F&P 950

F&P 950™ Respiratory Humidifier

USER INSTRUCTIONS

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Fisher&Paykel HEALTHCARE

Contents

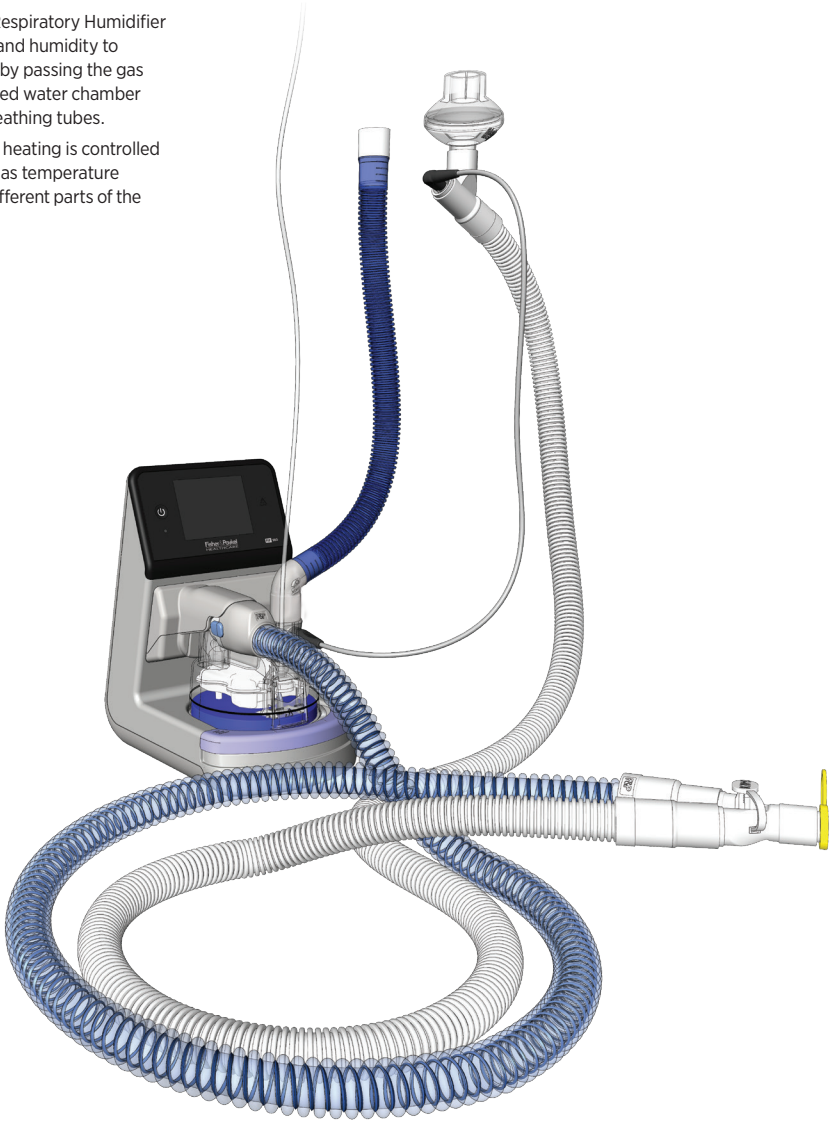
Indications for use

The F&P 950 Respiratory Humidifier is intended to provide heat and humidity to respiratory gases delivered to patients.

Operating principle

The F&P 950 Respiratory Humidifier provides heat and humidity to medical gases by passing the gas through a heated water chamber and heated breathing tubes.

The amount of heating is controlled based on the gas temperature measured at different parts of the humidifier.

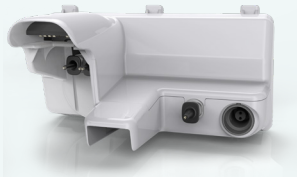


Package contents

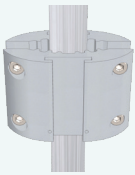
F&P 950 Heaterbase
(e.g. 950ANZ)

Power cord
(e.g. 950XPI)

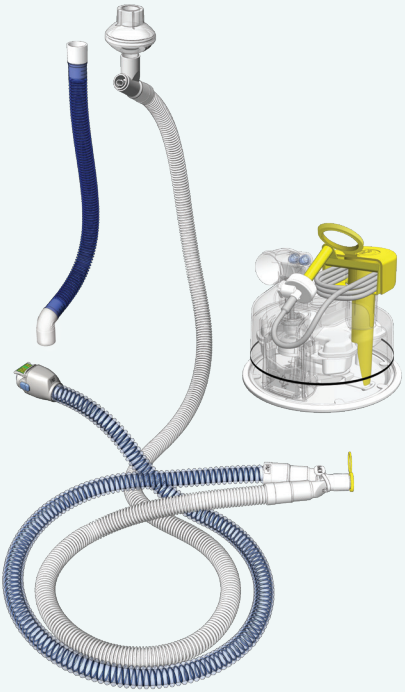
Accessories to complete the F&P 950 Respiratory Humidifier



