.

WARNING:

- In case of an Alarm, immediately switch off the humidifier and disconnect from the patient unless the cause is indentified and rectified, or assessed to be of no hazard to the patient.
- Incorrect insertion of the Airway temperature probe into the patient end of the inspiratory circuit may cause the gas temperature delivered to the patient to exceed 41°C.
- DO NOT touch the heater plate or other accessible metal surfaces as surface temperatures may exceed 85°C.
- Always check the gas supply is flowing through the humidifier before connecting to the patient.
- DO NOT use a heated breathing circuit in the presence of flammable anaesthetics.
- Verify with gas manufacturer that degradation of anaesthetic agents will not occur.
- DO NOT fill the chamber past the maximum level mark and regularly monitor the water in the chamber or supply source.
- Consistently monitor the water level in the humidification chamber to maintain adequate volume and avoid overheating.
- The saturation of gas at the Chamber output may exceed 44 mg/L if operating temperatures greater than 37°C are selected.
- Electric shock hazard – DO NOT remove cover. Should a fault occur, refer to a qualified service technician.
- High frequency, shortwave or microwave emissions may affect the function of the humidifier. If this occurs, move the humidifier away from the source of such emissions.
- Turn off the Humidifier if the gas flow or chamber is removed.

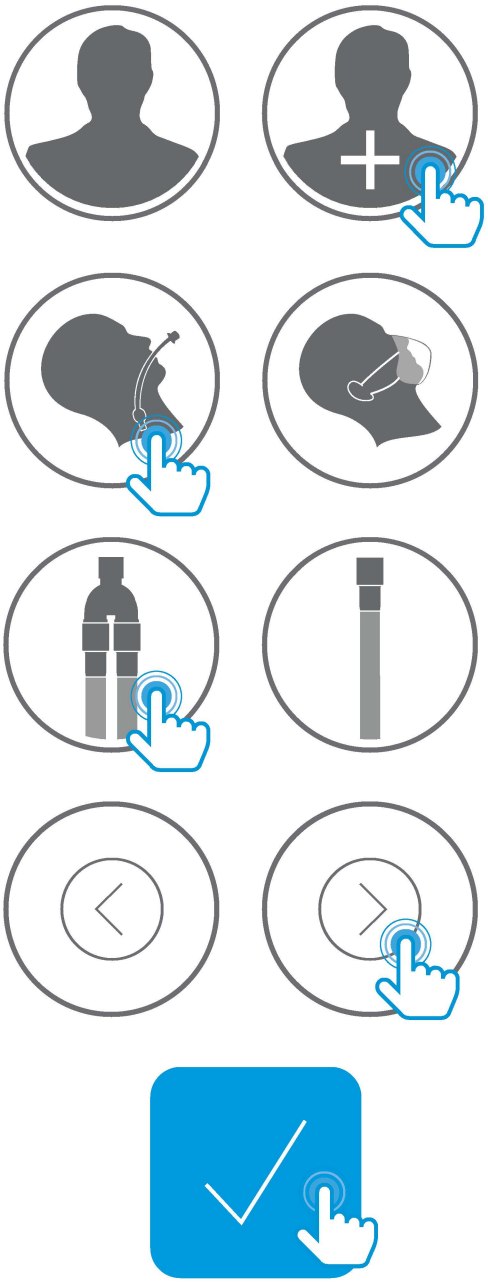
Pressure Regulated Ventilators: With some pressure regulated ventilators, disconnection and reconnection of the inspiratory limb or disconnection of the expiratory limb may result in high temperatures reaching the patient. It is recommended that the humidifier is switched off 5 minutes before disconnection.

- DO NOT cover the Airway temperature probe with any bedding or locate inside an incubator.

Humidifier Operation

Patient Setup

Once the circuit and chamber have been installed according to the instructions, the FL-10000 is ready to be set up.
At any stage, you can return to the previous screen by pressing the Back button in the top left corner of the screen.



1. If you have turned off FL-10000 and want to resume your last used settings, press the Same Patient Same Setting icon.

To begin a new session, press New Patient New Setting to choose new settings.

Your selection will appear flash blue once pressed.

2. Select your therapy type by pressing either the Invasive or Non-Invasive mode icon.

3. Select either a Dual Limb or Single Limb circuit setup.

4. On the Confirm Setup screen, press the left or right arrows to select the mode that matches your circuit type that you have connected to the FL-10000 Respiratory Humidifier and Ventilator.

The full list of available selections are:
- Dual Limb Dual Heated Wire
- Dual Limb Single Heated Wire
- Dual Limb Non-Heated Wire
- Single Limb Single Heated Wire
- Single Limb Non-Heated Wire

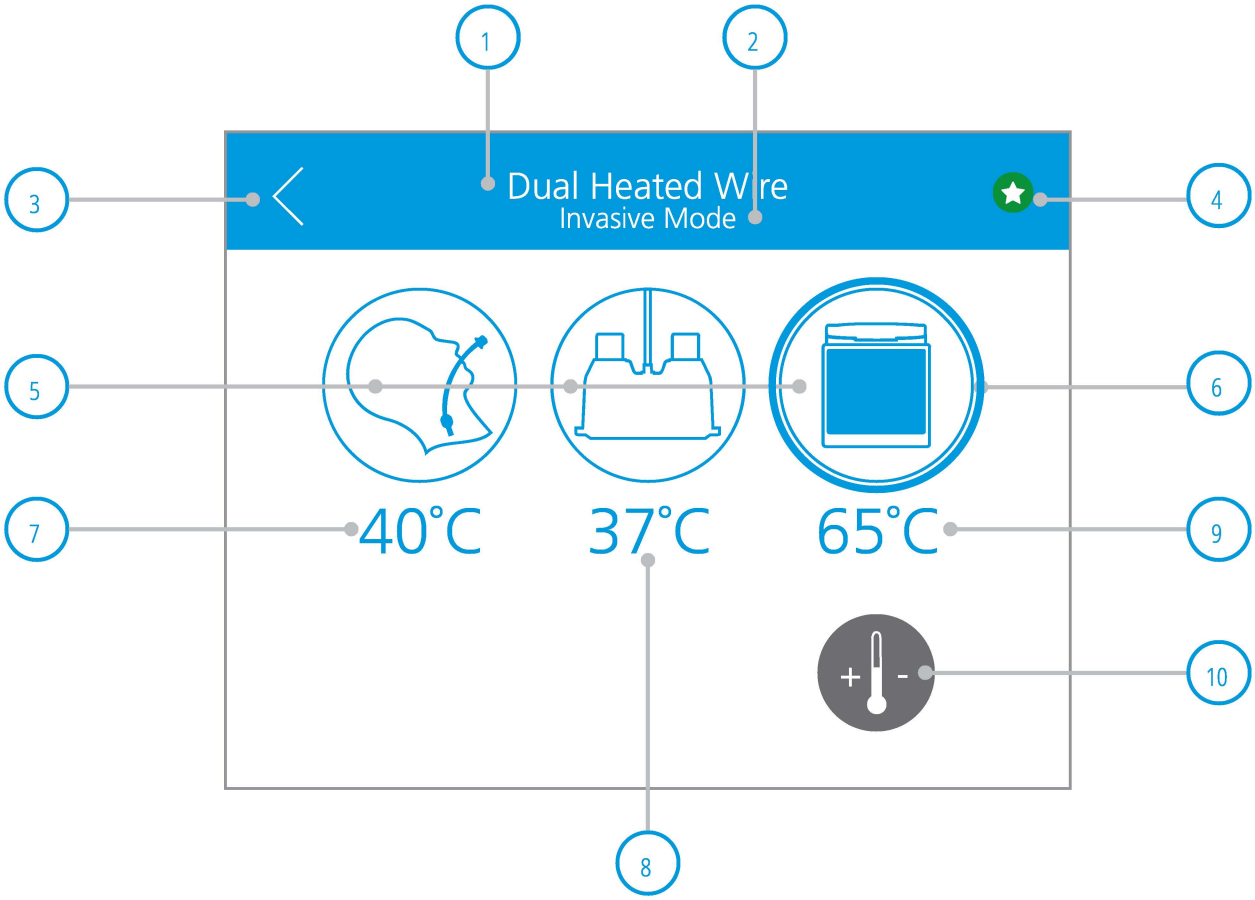
5. Confirm your selection with the Check Mark button in the top right hand corner of the screen.

