POOYANDEGAN RAH SAADAT

OPERATOR'S MANUAL

Respimo-M2 Humidifier

CE 2195

D01034-V5

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Manual Purpose

This manual contains the instructions necessary to operate the humidifier safely and in accordance with its functions and intended use.

This manual is an integral part of the product and describes its intended use. Observance of the manual is a prerequisite for proper product performance and correct operation and ensures patient and operator safety.

Intended Audience

This manual is provided for the clinical medical professionals. Clinical medical professionals are expected to have working knowledge of medical terminology and procedures as required for humidifier.

Version information

This manual has a version number. The version number changes whenever the manual is updated. The version information of this manual is as follows.

Version	Date	Remarks
5	Aug 2022	According to software version :305

Contents

Chapter 1. Introduction

Product Description and Working Principle

Respiratory Humidifier is intended to be used next to the ventilator in the intensive care unit (ICU). This device is used to warm and humidify gases delivered to patients who require mechanical ventilation or other respiratory support. The humidifier is designed to be used on masked (non-invasive) or intubated (invasive) patients. It is used for adult, child and infant patients in permissible flow range (mentioned in Technical Specification chapter).

Contraindication

There are no contraindications for use of the humidifier. Respiratory support using the humidifier is a medical decision, based on clinical or patient needs.

General Warnings

- Read this manual carefully before using of the respiratory humidifier for the patient.
- This device is intended for use by qualified, trained personnel.
- Do not touch the heater plate while the device is working.
- A possible explosion hazard may exist if use in the presence of flammable anesthetic gases.
- Switch the humidifier off if gas flow is stopped or interrupted.
- Ensure that the water level in the chamber is periodically monitored.
- Make sure that gas delivered to the patient is continuously monitored and checked periodically.
- The location of the device shall be such that when necessary, the plug of the device can be easily disconnected from the electrical outlet.
- Keep power cable away from heat sources and hot surfaces.
- No modification of this humidifier is allowed by user.
- Please keep the humidifier away from the high-frequency surgical apparatus, shortwave or microwave equipment. It may affect its performance.
- Avoid tilting this device more than 10°, keep humidifier horizontally.

- Do not use the humidifier at an altitude above maximum rated altitude (from sea level) or outside a ambient temperature of rated range (Mentioned in technical specification chapter). Using the humidifier outside of this temperature range or above this altitude can affect the quality of the therapy or injure the patient.
- There will be some risks of polluting the environment associated with the disposal of the device and cables. The device and accessories shall be disposed in accordance with national laws after their useful lives.

Notes

- The warranty does not cover damages resulting from the use of accessories and consumables from other manufacturers which are not approved by SAADAT.
- Pooyandegan Rah Saadat Co. is responsible for the effects on safety, reliability, and performance of the product, only if:
  - Assembly, operations, extensions, readjustments, modifications, or repairs are carried out by the personnel authorized by Pooyandegan Rah Saadat Co.
  - The device is used in accordance with the instructions for use.
- For continued safe use of this equipment, it is necessary that the listed instructions be followed. However, instructions listed in this manual in no way supersede established medical practices concerning patient care.
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- The Respimo M2 respiratory humidifier is designed to comply with the international safety standard requirements for medical electrical equipment.

Symbols used in the respiratory humidifier

	Manufacturer address
	Refer to the operator's manual.
	Dispose according to Council Directive 2012/19/EU or WEEE (Waste Electrical and Electronic Equipment): This symbol indicates that the equipment shall be disposed of in an environmentally-friendly manner.
	Manufacture Date
SN	Serial Number
CE	CE sign & NB identification number
	TYPE BF Applied Parts
	TYPE B Applied Parts
	Caution, hot surface
IPX 1	Can resist water that drips vertically onto the product.
EC REP	Information of EU Authorized Representation
	Caution
	Protective earth (ground)

Environmental conditions

- Magnetic and electric fields may interfere with the humidifier, so make sure the electric devices around the humidifier meet relevant EMC requirements.
- Keep the humidifier away from the presence of Magnetic Resonance Imaging (MRI) equipment.
- Keep the humidifier away from the presence of a flammable Anesthetic Mixture with Air or with Oxygen or Nitrous Oxide.
- Do not use this equipment in the presence of flammable anesthetics, vapors or liquids.
- Do not use cellular phone in the vicinity of this equipment. High level of electromagnetic radiation emitted from such devices may result in strong interference with the humidifier performance.
- Electromagnetic Compatibility (EMC) - The equipment needs special precautions if it is placed close to a strong transmitter such as X-ray equipment, MRI devices, TV, AM/FM radios, police/fire stations, a HAM radio operator, an airport, or cellular phone. Their Signals could interfere with the humidifier, which may result in disruption of performance of this device.