F&P 950 Sensor Cartridge
(e.g. 950S02)



Equipment mount
(e.g. 900MR030)

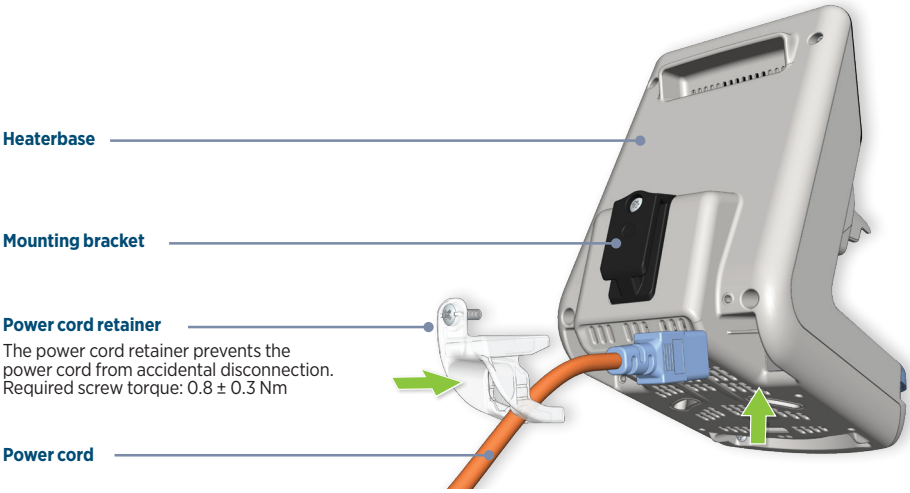


F&P 950 Breathing Circuit Kit
(e.g. 950A81, 950N80)

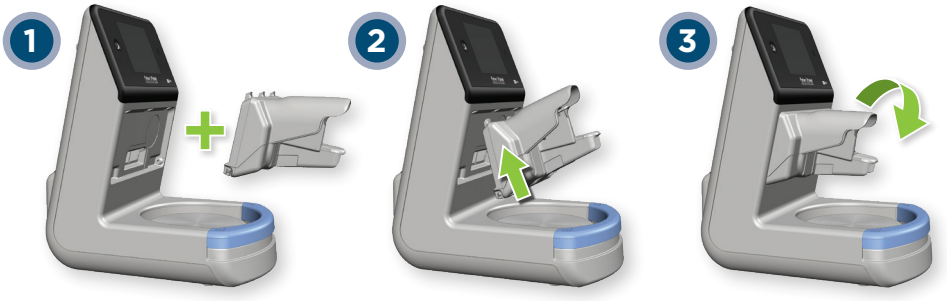
F&P 950 Expiratory Heater Wire Adapter
(e.g. 950X00)

F&P 950 Respiratory Humidifier setup

Attach the power cord and power cord retainer to the heaterbase.



Attach the sensor cartridge to the heaterbase.



WARNING

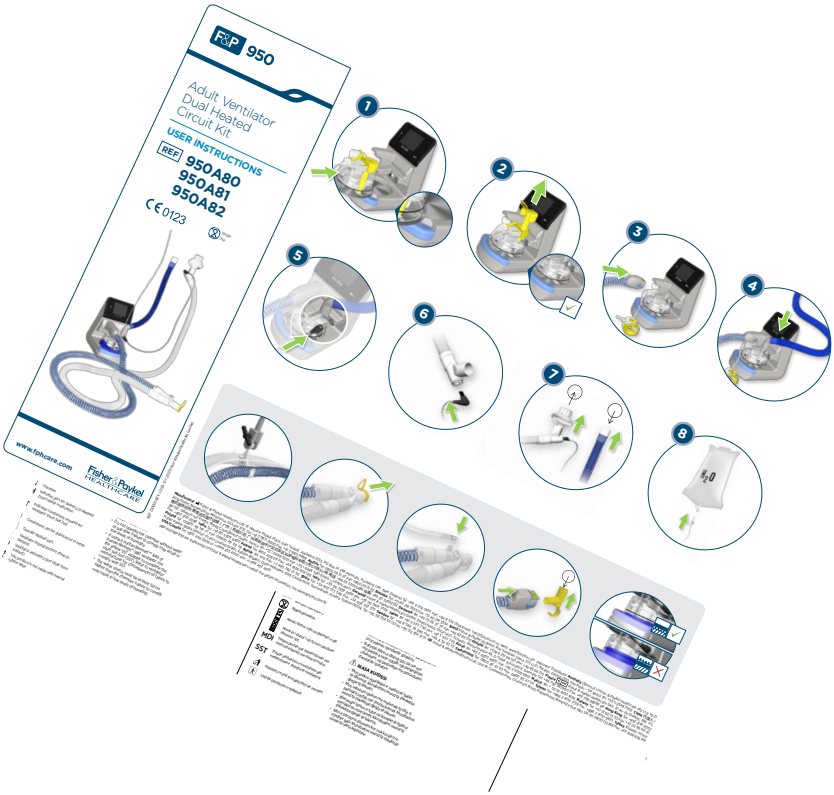
When mounting the heaterbase on equipment, check the manufacturer's user instructions to ensure the equipment is capable of remaining stable whilst supporting 4 kg.
Failure to comply may result in damage to the equipment mount and heaterbase, and potentially cause serious patient harm.

