F&P 850

MR850 Respiratory Humidifier

USER INSTRUCTIONS

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INTENDED USE

The MR850 Respiratory Humidifier is used to warm and humidify gases delivered to patients requiring mechanical ventilation, positive-pressure breathing assistance, or other medical gases.

ATTENTION: This product is for use under the supervision of trained medical personnel.

WARNINGS

- The use of breathing circuits, chambers, other accessories or parts which are not approved by Fisher & Paykel Healthcare may impair performance or compromise safety.
- Use of damaged components or accessories may impair the performance of this device or compromise safety.
- When mounting a Humidifier adjacent to a patient ensure that the Humidifier is always securely mounted and positioned lower than the patient.
- Do not use this device without gas flow. If gas flow is interrupted, turn the Humidifier off.
- Gas mixes, such as helium-oxygen mixtures, that have different physical or thermal properties from an air or air-oxygen mixture may impair performance or compromise safety.
- This device is not suitable for delivery of flammable anesthetic mixes or nitrous oxide.
- Remove any sources of ignition, such as cigarettes, an open flame, or materials which burn or ignite easily at high oxygen concentrations.
- 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.
- Hot surfaces may exceed 74 °C; avoid touching these.
- Do not fill the chamber with water in excess of 37 °C.
- Do not touch the glass tip of the Chamber Probe during use. It may cause a skin burn.
- To avoid the risk of electric shock, this equipment must only be connected to a mains power supply with protective earth.
- Ensure that Invasive Mode is set for patients who have bypassed airways.
- Ensure that both Temperature Probe sensors are correctly and securely fitted. Failure to do so may result in gas temperatures in excess of 41 °C being delivered to the patient.
- Do not use the Humidifier at an altitude above 3000 m (700 hPa) or outside a temperature of 18 – 26 °C. Using the Humidifier above this altitude or outside of this temperature range can affect the quality of the therapy or injure the patient.
- Ensure that appropriate ventilator and/or patient monitor alarms are set, connections are secure and a leak test is completed before use.
- To prevent disconnection of the tubing or tubing system during use, only tubes in compliance with ISO 5367 or ISO 80601-2-74 should be used.
- No modification of equipment or replacement of individual components is allowed.
- Do not position the Humidifier so that it is difficult to disconnect the mains plug.
- This device must not be used in a flammable or explosive environment.

CAUTIONS

- Use USP sterile water or equivalent for humidification. Adding other substances to the water can have adverse effects.

SPECIFICATIONS

Dimensions:	140 mm x 173 mm x 135 mm (without chamber fitted)
Weight:	2.8 kg (without chamber fitted) 3.1 kg (chamber fitted and filled with water)
Mains Supply:	115 V~, 60 Hz
Rated Power:	220 VA
Heater-plate Output:	150 W
Heater-wire Output:	22 V~, 2.73 A, 60 W
Essential Performance:	Delivery of specified humidification output or generation of an alarm condition

	Invasive Mode	Noninvasive Mode
Humidity Performance:	≥ 33 mg/L	≥ 12 mg/L
Flow Range:*	≤ 60 L/min	≤ 120 L/min
Chamber Outlet Control Temperature Range:	35.5 – 42 °C	31 – 36 °C
Airway Control Temperature Range:	35 – 40 °C	28 – 34 °C
Warm-up Time:	< 30 minutes	< 30 minutes

Recommended Environmental Conditions:*	Ambient temperature: 18 – 26 °C Ambient humidity: 10 – 95% RH Ambient pressure: 700 – 1060 hPa
Temperature Display Range:	10 – 70 °C
Gas Temperature Measurement Accuracy:	± 2 °C (Temperature Probe Accuracy: ± 0.3 °C, in 25 – 45 °C range)
Software Version:	Refer to MR850 System Technical Manual (available from your Fisher & Paykel Healthcare representative or your supplier)
Alarm Sound Pressure Level:	> 50 dBA at 1 m
Audio Information Signal:	Single beep or double beep
Maximum Operating Pressure:	Refer to chamber and breathing circuit specifications
Service Life:	7 years (if used in accordance with this User Instructions booklet)

*Refer to Breathing Circuit User Instructions for specific range.