FL-10000 will then start up in the Live Screen with your chosen selection and begin warming up.

Live Screen

Once the mode has been selected, FL-10000 will display live temperature readings and give the user chance to adjust settings, display alarm notifications or return to previous menus.

Screen will vary depending on the mode selected.



Key

1. Selected Circuit Configuration
2. Patient Mode Indicator
3. Back to Previous Screen
4. Default Temperature Settings Indicator
5. Set Parameter Settings Button (see page 16)
6. Heater Plate On Indicator
7. Current Airway Temperature
8. Current Chamber Temperature
9. Current Heater Plate Temperature
10. Custom Temperature Settings Menu (see page 16-17)

Default and Custom Setting Indicators

FL-10000 will automatically use the default temperatures for Airway, Chamber and Heater Plate. The defaults can be customised in the Advanced Custom Temperature Settings Menu.

Resume Custom Settings

For convenience, if the FL-10000 is switched off, then the user can resume their custom settings next time the Heater is switched on and select **Same Patient Same Setting** during startup.



Default Settings Indicator

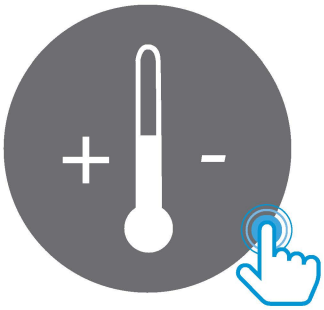


Custom Settings Indicator

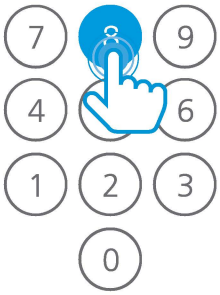
Custom Temperature Settings

The Default Airway or Chamber Temperatures can be changed manually after the setup has been completed.
To prevent misuse, the Settings Menu is protected by a four-digit passcode.

Note:
Chamber Temperature can only be changed when in Heated Wire Mode and a Heated Wire Breathing Circuit is connected to the Humidification Chamber.



1. From the Live Screen, press the Settings button.



2. Type in your passcode: 8888.



3. Press the Go button.
If you make a mistake, press the clear button and start again.

Incorrect Passcode

If you enter an incorrect passcode, then Incorrect Passcode text will appear and the top bar will turn to red.
The area where you typed in the passcode will automatically clear, so simply repeat steps 1-3 above.

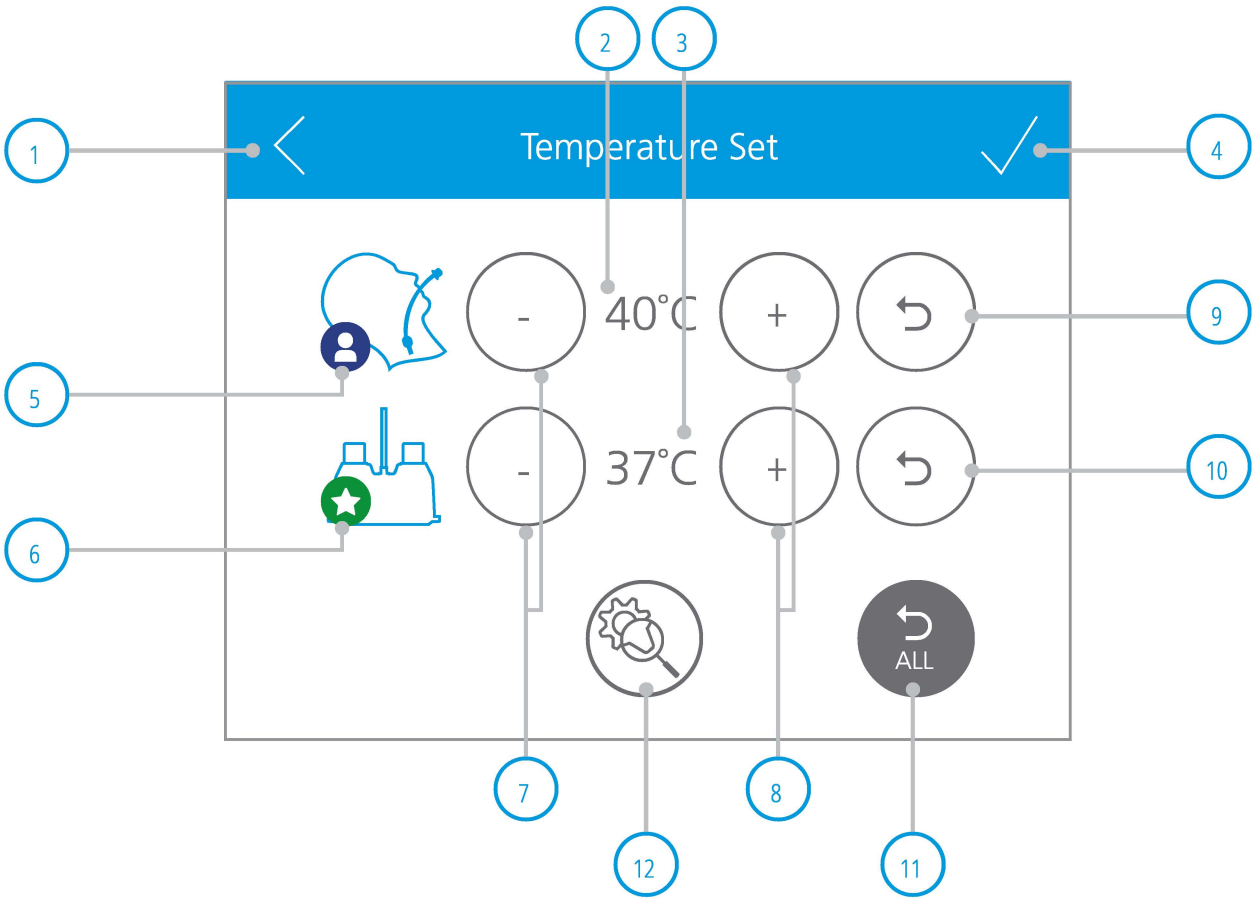
If you do not have your passcode, contact local distributor or Flexicare.