NOTES

- Ensure the heaterbase does not block access to the power supply outlet.
- Update the heaterbase software to Rev J (6.0.10) or later before attaching the 950S02 Sensor Cartridge.

F&P 950 Respiratory Humidifier setup

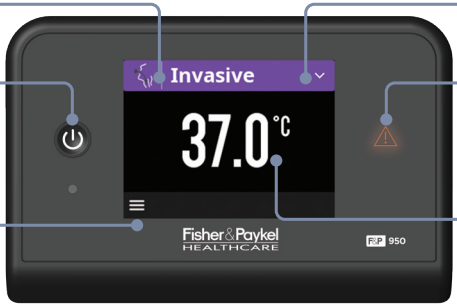
The range of F&P 950 breathing circuit kits each come with a set of customized user instructions containing specific setup instructions and warnings.



When turning on the humidifier, an audible single beep sound should be heard.

User interface

Screen navigation



Mode banner
Displays current mode.

Standby button
Turn standby on/off. Disconnect from power source to de-power the humidifier.

Menu button
Access information and service menus.

Drop-down menu button
Access operating mode.

Caution LED
Lights up solid yellow for > 5 seconds when a fault condition occurs.

Estimated dew point
Estimated dew point of the gas reaching the patient.

Modes

The modes available will depend on the type of breathing circuit connected. The availability and operating principles for each mode are shown below.

Breathing Circuit Kit	Modes		
Adult & Pediatric Breathing Circuit Kits	**Invasive** **Invasive mode** is intended for patients whose upper airways have been bypassed by either a tracheostomy or endotracheal tube.	**Mask** **Mask mode** is intended for patients whose upper airways have not been bypassed but are receiving gas via a face mask or similar.	**Optiflow** **Optiflow™ mode** is intended for patients who require respiratory therapy through an Optiflow interface.
Neonatal Breathing Circuit Kit (Additional modes disabled)	**Neonatal** **Neonatal mode** is intended for neonates who require respiratory support.		
Neonatal Breathing Circuit Kit (Additional modes enabled)	**Invasive** **Invasive mode** is intended for patients whose upper airways have been bypassed by either a tracheostomy or endotracheal tube.	**CPAP | NIV** **CPAP | NIV mode** is intended for patients whose upper airways have not been bypassed and are receiving positive pressure therapy through a sealed or nasal interface.	**Optiflow** **Optiflow mode** is intended for patients who require respiratory therapy through an Optiflow interface.
Optiflow Oxygen Kit	**Optiflow** **Optiflow mode** is intended for patients who require respiratory therapy through an Optiflow interface.		

User interface

When multiple modes exist for a type of breathing circuit kit, selection can be accessed via the drop-down menu button.

User interface

Comfort settings

With an adult or pediatric inspiratory limb connected, it is possible to change the set point in Mask and Optiflow modes, to provide conditions which may encourage patient comfort.

The set point is the target humidity at the end-of-hose connection specified as a dew point temperature in units of degrees Celcius.

When additional neonatal modes are enabled, changing the set point in CPAP | NIV and Optiflow modes is also possible.