Note

- To access information about operating and storage and transport temperature and humidity, refer to Technical Specification chapter.

Chapter 2. Function Description

The respiratory humidifier has three operating modes:

- **Invasive mode:** This mode is intended to use for intubated patients. Activate this mode, LED of Mode key and LED will light up. Adjustable temperature range for the Airway is 39 to 40 °C and for the Chamber is 37 to 42 °C. The permissible flow range in this mode is 5 to 30 L/min. The minimum humidity in this mode is 33 mg/L.
- **Non-Invasive mode:** This mode is intended to use for masked patients. Activate this mode, LED of Mode key and LED will light up. Adjustable temperature range for the Airway is 31 to 38 °C and for the Chamber is 31 to 36 °C. The permissible flow range in this mode is 5 to 60 L/min. The minimum humidity in this mode is 10 mg/L.
- **Non-Heater Wire mode:** This mode can only be used for masked patients. Activate this mode, LED of Mode key will be off and LED will light up. Adjustable temperature for the Plate is 45, 60 or 70 °C. The permissible flow range in this mode is 5 to 60 L/min. The minimum humidity in this mode is 10 mg/L.

Indicator	Mode	Available Setting	Flow Range	Humidity performance
	Invasive	Airway Temperature: 39~40 °C Chamber Temperature: 37~42 °C	5~30 L/min	>33 mg/L
	Non-Invasive	Airway Temperature: 31~38 °C Chamber Temperature: 31~36 °C	5~60 L/min	>10 mg/L
	Non-Heater Wire	Plate Temperature: 45/60/70 °C	5~60 L/min	>10 mg/L

Note: In Invasive and Non-Invasive modes, you should connect the device accessories including the temperature probe and the heater wire adapter. It is also necessary to use a heated wire breathing tube in the inspiration path. The expiratory path can be equipped with heated wire or water-trap.

Note: In Non-Heater Wire mode, there is no need for the device accessories (temperature probe and heater wire adapter). Use breathing tubes with the water-trap in this mode (for both inspiration and expiration paths).

Note: In Non-Heater Wire mode, temperature of delivered gas to patient in ambient temperature of 26°C and inlet gas temperature of 31°C is according to the below table (results are calculated using Fisher & Paykel breathing circuit, type: RT225 and RT206):

Plate Heating Level	Constant flow range (L/min)	Delivered gas temperature (°C)
1 (45°C)	5 to 60	24 to 27
2 (60°C)	5 to 60	25 to 31
3 (70°C)	5 to 60	28 to 34

Note: Use Adult breathing circuit for flow rate higher than 9 L/min and use neonate breathing circuit for flow rate higher than 5 L/min.

Note: Using the device in the extremes of ambient temperature, gas inlet temperature and/or flow rate (see Technical Specification) may affect the temperature and humidity output of the device and/or cause nuisance alarms.

Note: Operating mode and temperature settings will be saved when the device turns off.

Display screen and Keys

The device settings can be changed with the help of keys. Also, the displays of this device, depending on the working condition and condition of the device, show information about the sensors or alerts related to the alarm conditions (Figures 1 and 2).