If you do not wish to continue to the Settings menu, Use the Back button to return to the Live Screen.

Temperature Set Menu

In the Temperature Set Menu, the user is able to customise the defaults for Airway or Chamber temperatures, or restore to default settings.

The menu is password protected. For more information, see page 15.
Screen will vary depending on the mode selected.



Key

1. Back to Previous Screen
2. Airway Temperature Setting
3. Chamber Temperature Setting
4. Confirm Selection
5. Custom Temperature Settings Indicator
6. Default Temperature Settings Indicator
7. Decrease Temperature
8. Increase Temperature
9. Return to Default Airway Temperature Setting
10. Return to Default Chamber Temperature Setting
11. Return to Default Airway and Chamber Temperature Settings
12. Settings Menu

Changing Temperature



Simply press the + or - buttons to increase or decrease the temperature to desired setting.



Press the Default button to automatically restore individual temperatures to factory settings.



Press the Default All button to restore all of the temperatures to factory settings.



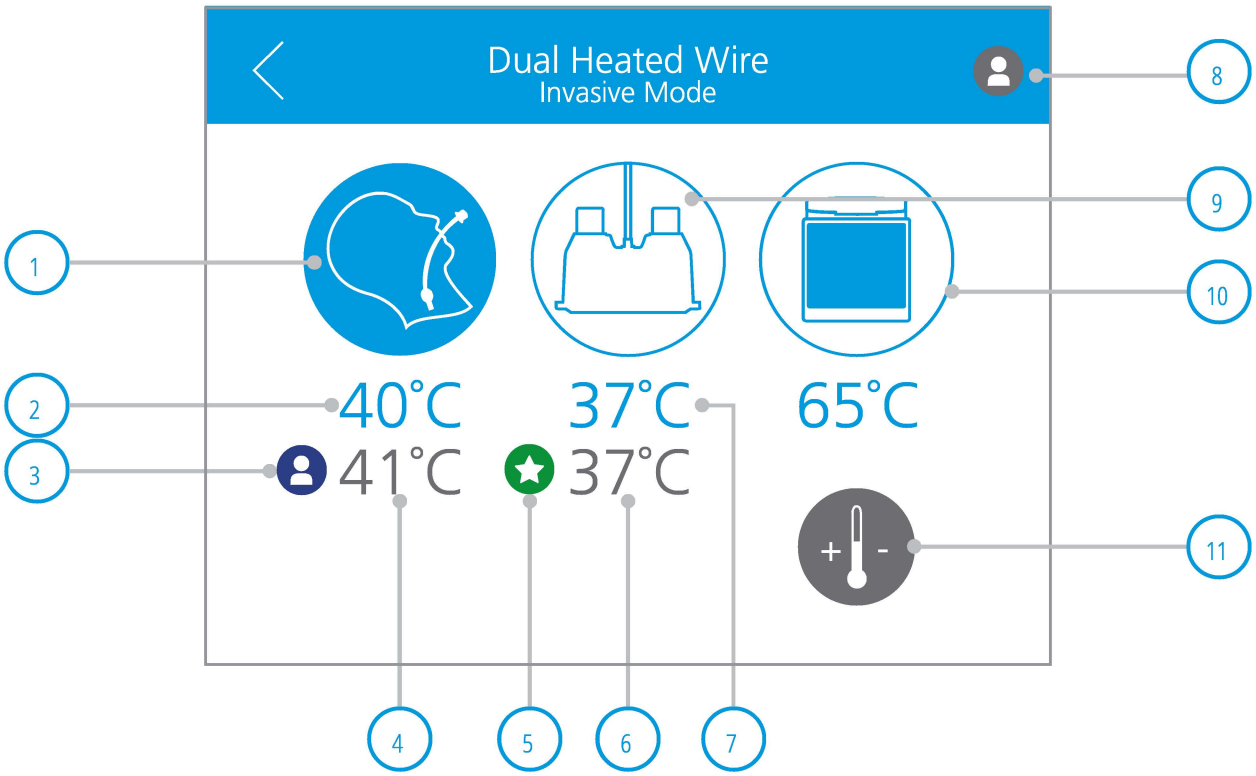
Press Confirm to return to the Live Screen with these Settings.

Check Settings

FL-10000 can allow users to compare the default, or custom settings to the current live temperature readings.

To activate the preview, simply press one of the Airway, Chamber or Heater buttons. The current settings will be displayed for 5 seconds underneath the live temperature readings.

Screen will vary depending on the mode selected.



Key

1. Airway Button (Selected)
2. Current Airway Temperature
3. Custom Temperature Setting Indicator
4. Set Airway Temperature
5. Default Setting Indicator
6. Set Chamber Temperature
7. Current Chamber Temperature
8. Custom Setting Indicator
9. Chamber Button
10. Heater Button
11. Custom Temperature Settings Menu (see page 15-16)

Example

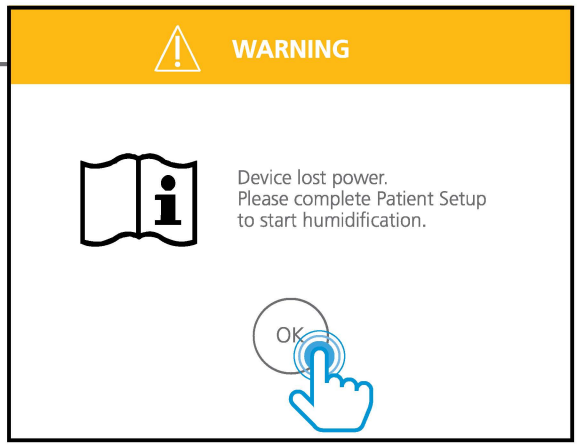
In the example illustrated above, the user has changed the default Airway temperature to 41˚C, but the current Airway temperature is at 40˚C. The Custom Setting indicator shows that this has been manually changed by the user.

Meanwhile, the Chamber temperature is still at the default 37˚C. This setting has not been changed by the user, so Default Setting Indicator is displayed.

Power Cycle Detection

If the FL-10000 has been switched on and detects that the heater plate is above 30˚C, this warning screen is displayed.

Press the OK button and follow the on-screen Patient Setup instructions (see page 13) to select and confirm your setup.

