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.

OPERATING PRINCIPLE

The MR850 Respiratory Humidifier is designed to add heat and moisture to respiratory gases by passing the gas through a humidification chamber. Heat is applied to the chamber and circuit with feedback-control on the temperature of the gas at the chamber outlet and the patient-end of the circuit.

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:	230 V~, 50/60 Hz (MR850ABU) 115 V~, 60 Hz (MR850JBU)
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:	8.xx (xx denotes minor software version number)
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.

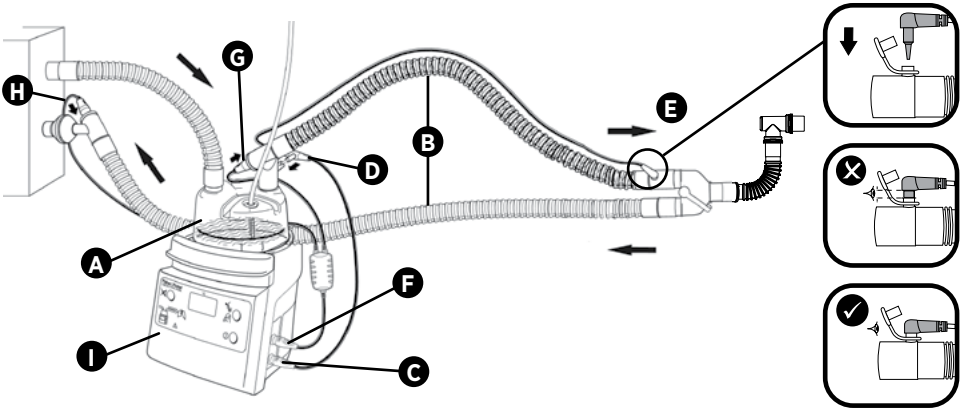
CLASSIFICATIONS

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 in this User Instructions booklet.



ACCESSORIES

- (**A**) Humidification Chamber (e.g. MR290)
- (**B**) Breathing Circuit (e.g. RT385)
- (**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.

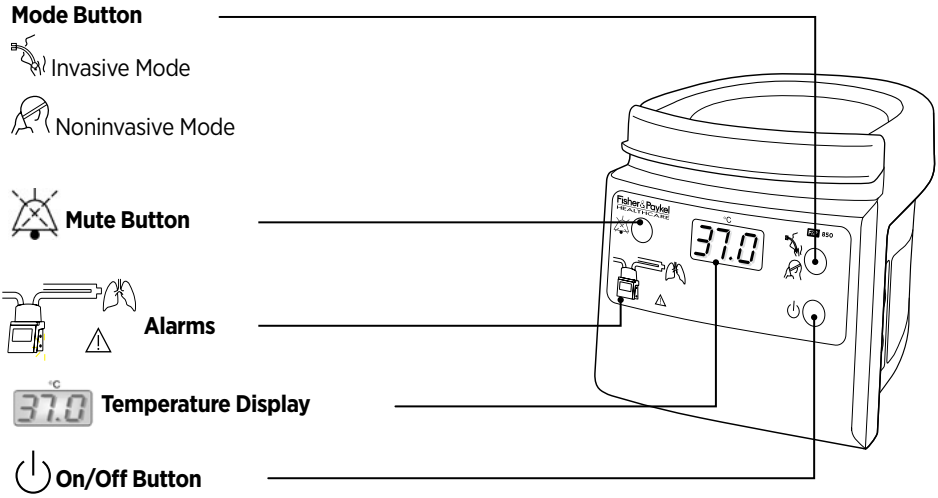
Please contact your local Fisher & Paykel Healthcare representative for recommendations.

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

WARNINGS

- Although the display is not illuminated, the unit may still be energized. Remove the mains plug to completely isolate power from this device before servicing.
- All servicing procedures shall be followed by a Humidifier performance test and an electrical safety test, to ensure proper operation.
- Ensure that fuse replacements are of the specified type and current ratings.

Refer maintenance and servicing to qualified service personnel. A full technical description, including maintenance schedule, performance test and service data, is available from your supplier or Fisher & Paykel Healthcare representative.

Visual Check (before each use)

1. Check all of the cables for insulation damage, kinks and cuts; replace if required.
2. Check that the Heater-plate springs back when pressed and check for damage; replace if required.
3. Check all electrical sockets/plugs for damage; replace if required.
4. Check that the finger guard can move freely and check for damage; replace if required.
5. Check the Humidifier and Heater-wire Adapter enclosure for damage; replace if required.
6. Check the Chamber and Airway Probes on the Temperature Probe for damage; replace if required.
7. Check the Chamber Probe's glass thermistor for damage; replace if required.
8. After turning on the Humidifier, check for display and alarm indicators to confirm that they turn on then off. Following this, listen for an audible tone to confirm that the sounder is functioning correctly.

Electrical Safety Check (recommended at least annually)

The Humidifier and associated accessories shall be tested to the current country-specific medical electrical standards for in-house testing (e.g. refer to AS/NZS 3551 for Australia and New Zealand).