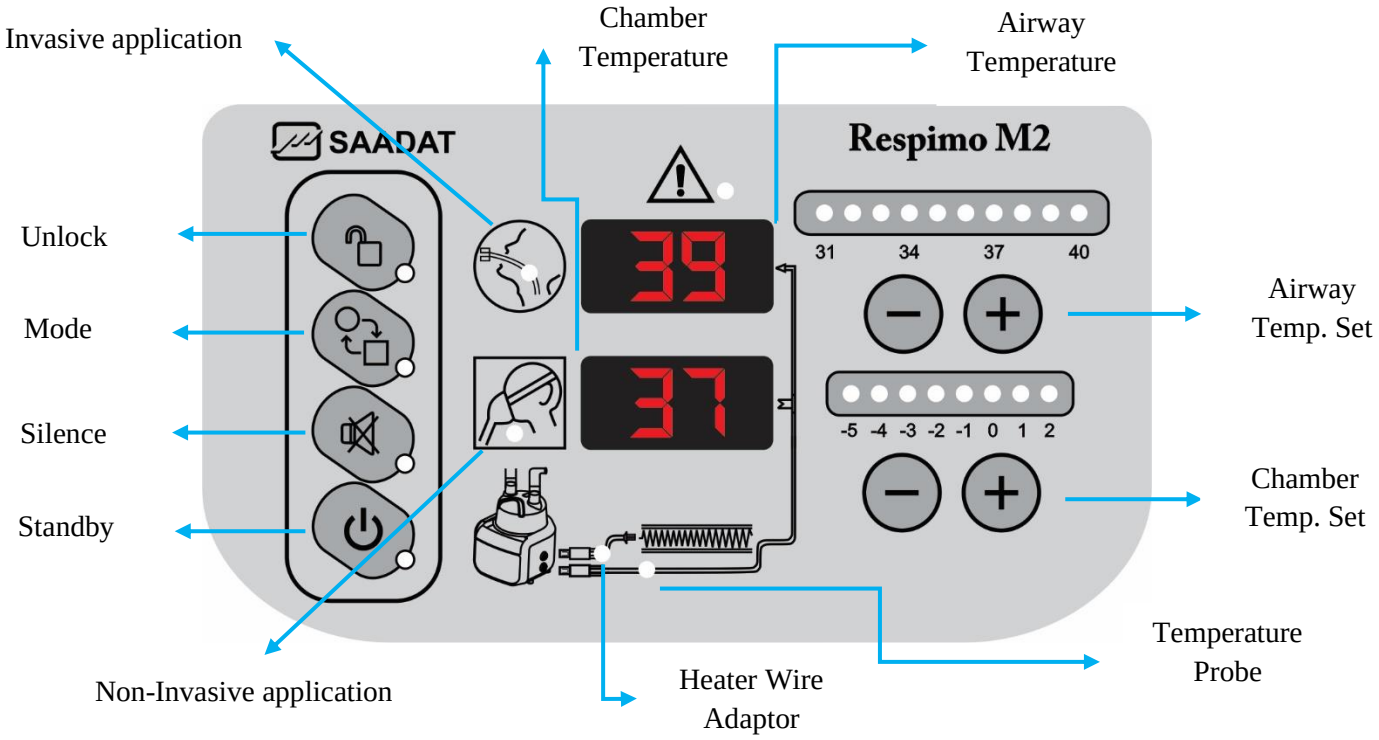


Figure 1(Keys, displays and LEDs in Invasive & Non-Invasive modes)

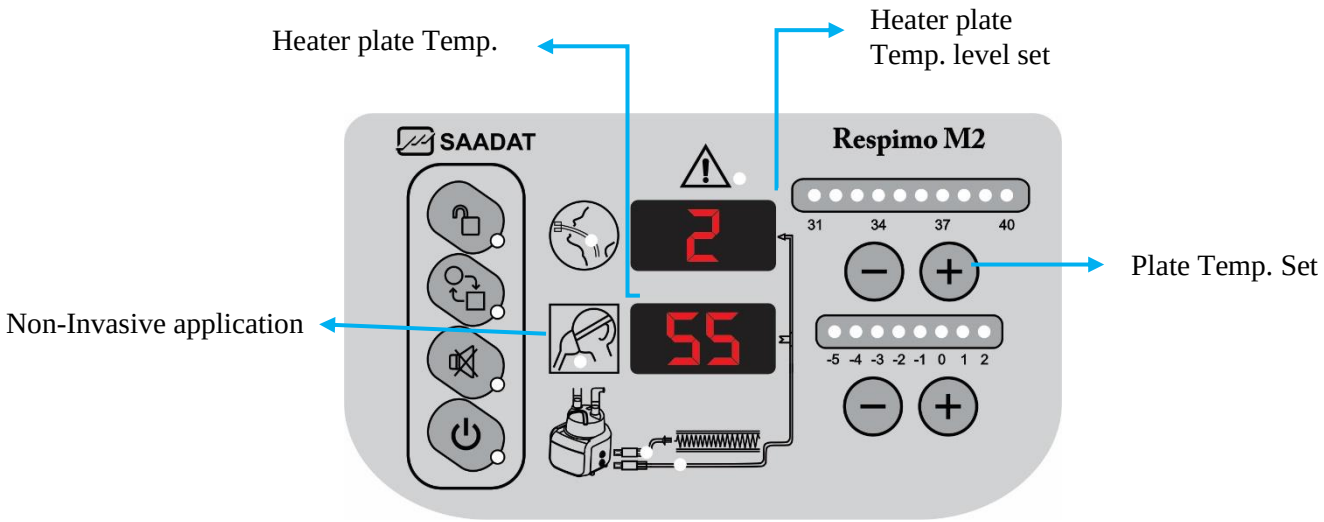
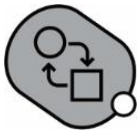
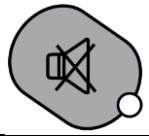
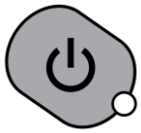
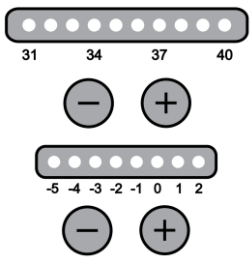