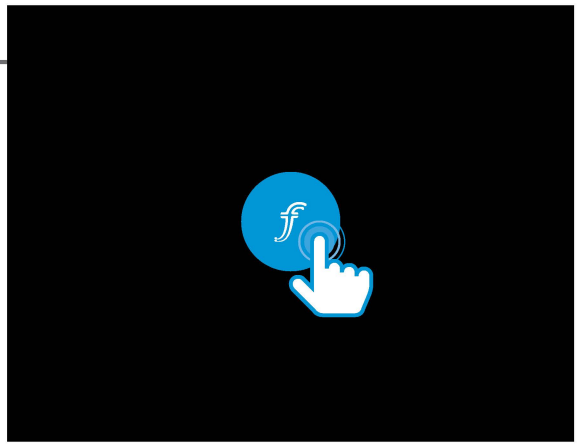


Screen Saver

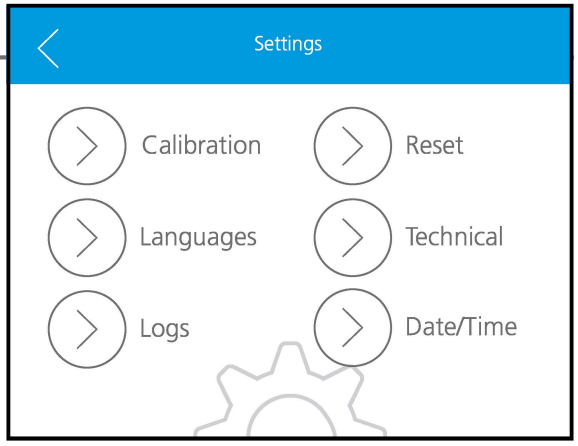
The FL-10000 will go into Screen Saver mode if no operations are made for a 5 minute period.

The Screen Saver mode's purpose is to help dim any background light during the night.

To return back to operation mode, touch the blue button. Any alarms will automatically override this screen.



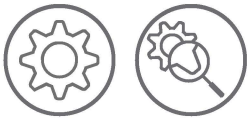
Settings Menu



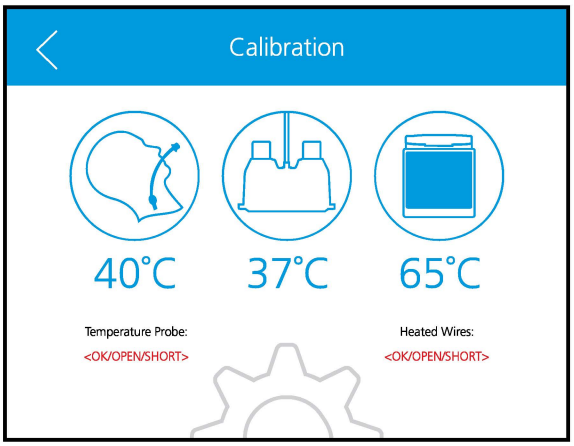
The Settings menu allows for further customization of the FL-10000. Please note, this area is for advanced users only and is protected by the device passcode.

The user can access the Settings menu by one of two methods:

1. Once the FL-10000 is switched on, press the Settings Menu button on the first screen.
2. From the Live Screen, touch the Temperature Settings button (see page 14), enter your passcode and then touch the Settings Button.



Calibration



The Calibration menu can be used to display the temperature of the probes and heater plate. It also shows the connection status of the temperature probes and heated wire cables.

Temperature Probes

Use the Calibration menu to check Temperature Probes along with this screen to ensure Temperature Probes are within manufacturer's specifications.

Heater Plate

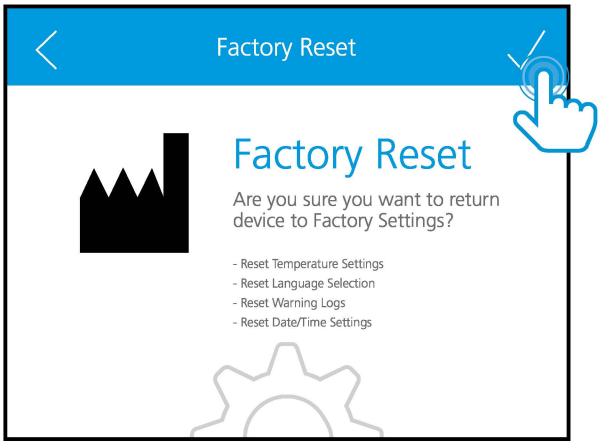
With the Calibration menu active, the temperature of the heater plate will be held at 40°C. This can be monitored with an external temperature probe.

Temperature Probe and Heated Wires

This screen can also be used for fault diagnostics. Temperature Probe and Heated Wire status is displayed at the bottom of the screen. The status is either:

OK	Connection has been confirmed and defined as suitable for use.
OPEN	No Probe or Heated Wire has been connected or there is a fault with the connected cable.
SHORT	The connected cable is faulty. This may also indicate an internal fault if no cable is connected.

Reset



Use this function to reset the FL-10000U to factory settings. After a factory reset, the Temperature and Language Settings will be returned to default. Upon first use after reset, the user will be prompted to re-select a language.

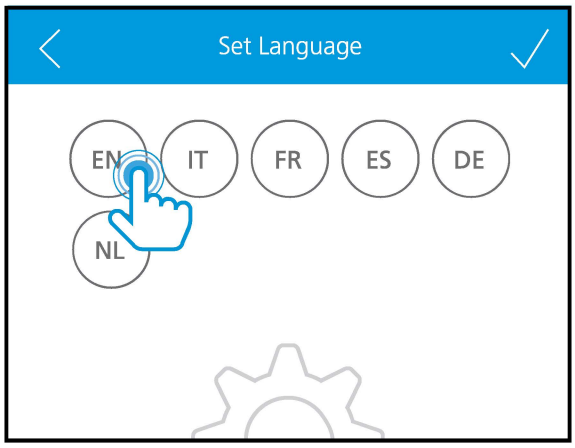
Touch the Tick button to start the Factory Reset.
To cancel, press the Back button.

Language

FL-10000 can be setup to display different languages. This can either be configured during first setup, after a factory reset or at any time by using the language menu item in the Settings menu.

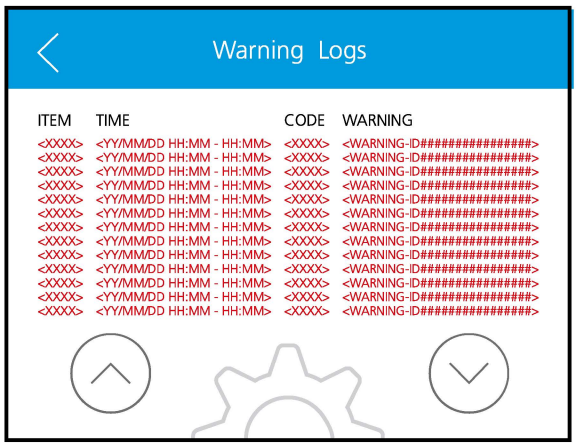
Select your language, then confirm by touching the Tick button.
To return to the previous screen, touch the Back button.

Languages available include English, Italian, French, Spanish, German, and Dutch.



Warning Logs

FL-10000 will keep a log of errors for diagnostic purposes.
Scroll up or down using the arrow buttons.
Press Back to return to the previous screen.

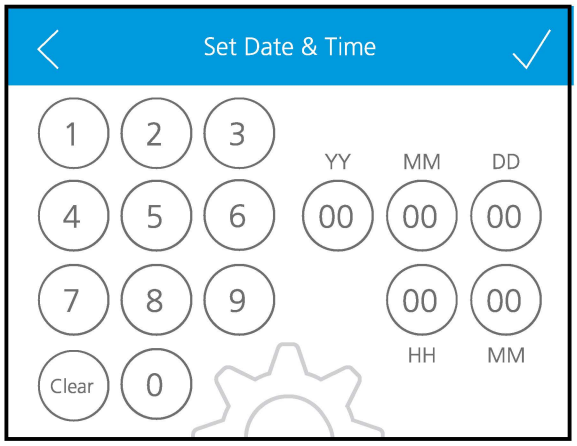


Set Date/Time

FL-10000 requires a date and time entry to allow the warning log to store errors correctly.