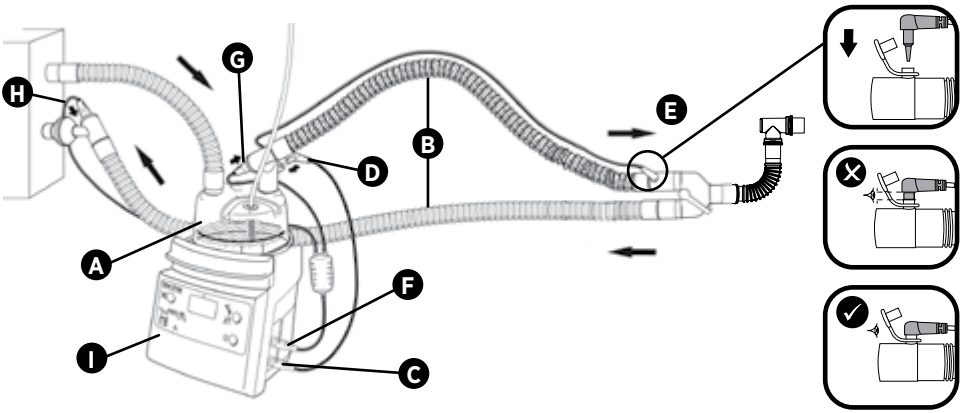
CLASSIFICATIONS

Electrical Classification:	Class I, continuous
Humidifier Classification:	Category 1
Type of Protection Against Ingress of Water:	IPX1
Degree of Protection Against Electric Shock:	Type BF applied part

SET-UP

MOUNTING

The **Humidifier** (**I**) can either be placed on a flat stable surface or mounted to a ventilator, pole stand or medical equipment rail with an approved mounting bracket. The system shall be installed according to Electromagnetic Compatibility information contained in MR850 System Technical Manual.



ACCESSORIES

- (**A**) Humidification Chamber (e.g. MR290)
- (**B**) Breathing Circuit (e.g. RT380)
- (**C**,**D**,**E**) Temperature Probe (e.g. 900MR869)
- (**F**,**G**,**H**) Heater-wire Adapter (e.g. 900MR805)
- Mounting Bracket (e.g. 900MR303)

Accessory choice will depend upon application.

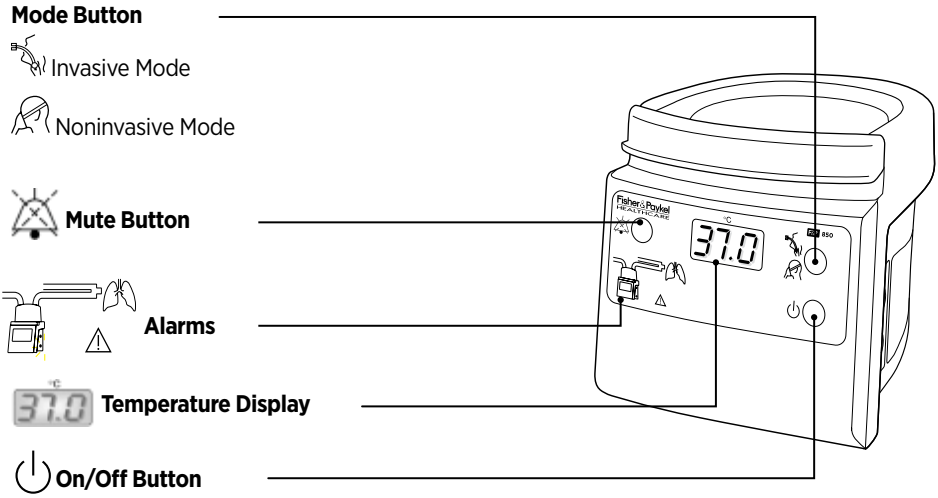
Please contact your local Fisher & Paykel Healthcare representative for recommendations.