Figure 2 (Keys, displays and LEDs in Non-Heater Wire mode)

Keys function

	**Unlock key**: Press “Unlock” button until the LED turns on, then you can operate the humidifier or power off. The device will be automatically locked if no action is taken within 10 sec. All buttons except **Mute** button are locked if the user doesn’t active the Unlock button.
	**Mode key**: Press Mode key to select one of the Invasive, Non-Invasive and Non-Heater Wire modes. When LED of the Mode key is on, one of the Invasive or Non-Invasive mode is activated corresponding to or indicator. If the Mode key is off, the Non-Heater Wire mode will be activated and indicator will light up.
	**Mute key:** The key is used to turn off alarm up to 120 sec. Duration of alarm silence depends on the alarm priority and condition.
	**Standby key**: Press this key to turn on the humidifier. To turn off the device, unlock it and hold this key for 3 seconds. **Note:** If the device is locked, pressing this key will display the software version.
	**Invasive Mode** **Upper (+) and (-)** keys: To adjust airway temp. It ranges from 39°C to 40 °C. **Lower (+) and (-)** keys: To adjust the chamber control set in range of -5 to +2 corresponding to the Airway temperature in range of 37°C to 42°C. **Example**: If airway temp. is 39 °C and chamber control set is -2 °C, the chamber temp. will be 39+(-2) =37°C. **Note**: Each time the airway temp. is changed, the chamber control set will turn to -2. **Note:** If the device is locked, the plate temperature is displayed by pressing the lower (-) key**.** **Non-Invasive Mode** **Upper (+) and (-)** keys: To adjust airway temperature from 31°C to 38 °C. **Lower (+) and (-)** keys: To adjust the chamber control set in range of -5 to +2 corresponding to the Airway temperature in range of 31°C to 36°C. **Non-Heater Wire Mode** Use upper (+) and (-) keys to set the heater plate temp level (1 to 3), the heater plate temp. will set according to the below table. The lower display shows the real-time heater plate temperature.

Heater plate temp level	1	2	3
Heater plate temp set-point	45°C	60°C	70°C

Chapter 3. Installation and Setup

1. Install a mounting bracket on the ventilator trolley and place the humidifier on the seat firmly and safely.

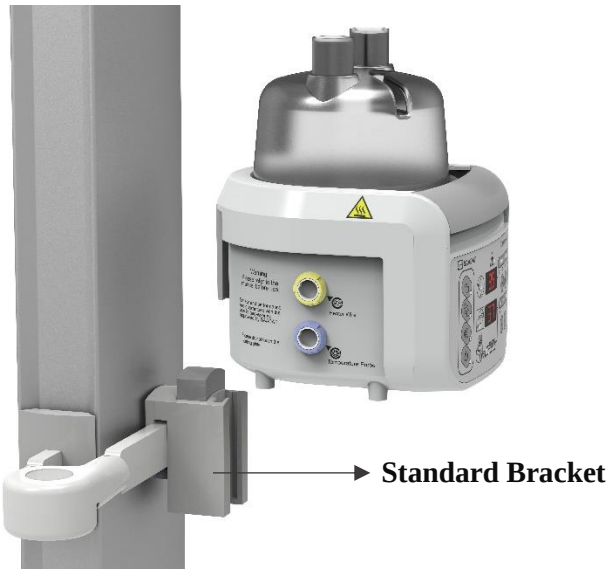


Figure 3. Humidifier Installation

- **Warning:** Ensure that the humidifier is always positioned lower than the patient's airway.
- **Warning:** Ensure the humidifier is securely mounted.