Press one of the YY / MM / DD / HH / MM buttons and then press Clear. Then, input the numbers using the keypad.
The time should be input as a 24hr clock.

Once complete, press the Confirm button.
Press Back to return to the previous screen.



Technical

This section is for use only by technicians. Please refer to separate Technical Manual.

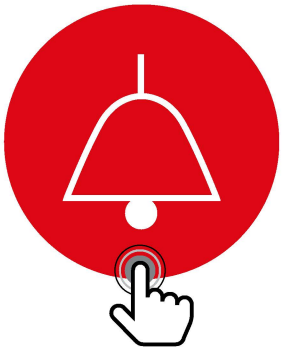
Alarm Notifications and Safety Features

FL-10000 is programmed to alert the user with audible and visual alarms with clear indications of any issue it detects to help users diagnose and correct problems before they impact on patient care. FL-10000 distinguishes HIGH (red) and MEDIUM (yellow) priority alarms which are visually and audibly recognizable.

During Alarm Notifications, the corresponding icon will turn red or yellow and text will appear on the Live Screen underneath the current temperatures. The alarm will automatically disappear once the issue has been resolved. The Settings menu will also be available to make any necessary adjustments.

NOTE: Alarm system will not function when power source is not connected or interrupted.
Alarm dBm value is over 50dBm at a distance of 1 meter.

WARNING:
- During Alarm Mute, ensure to monitor the patient closely based on the current clinical status. The user must pay close attention to the patient when using the alarm mute function. Muting the alarm may provide potential risk to the patient.





Alarm Muted
1:59

Mute Button

When an Alarm Notification appears on screen, a Mute button will also be visible in the lower left corner of the screen.
Press once to silence an audible alarm for 2 minutes. A countdown timer will begin on screen.

In the case of multiple alarms sounding simultaneously, the Mute button will need to be pressed for each individual alarm. Text will cycle between each issue.

When an issue has been resolved, the countdown will automatically stop and the icons and text will return their normal colours. If an error remains unresolved, the audible alarm and red colour will return until resolved or muted.

Mute button is to be used according to the patients actual condition. The user must pay close attention to the patient when using the mute button.

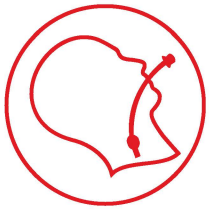
Alarm Notifications and Safety Features



Airway Temperature High

Heated Wire:
If the manually set temperature is 41°C or above, or if Airway Temperature exceeds 42°C.

Non-Heated Wire:
If Airway Temperature exceeds 41°C.



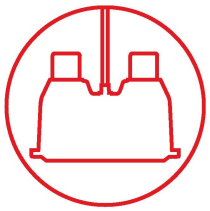
Airway Temperature Low

Heated Wire:
If Airway Temperature remains at or below 29.5°C for 10 minutes, or at/below 34.5°C for 60 minutes.

If the Airway Temperature remains below 34.5°C for 25 seconds after warming up.

Non-Heated Wire:
If Airway Temperature remains at or below 29.5°C for 10 minutes in Invasive mode.

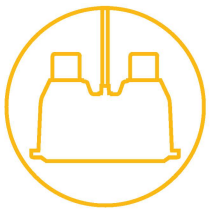
If Airway Temperature remains at or below 26°C for 10 minutes in Non-Invasive mode.



Chamber Temperature High

Heated Wire:
If Chamber Temperature exceeds 41°C.

Non-Heated Wire:
If Chamber Temperature exceeds 66°C.



Chamber Temperature Low

Heated Wire:
If Chamber Temperature remains below 26°C for 10 minutes.

Non-Heated Wire:
If Chamber Temperature remains below 26°C for 10 minutes.



Heater Plate Temperature High

Heated Wire:
If Heater Plate Temperature exceeds 105°C for 30 seconds.

Non-Heated Wire:
If Heater Plate Temperature exceeds 112°C.



Heater Plate Temperature Low

Heated Wire:
If Heater Plate Temperature remains below 30°C.

Non-Heated Wire:
If Heater Plate Temperature remains below 30°C.

NOTE: Airway and Chamber alarms will occur if the temperatures exceed ±2°C from the set temperature.

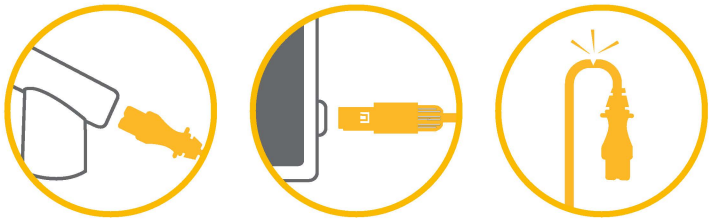
Alarm Notifications and Safety Features

Some Alarm Notifications require immediate action by the user. In these cases, the relevant Alarm Notification will override the Live Screen until the issue can be resolved.



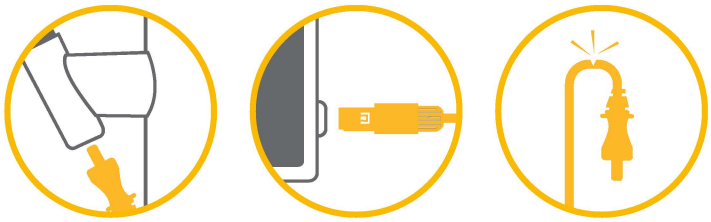
Temperature Probe Lead

Red warning message will flash with audible alarm if the Airway Temperature Probe is not connected, loose or faulty.



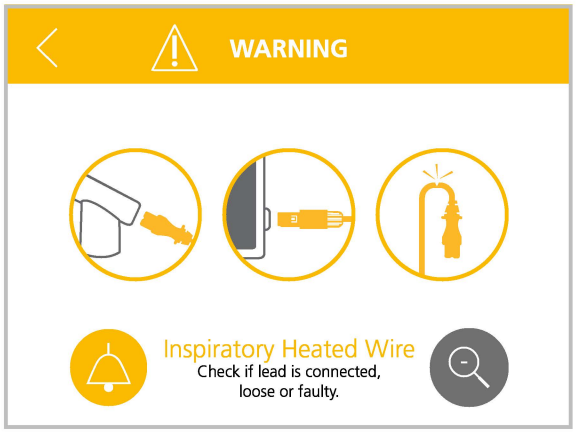
Inspiratory Heated Wire Lead

Yellow warning message will flash with audible alarm if the Inspiratory Heated Wire is not connected, loose or faulty.