The available comfort settings are:

Adult & Pediatric

Mode	Default	Medium	Low
Invasive	37 °C	-	-
Mask	31 °C	29 °C	27 °C
Optiflow	37 °C	35 °C	33 °C

Neonatal

Mode	Default	Medium	Low
Neonatal	37 °C	-	-
Invasive*	37 °C	-	-
CPAP | NIV*	37 °C	34 °C	31 °C
Optiflow*	37 °C	35 °C	33 °C

* with additional modes enabled

The humidifier will reset to the default set-point if the mode is changed or the humidifier is turned off and back on. It is possible for service personnel to change the default set-point for Mask, CPAP | NIV and Optiflow modes in the service menu.

Alarms

Alarm signals

The F&P 950 Respiratory Humidifier has visual and audible alarms to warn about interruptions to treatment. These alarms are generated by an intelligent alarm system, which processes information from the sensors and target settings of the unit and compares this information to pre-programmed limits.

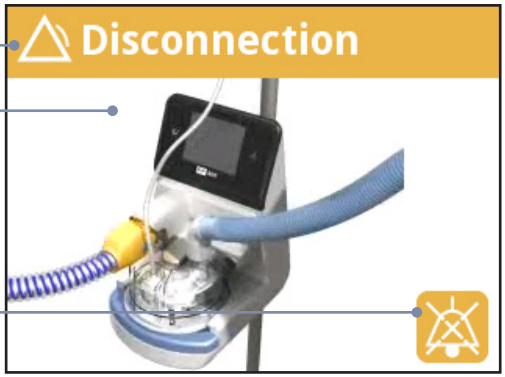
Alarm type

Text or animation tutorial

Demonstrates corrective action – see "alarm conditions" table on the next page.

Mute/unmute alarm

2 minutes.



Alarms

Alarm conditions

All possible alarm conditions are listed on the following pages, and all are classified as medium or low priorities.

As the F&P 950 Respiratory Humidifier does not include patient monitoring, these alarms are considered technical indicators of humidifier performance. It is possible to have multiple alarm conditions occur simultaneously; under these conditions the humidifier uses an internal ranking system to display the highest-ranked alarm.

Medium priority alarms have been designed to be detectable within one meter of the heaterbase, with the alarm signal being three beeps repeated every five seconds.

Low priority alarms have been designed to be detectable within one meter of the heaterbase, with the alarm signal being one beep repeated every five seconds.

Checking alarm system functionality

⚠ **WARNING:** Do not remove breathing circuit when connected to a patient. Failure to comply may compromise safety, including serious patient harm.

To check alarm functionality, remove the heated breathing tube at any time while the humidifier is powered on **but not connected to a patient**. This action should activate the "Disconnection" visual and audible alarms. If either signal is absent, do not use the humidifier. Contact your servicing department for assistance.

In the event of an unexpected shutdown, the humidifier shall resume the operating mode and alarm settings (except algorithm-based alarms) prior to the reset if the interruption is less than or equal to 30 seconds.

Alarms

Alarm Priority: Medium

ALARM CONDITIONS	REQUIRED ACTION
The Disconnection alarm activates when the humidifier detects a disconnection of the inspiratory circuit. Delay: < 10 seconds	Connect inspiratory circuit and fully insert the chamber for complete connection.
The No Water alarm activates when the humidifier detects that the chamber is empty or almost empty of water. The time-to-alarm signal generation is dependent on the operating mode set-point and flow rates. Lower flow rates and operating modes with lower set points (such as Mask and Optiflow) will result in longer alarm delay times as this combination reduces the water evaporation rate. Delay: < 60 minutes* ** with the exception of low flow therapy (< 4 L/min) with a pediatric breathing circuit.If used in Optiflow mode at a set-point of 33 °C , the delay may be up to 3 hours.*	Replace the empty water bag.
The Check Setup alarm activates when the breathing circuit is connected to the ventilator such that gas is flowing to the patient before passing through the humidifier. The alarm activates when the humidifier detects a repeated elevated temperature condition at the chamber outlet. The alarm threshold is 43 °C. The time-to-alarm signal generation is dependent on the flow rates. The Check Setup alarm activation depends on the timing of the heating and cooling cycles, with higher flow rates decreasing the alarm delay time. Delay: < 60 minutes	Check the breathing circuit is connected to the correct ports on the ventilator. Gas must flow through the humidification chamber before reaching the patient.
The Low Temperature alarm activates when the humidifier detects a low temperature condition at the patient end or chamber outlet for a continuous period of time. Alarm delay reduces with lower temperatures. The alarm threshold is 2 °C below the set-point temperature. The time-to-alarm signal generation is dependent on the flow rates. Delay: 10–60 minutes	Check the humidifier is receiving flow within the range stated in this user instruction. Check the humidifier setup.
The High Temperature alarm activates when the humidifier detects a high temperature condition at the patient end. The alarm threshold is a patient end temperature of > 43 °C. Delay: < 30 seconds	Check the humidifier is receiving flow within the range stated in this user instruction. Check connections to the flow source. Check the humidifier setup.
The Cartridge Disconnection alarm activates when the humidifier detects that the sensor cartridge is not electrically connected. Delay: < 10 seconds	Connect the sensor cartridge.
The Breathing Circuit Fault alarm activates when the humidifier detects a faulty breathing circuit. Delay: < 10 seconds	Replace the faulty breathing circuit when safe to do so.