2. Slide the humidification chamber onto the heater plate. Push the chamber forward to plate. Make sure it is well-seated.

Figure 4. Humidifier Chamber

3. Fill the chamber with distilled water to the marked location.
   - **Warning:** Do not fill the chamber above the maximum fill level. Liquid could enter the breathing circuit if the chamber is overfilled.
   - **Warning:** The chamber must only be filled with water. Do not add medicine or chemical.
   - **Warning:** Do not fill the chamber with hot water.

4. Connect the breathing tubes according to one of Figure 5 or 6, depending on the device settings.
   - **Warning:** Ensure that both temperature probe sensors are correctly connected to the breathing tube. Failure to do so may cause a temperature in excess of 41°C being delivered to the patient.
   - **Warning:** Breathing circuits should be changed according to local clinical guidelines to avoid infection.
   - **Warning:** Before connecting the breathing tubes to the patient, make sure that the gas flow passes through the humidifier and the temperature probe and heater wire adapter are connected to the device and tubes.

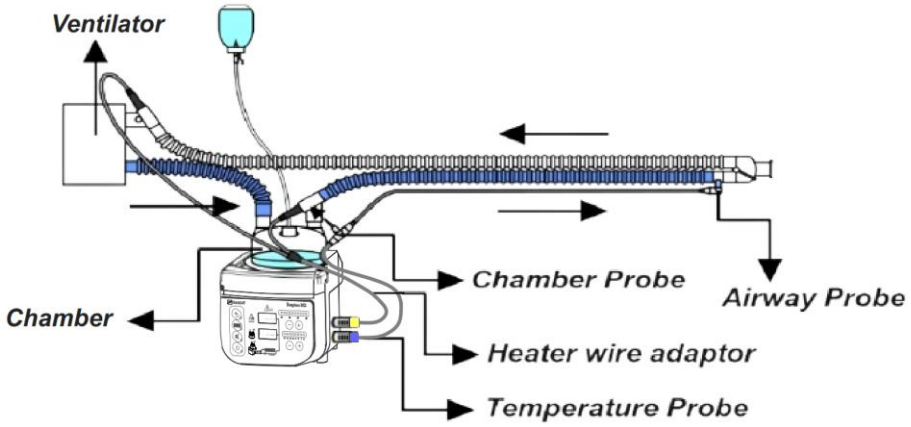


Figure 5. Breathing circuit system in Invasive & Non-Invasive modes

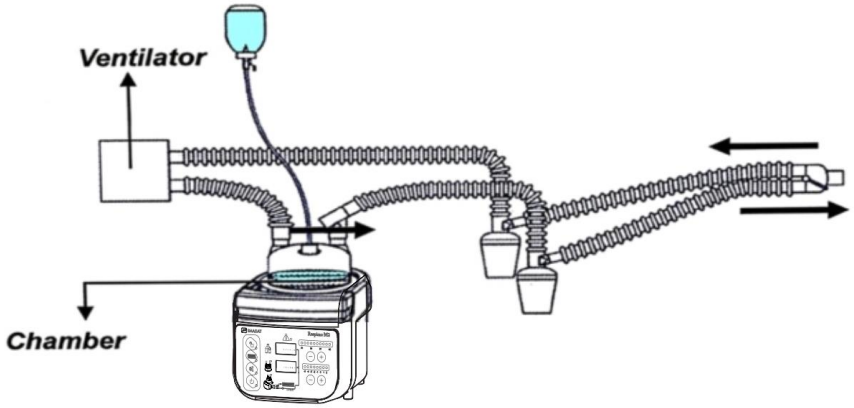


Figure 6: Breathing circuit system in Non-Heater Wire mode

5. Plug the humidifier power cable into an AC supply of the voltage and maximum power rating as specified on the device.

- **Warning:** The device must only be connected to the mains socket with protective earth.

6. Switch on the ventilator or gas supply.
7. Set the humidifier to one of the Invasive, Non-Invasive or non-Heater Wire mode and adjust the temperature (according to the chapter 2).

- **Warning:** If Invasive mode is not used for intubated patients, the required humidity may not be provided and the patient may be harmed.

Chapter 4. Alarms

To avoid any harm and injury to patient and to make user alert of functional errors, the device provides different alarms. Furthermore, some alarms are enabled by the device in case of connection failure of two connectable accessories.