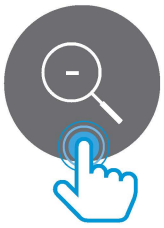


Expiratory Heated Wire Lead

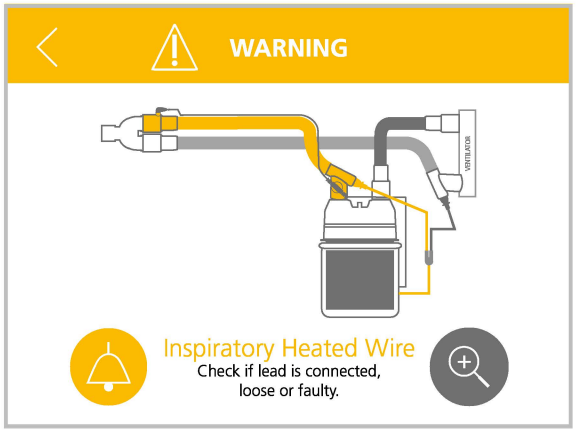
Yellow warning message will flash with audible alarm if the Expiratory Heated Wire is not connected, loose or faulty.

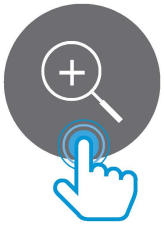


Zoom



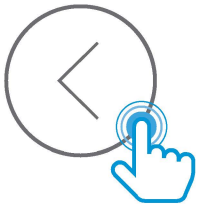
To help the user diagnose the problem faster, press the Zoom button. There will be an alternative display which will show the selected circuit setup with the lead highlighted in red (or yellow if alarm has been muted).





Once in the Circuit View, press the Zoom button again to return to the icons.

Alarm Notifications and Safety Features



During an Alarm Notification, the user can press the Back button at any stage to go back to the Setup process.

No Alarm Notifications will begin until the user has confirmed their Circuit Selection and entered the Live Screen for the first time.

WARNING:

If a user presses Back to go to the Set Up process, any alarms will cease and audible alarm will be silenced. The patient should remain connected to the FL-10000 respiratory humidifier. If a new selection is not confirmed, the Airway, Chamber and Heater Plate temperatures could still be too high or too low for optimal patient care.

Overheat Protection

If the FL-10000 heater plate temperature exceeds 115±3°C, a thermostat cuts the power to the humidifier. Remove the FL-10000 humidifier from the patient and replace with a new humidifier.

Resetting the overheat protector should only be carried out by a qualified service technician.

Critical Error Codes

A red warning Error 1, Error 2, Error 3, Error 4, or Error 5 message appears and audible alarm indicates a serious fault. Immediately disconnect unit from the patient and replace with a new humidifier. Contact your local distributor or Flexicare Medical Limited for servicing or repair.

Cleaning & Routine Maintenance

Cleaning

Always disconnect from electrical power supply before cleaning to avoid risk of shock.
Wipe the surface with a soft "lint-free" damp cloth, 70% Ethanol, or an Isopropyl Alcohol wipe.

Routine Maintenance / Monthly Checks

- Regularly check the humidifier for physical damage, wear and contamination.
- Check all humidifier leads for damage. Replace as necessary.
- Check the heater plate for deep scratches, pitting or other damage. Replace as necessary.
- Check the temperature probe for damage to sensor tips, abrasion of the lead or tarnishing of electrical contacts. Replace if necessary.
- Probes should be cleaned with an alcohol wipe.
- The heated plate may be cleaned by using a soft cloth.
- Connect a probe and heated wire assembly into the heater base, switch on and check that the humidifier conducts the self-test. Check for correct display of ambient temperature and that no alarms are immediately activated.
- It is recommended that the unit is serviced every 12 months.
- The power cord is not removable. If the power cord is damaged or needs replacing, please contact the equipment manufacturer.



CAUTION

- Disconnect the FL10000 from mains voltage before undertaking any cleaning or maintenence.
- DO NOT use liquid antiseptic, abrasives or sharp instruments to clean the surface.
- The use of cleaning solutions which are not recommended by Flexicare may result in damage to the device and/or accessories.
- DO NOT immerse the Humidifier.

Calibration Check of Reusable Temperature Probes

Reusable Temperature probes should be checked every 12 months to ensure they are operating within manufacturer's specifications.

Accessories or Test Equipment Required

- Calibrated thermometer
- Container of water (32-40°C)

The following Calibration Check procedure should be carried out by a technician:

1. Place a mercury thermometer and the patient end of the probe into a container of water at between 32°C and 40°C.
2. Turn on the humidifier and go to the calibration in the setting menu. When the temperature of the probe and thermometer have stabilised, compare the temperature displayed to the reading on the thermometer.
3. Replace the probe if the reading differs from the thermometer reading by more than ± 0.5°C.
4. Conduct routine maintenance to ensure continued safe usage.

Disposal Guidelines

When the equipment and/or the accessories are not serviceable, they must be disposed of in accordance with the relevant local laws and regulations or hospital rules and regulations.

Alarm System Check
The alarm system should be checked every 12 months to ensure they are operating within the manufacturers specifications.
The following Alarm Check procedure should be carried out by a technician;

Connection Status (Configuration Menu)
1. Enter the Settings menu (Passcode required)
2. Enter Calibration
3. Connect the Temperature and heated wire leads.
   - Connect the heated wire leads to a dual heated wire circuit
4. The Calibration screen shows the status of the Temperature Probe and Heated wires.
   - Status should be OK for both
5. Remove the temperature probe and confirm the status text changes from OK to OPEN.
   - OPEN identifies an open circuit / not connected
6. Remove the Inspiratory limb connection and wait a few seconds for the OK status to change to OPEN.
7. Replace the Inspiratory limb heated wire connector and repeat steps 6 for the Expiratory limb.

Audible Alarms (Operational Alarms)
Accessories or Test Equipment Required:
- Calibrated thermometer
- Container of water (>45°C)
- Container of water (<21°C)

1. Set up the FL-10000 with a ventilator for an invasive circuit, dual heated wire circuit with the Temperature Probes and both Heated Wires connected
   - Allow the FL-10000 temperatures to stabilise (Approximately 15 to 30 minutes)
2. Use the following table to test the alarm functions for temperature and missing leads.

	ALARM TEST	METHOD	CHAMBER (°C)	AIRWAY (°C)	WARNING
1	Inspiratory Limb	Remove the Connector from limb position	n/a	n/a	Inspiratory Heated Wire
2	Expiratory Limb		n/a	n/a	Expiratory Heated Wire
3	Heated Wire Lead missing	Remove the heated wire lead from the FL-10000			Multiple Heated Wire Warning
3	Chamber Temperature Low	Remove the temperature probe from the Chamber/ Airway position and place in cold or warm water. Depending on alarm condition being tested.	<26		Chamber
4	Airway Temperature Low			<34.5	Airway
5	Chamber Temperature High		>41		Chamber
6	Airway Temperature High			>41	Airway
7	Temperature Probe Missing	Remove the temperature probe lead from the FL-10000	n/a	n/a	Temperature Probe Lead

NOTE: For tests 3-6, water temperature must be above or below the alarm activation temperature

Servicing and Maintenance
A servicing manual will be made available to service personnel only. The servicing manual contains, circuit diagrams, parts list, repair instructions and extended calibration routines. Contact your local sales representative for information.