Alarms

Alarm Priority: Medium

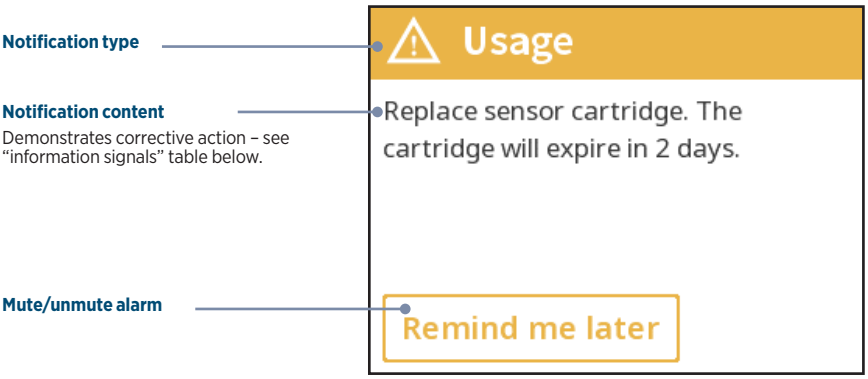
ALARM CONDITIONS	REQUIRED ACTION
The Service Required alarm activates when the humidifier detects a potential fault that requires the humidifier to be serviced. Delay: 10 seconds to 5 minutes	Turn off the humidifier as soon as appropriate and remove from use. Contact a technician for servicing.
The Caution Indicator LED light illuminates when the humidifier detects that there is a potential fault with the humidifier and the screen is not operational. Delay: < 10 seconds	Turn off the humidifier as soon as appropriate, remove from service, and contact a technician.
The Cartridge Service Life alarm activated when the humidifier detects the sensor cartridge has exceeded the recommended service life. The sensor cartridge should be replaced at the next opportunity that it is safe to do so (when not in use by a patient). Delay: 15,000 hours of use. If the alarm is paused, it will reappear 4 hours later.	Press "Pause Alarm" button to dismiss the alarm screen. Contact technician to replace sensor cartridge as soon as appropriate.

Alarm Priority: Low

ALARM CONDITIONS	REQUIRED ACTION
The Check Adapter alarm activates when the humidifier detects the expiratory heater wire adapter is disconnected. If the alarm is minimized, it will re-appear after 2 minutes. *Note: This alarm is enabled by default for NIV|CPAP mode. For all modes, this alarm can be enabled or disabled through the service menu.* Delay: < 20 seconds	Connect the expiratory heater wire adapter between the sensor cartridge and the expiratory circuit. If an expiratory limb is not required, minimize the alarm screen and ensure the humidifier is in the correct operating mode.

Alarms

Information signals

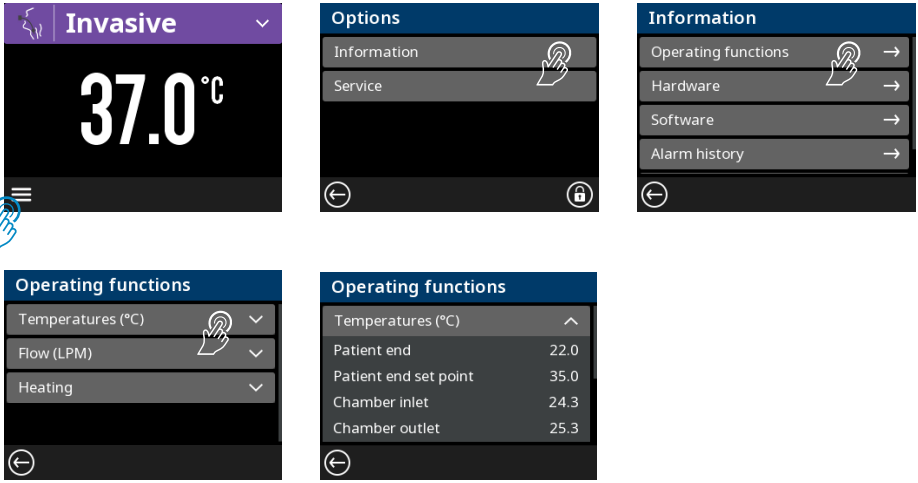


INFORMATION SIGNALS	POSSIBLE ACTIONS
The Cartridge Service Life warning activates when the humidifier detects the sensor cartridge is approaching the end of its recommended service life. At this point the sensor cartridge has one month of service life remaining and a sensor cartridge should be made available for replacement. Delay: 30 days prior to expiry and will reappear every 24 hours, or every 8 hours if less than 7 days remaining	Press "Remind me later" button to dismiss the warning screen. Contact technician to replace sensor cartridge as soon as appropriate.