Depending on alarm conditions and the severity of its cause, the device may stop heating power or only enable alarm functions.

However, user is able to mute audio alarm up to 120 seconds. This time also depends on alarm type and conditions.

Audio alarm beeps three times per 10 seconds.

Non-Heater Wire Mode Alarms

The below alarms will be enabled in this mode based on the heater plate temperature.

Alarm	Cause	Alarm announcement
High temp (Plate)	The temperature tolerance (between the plate temperature and setting) is more than 5°C.	- Audio alarm is enabled. - The upper display shows “Hi”. - The lower display flashes.
Low temp (Plate)	The temperature tolerance (between the plate temperature and setting) is lower than 5°C.	- Audio alarm is enabled. - The upper display shows “Lo”. - The lower display flashes.
Safe temp (Plate)	The plate temperature exceeds 85°C for any reason.	- Audio alarm is enabled. - The lower display flashes.

Invasive & Non-Invasive Modes Alarms

The below alarms will be enabled in this mode based on the accessories attachment (The temperature sensor and the Heater wire adaptor).

Alarm	Cause	Alarm announcement
Temperature Probe	The temperature Probe is disconnected or malfunctions.	- Audio alarm is enabled. - Temperature Probe LED flashes. - Both displays show **'---'.**
Heater Wire Adaptor	The adaptor is disconnected from the humidifier or breathing tube.	- Audio alarm is enabled. - Heater wire adaptor LED flashes.

The alarms of the Airway temperature are as below:

Alarm	Cause	Alarm manifestation
High temp (Airway)	The temperature tolerance (between the Airway temperature and setting) is more than 2°C .	- Audio alarm is enabled. - The upper display flashes.
Low temp (Airway)	The temperature tolerance (between the Airway temperature and setting) is lower than 4°C .	
Safe temp (Airway)	The Airway temperature exceeds 41°C for any reason.	

The alarms of the Chamber temperature are as below:

Alarm	Cause	Alarm manifestation
High temp (Chamber)	The temperature tolerance (between the Chamber temperature and setting) is more than 4°C for a duration of 20 minutes.	- Audio alarm is enabled. - The lower display flashes.
Low temp (Chamber)	The temperature tolerance (between the Chamber temperature and setting) is lower than 4°C for a duration of 20 minutes. (if Chamber setting lower than 35°C)	
	The Chamber temperature is lower than 31°C for a duration of 20 minutes. (if Chamber setting is above 35°C)	
Safe temp (Chamber)	The temperature tolerance (between the Chamber temperature and setting) is more than 10°C.	

Note 1: If the plate temperature exceeds 85°C, audio alarm will be enabled for patient safety.

Note 2: If the airway (chamber) temperature exceeds 70°C or falls below 10°C, “Hi” or “Lo” will be shown on the upper (lower) display and an audible alarm will be activated.

Exclamation

If exclamation mark lights up, connect after sales service of SAADAT Co.

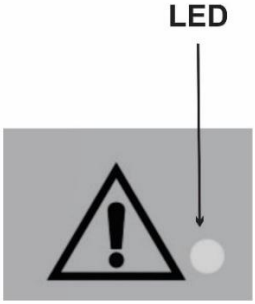


Figure 7. Exclamation mark

Chapter 5. Accessories

Accessory	Manufacturer	Part number (Manufacturer)	Part number (SAADAT Co.)	Disposable
Chamber	VADI	G-314003-P	P26311	✓
	Fisher & Paykel	MR290	P49079	
Adaptor cable	Shenzhen Pray-Med Technology Co	PHDT710	P49049	--
Temperature Probe	Shenzhen Pray-Med Technology Co	PHDT700	P49050	--
Adult Breathing Circuit (Heater Wire)	Fisher & Paykel	RT206	P49076	✓
Infant Breathing Circuit (Heater Wire)	Fisher & Paykel	RT225	P49077	✓
Adult Breathing Circuit	Altech	AL1222.V006	P26301	✓
Pediatric Breathing Circuit	Altech	AL1512.V001	P26302	✓

Warning:

- Ensure the compatibility of the humidifier and all of the parts and accessories used to connect to the patient or other equipment before use.
- To prevent disconnection of the tubing or tubing system during use, only tubes in compliance with ISO5367 or ISO 8185 should be used.
- Covering breathing tubes with a blanket or heating them in an incubator or with a heater can affect the quality of the therapy or injure the patient
- Do not use any accessory not listed in this chapter to the humidifier, otherwise the humidifier might malfunction and affect the quality of the therapy or injure the patient.