Replacing Fuses (when required)

1. Ensure that mains power has been disconnected from the unit.
2. Remove the four screws at the back of the Humidifier. Pull the front half of the case away from the rear. The control Printed Circuit Board (PCB) is attached to the front half of the case and is connected via ribbon cable to the power PCB fitted to the rear half of the case.
3. Slide the power PCB forward with the side panel (the side panel is attached to the power PCB). The side panel will need to be pushed inwards during this action in order to unlatch and be clear of the electrical connectors.
4. The fuses can now be accessed and replaced. Refer to a Fisher & Paykel Healthcare representative for a list of fuse spare parts.
5. Reassemble the PCB and front case in the reverse order of disassembly (steps 3 then step 2). Make sure that all harnesses that were previously disconnected have been reconnected.
6. Turn the power on and complete a Humidifier performance test.

Replacing the Mains Cable (when required)

1. Ensure that mains power has been disconnected from the unit.
2. Remove the four screws at the back of the Humidifier. Pull the front half of the case away from the rear. The control PCB is attached to the front half of the case and is connected via ribbon cable to the power PCB fitted to the rear half of the case.
3. Slide the power PCB forward with the side panel (the side panel is attached to the power PCB). The side panel will need to be pushed inwards during this action in order to unlatch and be clear of the electrical connectors.
4. Unscrew the three mains cord wires from the terminal block on the power PCB, and cut the cable tie to release the wires.
5. Replace the power cord, and affix to the case by forcefully pushing the retainer back into position (towards the rear of the case).
6. Connect the three mains cord wires to the terminal block on the power PCB, using a recommended 0.5N/m torque setting for the terminal block screws (see Table A for correct mains cable wiring). Secure the wires to the PCB with a new cable tie.
7. Reassemble the PCB and front case in the reverse order of disassembly (step 3 then step 2). Make sure that all harnesses that were previously disconnected have been reconnected.
8. Perform an electrical safety check.
9. Turn the power on and complete a Humidifier performance test.

Table A – Power Cord

Cord type for models	Phase	Neutral	Earth
MR850JBU and MR850ABU	Brown	Blue	Green/ Yellow

ELECTROMAGNETIC HUMIDIFIER COMPATIBILITY

The device complies with the electromagnetic compatibility requirements of IEC60601-1-2. Users shall install and use according to the electromagnetic compatibility information in this User Instructions booklet.

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.

Guidance and manufacturer's declaration – Electromagnetic emissions

<table>
<tr><td colspan="4">The MR850 Humidification System is intended for use in the electromagnetic environment specified below. The customer or the user of the MR850 Humidification System should assure that it is used in such an environment.</td></tr>
<tr><td>Emissions test</td><td colspan="2">Compliance</td><td>Electromagnetic environment – guidance</td></tr>
<tr><td>RF emissions CISPR 11</td><td colspan="2">Group 1</td><td>The MR850 Humidification System 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.</td></tr>
<tr><td>RF emissions CISPR 11</td><td colspan="2">Class B</td><td rowspan="4">The MR850 Humidification System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td></td><td>MR850ABU</td><td>MR850JBU</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td><td>Not applicable</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions
IEC 61000-3-3</td><td>Complies</td><td>Not applicable</td></tr>
</table>

Guidance and manufacturer's declaration – Electromagnetic immunity *(continued)*

The MR850 Humidification System is intended for use in the electromagnetic environment specified below. The customer or the user of the MR850 Humidification System should assure that it is used in such an environment.			
Immunity test	**IEC 60601-1 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 1 5 kV air	± 8 kV contact ± 1 5 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 100 KHz repetition frequency	± 2 kV for power supply lines 100kHz repetition frequency no applicable input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage Dips: 0% U_T for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T for 1 cycle and 70% U_T for 25/30 cycles, single phase at 0° Voltage interruptions: 0% U_T for 250/300 cycle	Voltage Dips: 0% U_T for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T for 1 cycle and 70% U_T for 25/30 cycles, single phase at 0º Voltage interruptions: 0% U_T for 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the MR850 Humidification System requires continued operation during power mains interruptions, it is recommended that the MR850 Humidification System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the a.c. mains voltage prior to application of the test level.

The MR850 Humidification System is intended for use in the electromagnetic environment specified below. The customer or the user of the MR850 Humidification System should assure that it is used in such an environment.			
Immunity test	**IEC 60601-1 test level**	**Compliance level**	**Electromagnetic environment – guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the MR850 Humidification System including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3Vrms , 6Vrms (ISM) 0,15 to 80 MHz	3Vrms , 6Vrms (ISM) 0,15 to 80 MHz	**Recommended separation distance** $d = 1,2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,7 GHz 80% AM at 1 kHz	10 V/m 80 MHz to 2,7 GHz 80% AM at 1 kHz	$d = 1,2\sqrt{P}$ 80 MHz to 800 MHz $d = 2,3\sqrt{P}$ 800 MHz to 2,7 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a] should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
Proximity fields from RF wireless communications equipment IEC 61000-4-3	9 – 28 V/m, 15 Radio Service Bands at 385 MHz - 5785 GHz	9 – 28 V/m, 15 Radio Service Bands at 385 MHz - 5785 GHz	d = 30 cm

NOTES:

- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and manufacturer's declaration – Electromagnetic immunity *(continued)*

NOTES:

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the MR850 Humidification System is used exceeds the applicable RF compliance level above, the MR850 Humidification System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the MR850 Humidification System.