Information and service menus

Options screen

The “Options” screen contains additional information about the humidifier and can be accessed by pressing the “Menu” button. Tapping on each option enables navigation through the screens.



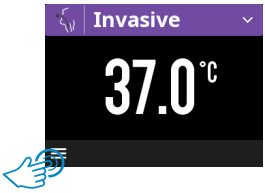
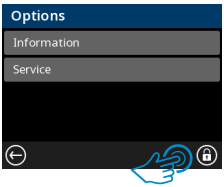
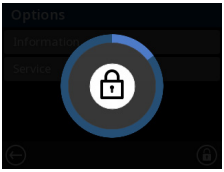
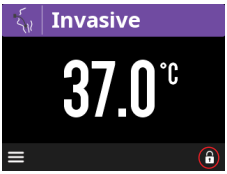
The servicing functions are password protected and should only be accessed by technical personnel. Refer to the Product Technical Manual for more information.

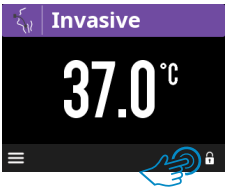
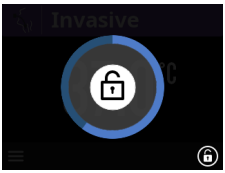
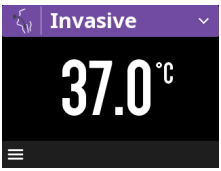
NOTE: The readings displayed in the Operating Functions page under the Information directory are additional information for troubleshooting purposes only. These values are not intended to be used to specify patient treatment or for patient diagnosis.

Information and service menus

Lock screen function

The F&P 950 Heaterbase screen can be locked to avoid unintentional changes to modes or settings. Follow the instruction below to enable or disable the feature:

STEP	INSTRUCTION	SCREENSHOT
1	Navigate to the "Options" screen by touching the menu icon in the bottom left corner of the "Main" screen.	
2	Press and hold the lock icon.	
	Hold down the icon until the countdown animation completes one full revolution.	
3	When the screen is locked, a "lock" icon is displayed.	

4	To unlock the screen, tap the lock icon once.	
	The icon will change to “unlock”. Press and hold the “unlock” icon.	
	Hold down the icon until the countdown animation completes one full revolution.	
5	When unlocked, the humidifier will return to the main screen and the user will be able to change the mode or settings.	

NOTE: Please refer queries relating to setup, troubleshooting, service, repair and unexpected operation of the humidifier or accessories, to your healthcare provider or local Fisher & Paykel Healthcare representative.

Cleaning and maintenance

Cleaning

Clean the heaterbase, sensor cartridge, or expiratory heater wire adapter using a cloth dampened with either isopropyl alcohol or neutral detergent. Always disconnect the humidifier from the power supply before cleaning.

NOTES:

- Do not immerse or autoclave the heaterbase, sensor cartridge, or expiratory heater wire adapter.
- Do not spray liquid into the vents or onto electrical connectors. Failure to comply may result in irreparable damage to the humidifier.
- Follow the responsible organization's guidelines for frequency of cleaning, rinsing, drying, handling and storage between uses.

Routine maintenance

A full technical description, including routine maintenance and service data, is contained in the Product Technical Manual available from your supplier or Fisher & Paykel Healthcare.

WARNING: The Product Technical Manual must be followed for all servicing and maintenance of the humidifier. Failure to comply may impair performance of the humidifier or compromise safety (including potentially causing serious harm).