Chapter 6. Care and Cleaning

Cleaning and disinfection

The following is the recommended cleaning procedure for the Respiratory Humidifier. Cleaning should be performed as required or after each patient.

1. Disconnect the humidifier from the electrical outlet.
2. Clean the humidifier using a cloth dampened with soapy water or a mild detergent. Use one of the following agents to disinfect the device:
   - 70% alcohol
   - Isopropyl alcohol
   - N-propanol
3. Wipe the humidifier clear of any cleaning residues before use.

Caution

- DO NOT immerse the humidifier in any liquid.
- Using other solutions may damage the humidifier.
- DO NOT autoclave or sterilize humidifier.

Please pay special attention to the following items:

1. The humidifier and its belongings shall be kept dust-free.
2. Do not use strong solvents such as acetone or ammonia.
3. Most cleaning agents must be diluted before use.
4. Don't use rough or sharp materials or your fingernail to remove stubborn stains.
5. Do not let the cleaning agents enter into the chassis of the system.
6. Do not leave the cleaning agents on any part of the equipment.

- **Warning:** Do not use EtO gas to disinfect the humidifier.
- **Warning:** Disconnect the mains plug from the socket before cleaning.
- **Warning:** There are not portions of the gas pathway through the humidifier that can become contaminated with body fluids or expired gases.

Breathing Circuit System

The breathing circuit system components and chamber are single-use. Dispose of them according to local regulations.

The following table summarizes cleaning, disinfecting and sterilizing procedures of different parts of the device:

Device parts	Single-use	Cleaning	Disinfection	Sterilization
External surface of device and accessories	-	In-between patients and as required, wipe gently using a moist cloth with warm soapy water or a mild detergent.	In-between patients or as required use: • 70% alcohol • Isopropyl alcohol • N-propanol	To avoid extended damage to the equipment, sterilization is not recommended for this device and its relevant accessories and supplies, unless indicated in the Instructions for use or when stipulated as necessary in the Hospital Maintenance Schedule.
Patient tubing system and chamber	Change for each patient.	-	-	-

Preventive Maintenance (PM)

To ensure that the device is kept in the best condition, it shall be kept clean and all requirements related to the maintenance of the device shall be met. There is no repairable part in the device and all repairs shall be done by the manufacturer.

Storage

The storage environment shall be clean and dry. If possible, use the original packaging of the device.

- **Note:** If the humidifier or equipment falls from a height and is damaged or if placed in an environment with high temperature and humidity, contact the company's after-sales service at the earliest opportunity to ensure the correct operation.
- **Note:** Thoroughly clean the device after that it has not been used for a while.

Weekly check of the following items is recommended:	Monthly check of the following items is recommended:
1. Device cleanness 2. Visual inspection of device (case, screen, keys and indicators) 3. Visual inspection of accessories	1. Calibration label 2. Visual inspection of device 3. Device cleaning 4. Function of keys and indicators 5. Visual inspection of accessories

The preventive maintenance (PM) checklist #PL-F-78/0 should be completed by responsible individuals of healthcare center. It should be noted that PM checklist only is used to perform systematic inspection of the equipment and will not guarantee their correct function.

Preventive Maintenance (PM) Checklist

SAADAT Co.					
Form No. : PL-F-78/0		**PM Form (humidifier)**			
State:	**City:**	**Medical Center:**	**Ward:**		
Device model:	**Serial number:**	**Installation date:**	**Inspection date:**		
No.	**Test and Inspection Item**		**OK**	**NOK**	**N/A**
1	Visual inspection	No damage or breakage in the casing			
		Check the heater plate for deep scratches			
		Check temperature probe for damage to sensor tips, abrasion of the cable or varnishing of electrical contacts.			
		Check the heater wire for damage to cable and both end plugs.			
2	Alarm	Alarm activation			
		Correct function of alarm LEDs			

Chapter 7. Troubleshooting

Repairing the internal parts of the humidifier must be only done by trained and authorized personnel of After Sale Service; otherwise manufacturer will not take any responsibility for any possible hazard to the patient and the humidifier.

Troubleshooting guide is intended to help users to solve the humidifier problems caused by user misuse of the humidifier or failure of accessories.

When you face any problem, please ensure that you have followed all procedures mentioned in Corrective Action column before you contact with After Sale Service.