ATTENTION: Refer to the User Instructions which accompany each accessory.

SET-UP INSTRUCTIONS

1. Visually inspect the **Humidifier** (**I**) and accessories for damage before use and replace if damaged.
2. Slide the **Humidification Chamber** (**A**) onto the **Humidifier** (**I**) and connect **Breathing Circuit** (**B**) (refer to the Humidification Chamber and Breathing Circuit User Instructions for further details).
3. Insert the **Temperature Probe Connector** (**C**) to the blue socket on the Humidifier.
4. Push the **Chamber Probe** (**D**) and **Airway Probe** (**E**) into the Breathing Circuit making sure they are correctly located and pushed into place. The probe lead can be secured using Breathing Circuit Clips.
5. Insert the **Heater-wire Adapter Connector** (**F**) to the yellow socket on the Humidifier.
6. Connect the other end(s) of the Heater-wire Adapter (**G**), (**H**) to the Breathing Circuit socket(s). The humidification system is now set up.
7. Turn on using the On/Off button. The Humidifier will default to Invasive Mode. After turning on the Humidifier, look at the display and alarm indicators to visually confirm that they turn on then off. Following this, listen for an audible tone to confirm that the sounder is functioning correctly. If a fault is detected, send for servicing.

   The humidification system is now ready for use.



On/Off Button
The Humidifier will turn ON if this button is held down briefly. The Humidifier will always default to Invasive Mode when it is turned on.

The button must be held down for more than 1 second to turn the Humidifier OFF. Remove mains plug to completely isolate power from this device.

Mute Button
The Mute Button silences the Humidifier's alarm. The duration of an audio pause is 2 minutes. Pushing the Mute Button can reactive the audio alarm. Mute status is shown with a green indicator.

Temperature Display
This displays the saturated gas temperature (the lower of the Airway and Chamber Outlet temperatures in °C) delivered to the patient. This display will normally show the Chamber Outlet temperature (around 37 °C for Invasive Mode, and 31 °C for Noninvasive Mode).
By pushing and holding the Mute Button for 1 second, the Chamber Outlet temperature then the Airway temperature is displayed. The display will then revert to normal operation.

Mode Button
This button switches between Invasive and Noninvasive Mode. Mode selection is shown with a green indicator.

- **Invasive Mode** for patients with bypassed airways.
  The system delivers gas as close to body temperature saturated (37 °C, 44 mg/L) as possible.
- **Noninvasive Mode** for patients receiving face mask or head-box therapy. The system delivers a comfortable level of humidity.

ALARMS

Alarm Priority

Medium Priority Alarm	Signaled by an audible alarm sound and a flashing visual alarm indicator (yellow).
Low Priority Alarm	Signaled by a constantly-lit visual alarm indicator (yellow).

List Of Alarms

Airway Probe
Indicates if the Airway Probe is not inserted into the Breathing Circuit (may take up to 15 minutes to alarm).

Chamber Probe
Indicates if the Chamber Probe is not inserted into the Breathing Circuit (may take up to 15 minutes to alarm).

Heater-wire
Indicates if the Heater-wire Adapter or Breathing Circuit has not been connected, or is faulty.

Water Out
Indicates when there is insufficient water in the chamber, by measuring gas flow and the amount of power used to maintain the Chamber Outlet temperature (may take up to 20 minutes to alarm)

Temperature Probe
Indicates if the Temperature Probe has not been connected, or is faulty.

See Manual
Indicates a hardware fault. The Humidifier and all accessories shall be replaced immediately and sent for servicing.