Troubleshooting Guide

Low Temperature

PROBLEM	POSSIBLE CAUSE	CORRECTIVE ACTION
LOW TEMPERATURE READING ON HUMIDIFIER DISPLAY, NO ALARM.	Humidifier warming up.	Allow time to achieve correct operating temperature.
	Temperature probe not secured in position.	Check temperature probe is securely fitted into sensor port and tip is in center of gas flow.
AIRWAY TEMPERATURE LOW ALARM ACTIVATED.	Gas flow stopped or interrupted.	Turn off humidifier until gas flow restored.
	Temperature probe not located in probe housing.	Securely fit temperature probe into sensor port.
	Gas flow rate too low.	Increase gas flow to over 5 liters per minute.
	Circuit fault	Check power connection to circuit and replace cable or circuit if faulty.
	Humidifier fault	Complete above checks first and replace/ service the Humidifier if required.
CHAMBER TEMPERATURE LOW ALARM ACTIVATED.	Poor thermal contact between base of humidification chamber and heater plate.	Check chamber base and heater plate are clean, smooth and flat and in good contact. If necessary clean or replace.
	Temperature probe not located in probe housing.	Securely fit temperature probe into sensor port.
	Gas flow rate too high for chamber	Use suitable chamber. Refer to chamber operating instructions.
	Heater element needs replacing.	Replace with new unit and send humidifier for repair.

High Temperature

PROBLEM	POSSIBLE CAUSE	CORRECTIVE ACTION
AIRWAY TEMPERATURE HIGH ALARM ACTIVATED.	Sudden spurious increase in gas flow.	Allow time for temperature to fall below threshold.
	Faulty Airway sensor on temperature probe (low resistance).	Check temperature probe and replace if necessary.
CHAMBER TEMPERATURE HIGH ALARM ACTIVATED.	No water in chamber.	Refill manual humidification chamber, or check water supply flow for Auto-Fill chamber.
	Faulty Airway sensor on temperature probe (low resistance). Can also be caused by sudden reduced gas flow.	Check temperature probe and replace if necessary.
	Humidifier fault	Complete above checks first and replace/ service the Humidifier if required.

Troubleshooting Guide

Fluctuating Temperature

PROBLEM	POSSIBLE CAUSE	CORRECTIVE ACTION
HIGH AND LOW TEMPERATURE ALARMS.	Ventilation rate too low or too erratic for proper humidifier temperature control.	Ventilation rates below about 6 bpm or of highly erratic nature may affect the stability of the temperature control.
	Humidifier temperature control influenced by external heating or cooling, eg air conditioning or nearby fan.	Shield breathing circuit from external influence.
	Temperature probes incorrectly or insecurely located.	Securely fit temperature probes into sensor ports.
	Faulty temperature probe (Could be intermittent short or open circuit)	Check probe, including manipulation to pick up any intermittent fault.
	Water in the chamber is low.	Check chamber and water bag level.

Excessive Water in Circuit

PROBLEM	POSSIBLE CAUSE	CORRECTIVE ACTION
EXCESSIVE RAIN-OUT IN INSPIRATORY LIMB.	Non-heated wire mode: water trap not at the lowest point of the circuit.	Reposition water trap.
	Heated wire mode: heater wire too close to temperature probe.	Ensure distance from heated wire to temperature probe is between 25mm and 100mm, ideally ≈30mm.
	Inspiratory limb being cooled, eg by air conditioning or nearby fan.	Shield circuit from cold air flow or use heated wire circuit.
	Chamber Temperature control set too high.	Reduce setting.
	Maximum permissible peak flow rate of humidification chamber has been exceeded.	Use suitable chamber. Refer to chamber operating instructions.
	Humidifier chamber tilted.	Ensure Chamber is horizontal.
	Faulty temperature probe (low resistance).	Check temperature probe and, if necessary, replace.
EXCESSIVE RAIN-OUT IN EXPIRATORY LIMB.	Expiratory limb being cooled, eg by air conditioning or nearby fan.	Shield circuit from cold air flow or use heated wire circuit.
	Non-heated wire mode: water trap not at the lowest point of the limb.	Reposition water trap.
WATER PASSING FROM HUMIDIFICATION CHAMBER INTO CIRCUIT.	Humidification chamber filled above maximum level.	Reduce water level.
	Flow rate above maximum permissible level of humidification chamber.	Use suitable chamber. Refer to chamber operating instructions.
	Humidifier chamber tilted.	Use suitable chamber. Refer to chamber operating instructions.

Troubleshooting Guide

Low Humidity

PROBLEM	POSSIBLE CAUSE	CORRECTIVE ACTION
LOW HUMIDITY.	Chamber control set too low.	Increase setting.
	No water in humidification chamber.	Refill manual humidification chamber, or check water supply flow for Auto-Fill chamber.
	Chamber temperature low.	Check chamber temperature is at correct setting. Check chamber base and heater plate are clean, smooth and flat and in good contact. If necessary clean or replace.
	Gas flow rate too high for chamber.	Use suitable chamber. Refer to chamber operating instructions

Temperature Display

PROBLEM	POSSIBLE CAUSE	CORRECTIVE ACTION
NO TEMPERATURE DISPLAY, NO ALARM LIGHTS.	Internal fuse blown.	Send unit for repair.
	Transformer overheat protector activated.	Send unit for repair.
NO TEMPERATURE DISPLAY, 'SEE MANUAL' INDICATOR LIGHT ON.	Control PCB fault.	Send unit for repair.

Breathing Circuit Leak

PROBLEM	POSSIBLE CAUSE	CORRECTIVE ACTION
BREATHING CIRCUIT LEAK.	Faulty circuit connections.	Check all circuit connections.
	Sterile water bag not connected.	Check bag connected and water flowing.
	Temperature probes incorrectly fitted.	Securely fit temperature probes into sensor ports.

External Water Leak

PROBLEM	POSSIBLE CAUSE	CORRECTIVE ACTION
WATER LEAK WITH REUSABLE CHAMBER.	Chamber O-ring faulty.	Check O-ring is clean and properly fitted. Replace if damaged.
WATER LEAK WITH DISPOSABLE CHAMBER.	Chamber used beyond lifespan or seal is faulty.	Replace with new chamber.