Warnings, cautions and notes

WARNINGS

- Refer to the instructions for use for breathing circuits, interfaces and accessories before operating the equipment. Failure to comply may impair performance of the humidifier or compromise safety (including potentially causing patient harm).
- This product is only designed and verified for use with accessories and spare parts approved by Fisher & Paykel Healthcare. Unauthorized accessories or spare parts which are used with the humidifier may impair performance of the humidifier, or compromise safety (including potentially causing serious patient harm), or result in increased electromagnetic emissions, or decreased electromagnetic immunity, resulting in improper operation.
- MR Do not use this product in or near a magnetic resonance imaging (MRI) scanner, where the intensity of electromagnetic disturbances is high. Failure to comply may impair the performance of the humidifier or compromise safety (including potentially causing serious patient harm).
- Remove any sources of ignition, such as: cigarettes, an open flame, or materials which ignite easily at high oxygen concentrations.
- This product is designed for the delivery of air and/or oxygen. It is not suitable for the delivery of flammable anesthetic gas mixes or Heliox gas. Failure to comply may impair performance of the humidifier or compromise safety (including potentially causing patient harm).
- The humidifier should always be level and positioned lower than the patient. Failure to comply may impair performance of the humidifier or compromise safety (including potentially causing serious patient harm).
- Visually inspect components and accessories for damage before use and replace if damaged. Use of damaged components or accessories (including degraded sensors) may impair performance of the humidifier or compromise safety (including potentially causing serious harm).
- Appropriate patient monitoring (e.g. oxygen saturation) must be used at all times. Failure to monitor the patient (e.g. in the event of an interruption to gas flow) may result in serious harm or death.
- Do not touch the electrical connectors and the patient simultaneously. Failure to comply may result in serious harm.
- Operation of the humidifier outside of the specified operating conditions (as described in these user instructions) may impair performance of the humidifier or compromise safety (including potentially causing patient harm).
- Monitor circuit condensate every six hours to prevent occlusion or build-up of fluid. Drain as required. Failure to comply may impair performance of the humidifier or compromise safety (including potentially causing serious patient harm).

Warnings, cautions and notes

- Follow the instructions of the oxygen device provider; keep oxygen regulators, cylinder valves, tubing, connections, and all other oxygen equipment away from oil, grease, or greasy substances. Spontaneous and violent ignition may occur if these substances come into contact with oxygen under pressure.
- California residents, please be advised of the following, pursuant to Proposition 65: This product contains chemicals known to the State of California to cause cancer, birth defects and other reproductive harm. For more information, please visit: http://www.fphcare.com/prop65
- The operation of high-frequency surgical apparatus, shortwave or microwave equipment in the vicinity of the humidifier may adversely affect its performance. If this occurs, remove the humidifier from the vicinity of such devices.
- Do not connect the humidifier directly to a medical gas pipeline system. The humidifier is intended for connection to a ventilator or gas mixer to control gas pressure and flow rate. Failure to control the gas delivery may result in a pressure injury to the patient.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, observe all equipment to confirm that it is operating normally.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm to any part of F&P 950 Respiratory Humidifier, including cables specified by the manufacturer. Otherwise, degradation of the performance of the equipment could result.
- The F&P 950 Respiratory Humidifier and accessories contain small parts which could cause injury or suffocation if inhaled or swallowed.
- Install the humidifier away from heat sources, such as direct sunlight, radiant heaters, fireplaces, ovens and kettles and cooling sources, such as dehumidifiers, fans, air conditioners and ventilators. Failure to comply may impair the performance of the humidifier or result in serious harm.
- To avoid strangulation or tripping, ensure the breathing tubes and power cord are positioned in a tidy manner away from the floor and patient, so they will not get entangled or wrapped around the limbs or neck.
- Consideration should be given to the possible hazards that could arise from children, pests and pets.

⚠ CAUTIONS

- Ensure that Invasive mode is set for patients who have bypassed airways. Prolonged exposure to reduced humidity will result in patient harm including decreased mucociliary clearance, atelectasis, or pneumonia.
- Do not touch the hot surface of the heater plate, chamber base or probes. Failure to comply may result in a skin burn.
- The F&P 950 Respiratory Humidifier does not contain material known to cause allergic reactions. If an allergic reaction occurs during use, contact the responsible organization immediately.

NOTES

- Use USP sterile water for irrigation, or equivalent. Adding other substances may have adverse effects.
- The F&P 950 Respiratory Humidifier contains an embedded software system licensed to Fisher & Paykel Healthcare by Microsoft. The license contains certain restrictions that are relevant to the use of the F&P 950 Respiratory Humidifier.

  Visit www.fphcare.com/microsoftlicensing for more information about such restrictions.
- The F&P 950 Respiratory Humidifier has an IP21 rating, which protects against solid foreign objects 12.5 mm in diameter and uniform flow of water drops over the enclosure area with a flow rate of 1 mm/min.
- This equipment's emissions characteristics make it suitable for use in industrial areas and hospitals (CISPR 11 class A) and residential environments (CISPR 11 class B).
- If a serious incident has occurred while using this device, please inform your local Fisher & Paykel Healthcare representative and, for European Union member countries, the Competent Authority in your country.