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

Recommended separation distances between portable and mobile RF communications equipment and the MR850 Humidification System

The MR850 Humidification System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MR850 Humidification System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MR850 Humidification System as recommended below, according to the maximum output power of the communications equipment.

	Separation distance according to frequency of transmitter (m)		
Rated maximum output power of transmitter (W)	**150 kHz to 80 MHz** $d = 1{,}2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1{,}2\sqrt{P}$	**800 MHz to 2,7 GHz** $d = 2{,}3\sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,38	0,38	0,73
1	1,2	1,2	2,3
10	3,8	3,8	7,3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTES:

- At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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	 Authorized representative in the European community	 Dispose of product in correct manner	 INMETRO Mark	

Manufacturer Fisher & Paykel Healthcare Ltd, 15 Maurice Paykel Place, East Tamaki, Auckland 2013, PO Box 14 348 Panmure, Auckland 1741, New Zealand Tel: +64 9 574 0100 Fax: +64 9 574 0158 Email: info@fphcare.co.nz Web: www.fphcare.com Importer/ Distributor **Australia** (Sponsor) Fisher & Paykel Healthcare Pty Ltd, 19-31 King Street, Nunawading, Melbourne, Victoria 3131. Tel: +61 3 9871 4900 Fax: +61 3 9871 4998 **Austria** Tel: 0800 29 31 23 Fax: 0800 29 31 22 **Benelux** Tel: +31 40 216 3555 Fax: +31 40 216 3554 **Brazil** Fisher & Paykel do Brasil, Rua Sampaio Viana, 277 cj 21, Paraíso, 04004-000, São Paulo – SP, Brazil Tel: +55 11 2548 7002 **China** 代理人/售后服务机构:费雪派克医疗保健（广州）有限公司, 广州高新技术产业开发区科学城科丰路31号G12栋301号 电话: +86 20 32053486 传真: +86 20 32052132 **Denmark** Tel: +45 70 26 37 70 Fax: +46 83 66 310 **Finland** Tel: +358 9 251 66 123 Fax: +46 83 66 310 **France** EC REP Fisher & Paykel Healthcare SAS, 10 Av. du Québec, Bât F5, BP 512, Villebon-sur-Yvette, 91946 Courtaboeuf Cedex, France Tel: +33 1 6446 5201 Fax: +33 1 6446 5221 Email: c.s@fphcare.fr **Germany** Fisher & Paykel Healthcare GmbH, Deutschland, Österreich, Schweiz, Wiesenstrasse 49, D 73614 Schorndorf, Germany Tel: +49 7181 98599 0 Fax: +49 7181 98599 66 **Hong Kong** Tel: +852 2116 0032 Fax: +852 2116 0085 **India** Tel: +91 80 2309 6400 **Ireland** Tel: 1800 409 011 Fax: +44 1628 626 146 **Italy** Tel: +39 06 7839 2939 Fax: +39 06 7814 7709 **Japan** Tel: +81 3 5117 7110 Fax: +81 3 5117 7115 **Korea** Tel: +82 2 6205 6900 Fax: +82 2 6309 6901 **Mexico** Tel: + 52 55 9130 1626 **Norway** Tel: +47 21 60 13 53 Fax: +47 22 99 60 10 **Poland** Tel: 00800 49 119 77 Fax: 00800 49 119 78 **Russia** Tel. and Fax: +7 495 782 21 50 **Spain** Tel: +34 902 013 346 Fax: +34 902 013 379 **Sweden** Tel: +46 8 564 76 680 Fax: +46 8 36 63 10 **Switzerland** Tel: 0800 83 47 63 Fax: 0800 83 47 54 **Taiwan** Tel: +886 2 8751 1739 Fax: +886 2 8751 5625 **Turkey** İthalatçı Firma: Fisher Paykel Sağlık Ürünleri Ticaret Limited Şirketi, İletişim Bilgileri: Ostim Mahallesi 1249. Cadde No:6, Yenimahalle, Ankara, Türkiye 06374, Tel: +90 312 354 34 12 Fax: +90 312 354 31 01 **UK** Fisher & Paykel Healthcare Ltd, Unit 16, Cordwallis Park, Clivemont Road, Maidenhead, Berkshire SL6 7BU, UK Tel: 0800 132 189 Fax: +44 1628 626 146 **USA/Canada** Tel: 1800 446 3908 or +1 949 453 4000 Fax: +1 949 453 4001

www.fphcare.com

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