Low Temperature
Warns if the displayed temperature falls below a predetermined performance threshold for a predetermined time. This alarm condition can be caused by many factors such as cold and/or drafty ambient conditions or very high or low gas flows.

For Invasive Mode, a “Low Priority” alarm is activated 25 seconds after the displayed temperature falls below **35.5 °C**. If the temperature remains low, a “Medium Priority” alarm is activated (depending on both the length of time the displayed temperature is below 35.5 °C as well as the level of temperature drop).

For Noninvasive Mode, a “Low Priority” alarm is activated 25 seconds after the displayed temperature falls below **26.0 °C**.

ALARMS *(continued)*

High Temperature
Warns if the gas temperature exceeds a predetermined performance threshold.

A Medium Priority alarm is activated immediately if at any time the displayed temperature reaches **41 °C**, or if the Airway Probe temperature reaches **43 °C**. The Humidifier will immediately power-down the Heater-wire and Heater-plate, followed by a flashing temperature display.

NOTES:

- Under cold or drafty conditions, the chamber outlet temperature may drop as low as 35.5 °C in order to minimize condensation forming in the Breathing Circuit.
- The Low Temperature Alarm is a "Low Priority" or "Medium Priority" alarm. All other alarms have been assessed as "Medium Priority" alarms.
- The alarm conditions are specified for an operator's position of within 1 meter of the device.

TRANSPORTATION AND STORAGE CONDITIONS

Temperature:	-10 – 50 °C
Humidity:	10 – 95% Relative Humidity
Date of manufacture:	Refer to product label

CLEANING

Humidifier: Using a damp cloth, clean the MR850 Humidifier with either isopropyl alcohol or normal dishwashing detergent.

Accessories: Refer to the User Instructions which accompany each accessory for cleaning guidelines.

NOTE: Do not immerse the Humidifier or accessory electrical connectors in any liquid.

DISPOSAL

At the end of service life, discard according to standard hospital procedure for electrical and electronic equipment.

ROUTINE MAINTENANCE AND SERVICING

Refer maintenance and servicing to qualified service personnel. A full technical description, including maintenance schedule, performance test and service data, is contained in MR850 System Technical Manual.

ELECTROMAGNETIC COMPATIBILITY

The device complies with the electromagnetic compatibility requirements of IEC60601-1-2. Users shall install and use according to the electromagnetic compatibility information contained in MR850 System Technical Manual.

Essential performance may be lost in the event of power failure or where the intensity of electromagnetic disturbance is high.

WARNINGS

- The device is intended to be used in a professional healthcare facility environment e.g. hospitals, except for areas where the intensity of electromagnetic disturbances is high, e.g. near active high-frequency surgical equipment, rooms used for magnetic resonance imaging, electrophysiology laboratories, or areas where short-wave therapy equipment is used.
- The device or system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device or system should be observed to verify normal operation in the configuration in which it will be used.
- Use of accessories, transducers, cables and spare parts other than those specified by Fisher & Paykel Healthcare could cause increased electromagnetic emissions or decreased electromagnetic immunity of the device or system resulting in improper operation.
- Portable radio frequency communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the MR850 Humidifier, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

SYMBOL DEFINITIONS

 Follow Instructions For Use	 Warning – Hot Surface	 General Warning	 Type BF Applied Part	 Resistant to Vertical Falling Drips
 Date of Manufacture	 Manufacturer	 Alternating Current	 Serial Port	 Fragile, Handle with Care
 Keep Dry	 This Way Up	 Transportation & Storage Temperature Limitation	 Transportation & Storage Humidity Limitation	 Lot Number
 Reference Number	 Serial Number	 Operating Instructions	 Electrostatic Sensitive Devices	 Protective Earth
 Equipotential Stud	Rx only Prescription Only	 Respiratory Humidifier with respect to electric shock, fire and mechanical Hazard only in accordance with UL60601-1 and CAN/CSA C22.2 No 601-1		

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