Troubleshooting Guide

Real Time Clock

PROBLEM	POSSIBLE CAUSE	CORRECTIVE ACTION
WRONG TIME	Time not set or incorrectly setup	Set the time through Date/Time in the settings menu
	Internal Real Time Clock (RTC) battery needs replacement (CR1220 – 3V – Lithium Battery)	Change the RTC battery. Refer to Technical Manual

Warnings

PROBLEM	POSSIBLE CAUSE	CORRECTIVE ACTION
WARNING TEMPERATURE PROBE LEAD	Temperature probe lead unplugged .	Check the connection.
	The connector of temperature probe dirty or loose.	Clean or re-insert connector.
	The Temperature probe cable is faulty.	Replace the Temperature probe cable.
WARNING AIRWAY TEMPERATURE LOW	Airway Temperature lead unplugged.	Check the connection.
	Airway temperature lead dirty or loose.	Clean or re-insert connector.
	The Temperature probe cable is faulty (sensor open).	Replace the Temperature probe cable.
WARNING AIRWAY TEMPERATURE HIGH	Airway Temperature lead unplugged.	Check the connection.
	Airway temperature lead dirty or loose.	Clean or re-insert connector.
	The Temperature probe cable is faulty (sensor short).	Replace the Temperature probe cable.
WARNING CHAMBER TEMPERATURE LOW	Chamber Temperature lead unplugged.	Check the connection.
	Chamber temperature lead dirty or loose.	Clean or re-insert connector.
	The Temperature probe cable is faulty (sensor open).	Replace the Temperature probe cable.
WARNING CHAMBER TEMPERATURE HIGH	Chamber Temperature lead unplugged.	Check the connection.
	Chamber temperature lead dirty or loose.	Clean or re-insert connector.
	The Temperature probe cable is faulty (sensor short).	Replace the Temperature probe cable.
WARNING CHAMBER TEMPERATURE LOW / AIRWAY TEMPERATURE LOW	Temperature probe cable is faulty (use non original cable or short of sensor).	Replace the Temperature probe cable.
WARNING CHAMBER TEMPERATURE HIGH / AIRWAY TEMPERATURE HIGH	Temperature probe cable is faulty (use non original cable or open of sensor).	Replace the Temperature probe cable.
WARNING INSPIRATORY HEATED WIRE	Connector of heated wire unplugged.	Check the connection.
	Connector of heated wire loose.	Re-insert connector.
	Heated wire is faulty (heated wire open).	Replace the heated wire or the adapter cable.
WARNING EXPIRATORY HEATED WIRE	Connector of heated wire unplugged.	Check the connection.
	Connector of heated wire loose.	Re-insert connector.
	Heated wire is faulty (heated wire open).	Replace the heated wire or the adapter cable.
WARNING ERROR 1	Heated wire short.	Replace heated wire limb.
		Replace Heated connection cable.
WARNING ERROR 2	Temperature sensor of heated plate open /short.	Return the unit to manufacturer for repair.
	Internal fuse of heat wire open (blown).	Send the unit to repair.
WARNING ERROR 3	Internal communication fault between the Humidifier PCB and the User Interface (Screen).	Send the unit for repair.
WARNING ERROR 4	Heater Plate has exceeded Temperature Limit.	Disconnect unit from the patient and consult instructions for use.
WARNING ERROR 5	Airway Temperature has exceeded Temperature Limit	Disconnect unit from the patient and consult instructions for use.

Warranty Statement for FL-10000 Respiratory Humidifier

Flexicare Medical Limited warrants that the Product you have purchased meets the labeled specifications of the Product and will be free from defects in materials and workmanship that occur within one (1) year from the date of purchase. Accessories used with the Product are warranted for ninety (90) days after the date of purchase.

The date of purchase is the date specified in our records.

This warranty does not cover damage caused by:
1) Handling during shipping
2) Use or maintenance contrary to labeling and instructions,
3) Alteration or repair by anyone not authorised by Flexicare Medical Limited
4) Accidents

If a Product or accessory covered by this warranty is determined to be defective because of defective materials, components, or workmanship, and the warranty claim is made within the warranty period described above, Flexicare Medical Limited will, at its discretion, repair or replace the defective Product or accessory free of charge.

You must obtain written return authorization from Flexicare Medical Limited to return your Product prior to sending it at your cost to Flexicare Medical Limited's designated agent.

This warranty is in lieu of all other warranties, express or implied, including but not limited to the implied warranties of merchantability and fitness for a particular purpose. Flexicare Medical Limited's obligation under this warranty is limited to repair or replacement of products containing a defect. Flexicare Medical Limited is not responsible for any indirect or consequential damages resulting from a product defect covered by the warranty.

This Warranty shall be governed by and construed in accordance with accordance with Flexicare Medical Limited's Terms and Conditions.

APPENDIX

Electromagnetic Compatibility Table

ELECTROMAGNETIC EMISSIONS		
FL-10000 is intended for use in the electromagnetic environment specified below. The user should ensure that the intended environment is suitable.		
Emissions test	**Compliance**	**Electromagnetic Environment Guidance**
RF emissions CISPR 11	Group 1	FL-10000 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	FL-10000 is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

RECOMMENDED SEPARATION DISTANCES BETWEEN FL-10000 AND PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT			
FL-10000 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the FL-10000 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and the FL-10000 as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 KHZ TO 80 MHZ $d = 1.2\sqrt{P}$	**80 MHZ TO 800 MHZ** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.8	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applied to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) given by the 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.			

Electromagnetic Compatibility Table Guide

ELECTROMAGNETIC IMMUNITY			
FL-10000 is intended for use in the electromagnetic environment specified below. The user should ensure that the intended environment is suitable.			
Immunity Test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic Environment Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % UT (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If continued operation during power mains interruptions is required, it is recommended that power from an uninterruptible power supply or a battery is used.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at typical levels for a commercial or hospital environment.
NOTE U_T is the AC mains voltage prior to application of the test level.			

ELECTROMAGNETIC IMMUNITY

FL-10000 is intended for use in the electromagnetic environment specified below. The user should ensure that the intended environment is suitable.

Immunity	IEC 60601 Test level	Compliance level	Electromagnetic Environment Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF transmitting equipment should be no closer to any part of the FL-10000 (including leads) than the recommended separation distance calculated from the equation applied to the frequency of the transmitter. Recommended separation distance (d) in meters (m): $d = 1.2\sqrt{P}$ 150 kHz to 80 MHz $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) given by the manufacturer, and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[1], should be less than the compliance level in each frequency range[2]. Interference may occur in the vicinity of equipment marked with the symbol on the left.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	

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.

[1] Field strengths from fixed transmitters, such as base stations for cellular/cordless telephones, mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast equipment, cannot be predicted theoretically with accuracy. To accurately assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey is required. If the measured field strength in the location in which the FL-10000 is used exceeds the applied RF compliance level above, it should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orientating or relocating the FL-10000.

[2] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Electromagnetic Compatibility (EMC) – Additional Notes

The ability of FL-10000 to operate in an environment containing other electrical/electronic equipment (including other medical devices) was independently tested to ensure the FL-10000 is unlikely to adversely affect the normal operation of other such equipment, and that other such equipment is unlikely to adversely affect the normal operation of the FL-10000.

Despite the testing undertaken, normal operation of the FL-10000 may be affected by some other electrical/electronic equipment, and some portable and mobile RF communications equipment. Therefore, as the FL-10000 is medical equipment, special precautions are needed regarding EMC (Electromagnetic Compatibility).

It is important that the FL-10000 is configured, installed, connected and used in accordance with the instructions and guidance provided.

Use of adapter and temperature probe leads other than those supplied may result in increased emissions or decreased immunity of the FL-10000 in relation to EMC performance.

The adapter and temperature probe leads provided with the FL-10000 should not be used on other equipment. To do so may result in increased emissions or decreased immunity of the other equipment in relation to EMC performance.

If the FL-10000 is used adjacent or stacked with other equipment, the FL-10000 and the other equipment should be observed and monitored to verify normal operation in the configuration in which it will be used.

Revision History

VERSION NUMBER	REVISION DATE	DESCRIPTION
VERSION 1	MAY 2022	First Release

flexicare®
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