Symbol definitions


Follow instructions for use - safety


Consult instructions for use. www.fphcare.com/950IFU


Manufacturer


Date of manufacture

Catalogue reference number

Batch code

Serial number


Type BF Applied Part


Class II equipment


Alternating current


Standby (On/Off)

IP Classification


Temperature limitations


Humidity limitations


USB 2.0


WEEE (Waste Electrical and Electronic Equipment)*

European representative*

European Conformity - TÜV SÜD*


Regulatory Compliance Mark*


Raise finger guard


Fragile, handle with care


Keep dry


Recyclable


Caution


Warning


Alarm


Menu


Warning: hot surface


Alarm audible pause


Alarm audible paused


Minimize


Invasive mode


Mask mode


Optiflow mode


Neonatal mode


Neonatal Invasive mode


Neonatal CPAP | NIV mode


Neonatal Optiflow mode


Sensor Cartridge service life warning


Accept

Cancel

Back arrow

Locked

Unlock

Date of expiration

For USA: prescription only*

Magnetic resonance (MR) unsafe

Importer

Distributor

Authorized representative for Switzerland*

UK responsible person*

Medical device*

Universal Device Identifier

UL Mark*

INMETRO Mark*

** symbol displayed on select models*

Technical specifications

Product specifications

	Heaterbase Specifications		
Dimensions (heaterbase only)	240 mm (D) x 154 mm (W) x 253 mm (H)		
Weight (heaterbase and power cord only)	3.45 kg		
Supply frequency	50/60 Hz		
Supply voltage	REF **950AXX**[1] 230 V ~ REF **950JXX**[1] 115 V ~ REF **950GXX**[1] 100 V ~		
Supply Current	REF **950AXX**[1] 1.5 A Max. REF **950JXX**[1] 3.0 A Max. REF **950GXX**[1] 3.5 A Max.		
Power rating	350 VA		
Maximum length of power cord	3.3 m		
Sound pressure level	Alarms exceed 45 dbA @ 1 m		
Auditory alarm pause	120 seconds		
Maximum temperature of delivered gas	43 °C		
Time to reach set temperature (gas flow is required)	< 30 minutes		
Maximum surface temperature of the breathing circuit (applied part section)	44 °C		
Component service life	Heaterbase: 7 years		
	Adult	**Pediatric**	**Neonatal**
Humidity performance (Except in the event of a humidifier alarm or power failure or electromagnetic disturbance)	**Invasive mode:** > 33 mg/L **Mask mode:** > 12 mg/L **Optiflow mode:** > 12 mg/L	**Invasive mode:** > 33 mg/L **Mask mode:** > 12 mg/L **Optiflow mode:** > 12 mg/L	**Neonatal Mode:** > 33 mg/L **Invasive mode:** > 33 mg/L **CPAP | NIV mode:** > 12 mg/L **Optiflow mode:** > 12 mg/L
Operating flow range (L/min, STPD)	**Invasive mode:** 5-60 L/min **Mask mode:** 5-120 L/min **Optiflow mode:** 5-70 L/min	**Invasive mode:** 1-60 L/min **Mask mode:** 1-60 L/min **Optiflow mode:** 1-60 L/min	**Neonatal Mode:** 0.5-40 L/min **Invasive mode:** 0.5-40 L/min **CPAP | NIV mode:** 0.5-40 L/min **Optiflow mode:** 0.5-36 L/min

[1]XX represents the country code

Technical specifications

Operating conditions

SPECIFICATION	ADULT	PEDIATRIC & NEONATAL
Room temperature	18–26 °C	20–26 °C
Incoming gas temperature	Minimum = Room temperature Maximum = 10 °C above room temperature (at 30% relative humidity)	Minimum = Room temperature Maximum = 10 °C above room temperature (at 30% relative humidity)
Operator position	<1 m from heaterbase	<1 m from heaterbase
Atmospheric pressure:	Minimum of 70 kPa (equivalent to a maximum altitude of 3000 m) Maximum 106 kPA	Minimum of 70 kPa (equivalent to a maximum altitude of 3000 m) Maximum 106 kPa

Storage conditions

SPECIFICATION	VALUE
Temperature	-20–60 °C
Humidity	10–95% relative humidity non-condensing

NOTE: If the humidification system has been stored outside the specified operating ambient temperature range, the system must be left for 24 hours within the specified operating temperature range before use.

Disposal

At the end of its life, users should dispose of the humidifier according to the responsible organization's guidelines, local authority guidelines, and national electrical and electronic equipment regulations.

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