This is a guide to possible corrective actions in the case of humidifier alarm condition or malfunction. It has been basically written for humidifiers using the heater wire. Thus, some parts of this guide would not be applicable for the humidifier in the Non-Heater Wire mode.

Fault Symptoms	Possible Cause	Corrective Action
The device does not turn on	• Connection failure to the power supply. • The power cord is faulty.	• Check POWER AC path • Call for service
The device not heating	• Loose connections	• Check electrical connections. Check on/off button after electrical connections. If the problem persists, contact your local Customer Service.
Temperature less than desired, no alarm.	• The humidifier is warming up. • The temperature sensor is not in position.	• Wait for a few minutes. • Check position of the temperature sensor in the circuit.
The airway temperature alarm activated.	• Sudden spurious increase in gas flow. • Gas flow is stopped or interrupted. • The temperature sensor is not in the housing. • Gas flow rate is too low.	• Wait for temperature to fall below the threshold. • Turn the humidifier off until gas flow resumes. • Fit the temperature sensor. • Increase gas flow to more than 5 L/min.
The chamber temperature alarm activated.	• Poor thermal contact between base of the chamber and the heater plate. • The temperature sensor is not inserted in the chamber outlet. • No water in the chamber.	• Check that the chamber base and the heater plate are clean and smooth. If necessary, clean or replace them. The humidification chambers which are not supported by SAADAT may not be suitable. • Fit the temperature sensor correctly. • Refill humidification chamber.

Temperature fluctuating	• Ventilation rate is too low or too erratic for proper humidifier temperature control. • The humidifier temperature control is influenced by external heating or cooling such as air conditioner. • The temperature sensors are incorrectly positioned. • Possibility of the temperature sensor malfunction (Could be intermittent short or open circuit).	• Ventilation rates lower than about 6 bpm or of a highly erratic nature may affect the stability of the temperature control. • Shield the breathing circuit from external influences. • Check the temperature sensor position in the circuit. • Check the sensor for wire cutting or breakage.
Excessive water in inspiratory circuit due to condensation.	• Water trap is not at the lowest point of the circuit. • The inspiratory circuit is being cooled by air conditioner. • The chamber temperature set is too high.	• Position the water trap at the lowest point of the circuit. • Shield the circuit from air conditioner. • Reduce the chamber setting.
Water ejected from humidification chamber into the circuit.	• The humidification chamber has been filled beyond the maximum water level. • The maximum permissible flow rate of humidification chamber has been exceeded. • The humidifier chamber is tilted.	• Reduce water level. • Use correct chamber. Refer to the operating instructions for the maximum flow rate. • The chamber should be balanced.
Low humidity.	• The chamber control setting is low. • No water in the humidification chamber. • The chamber temperature is low. • Gas flow rate is too high.	• Increase the setting. • Fill the chamber. • The chamber base and the heater plate are smooth, clean and in good contact. (The chambers not supported by Saadat may not be suitable). • Check the maximum flow rate in the operating instructions.
Temperature sensor alarm (‘---’ appears on the display).	• The temperature probe is unplugged. • The temperature probe plug is dirty. • The temperature probe is faulty.	• Check connection. • Clean the plug. • Replace the probe.
The heater wire alarm	• The heater wire is unplugged. • The heater wire is damaged. • The heater wire adaptor is not connected to the breathing tube.	• Check connection. • Replace the heater wire. • Connect the adaptor to the breathing tube.
Exclamation mark alarm	• Improper condition of the device use. • Hardware failure	• Allow the heater plate to cool to ambient temperature, then turn on the humidifier. • Call for service.

Chapter 8. Technical Specifications

Electrical Specification	Frequency	50/60Hz
	Voltage	220 VAC
	Heater Plate Power	100W
	Heater Wire Power	60W
Operating Condition	Ambient Temperature	18~26 ℃
	Humidity	30~85% (non-condensing)
	Pressure	70~106 KPa
	Altitude	3,000 m above sea level
Storage &transport Condition	Temperature	-10~60 °C
	Relative humidity	5% – 95% (non-condensing)
Gas inlet temperature	Minimum = Ambient temperature, Maximum = 5°C above ambient temperature	
Warm-Up time	≤30 minutes	
Invasive Mode	Airway Temp: 39~40 °C Chamber Temp: 37~42 °C Flow Rate: 5~30 L/min	
Non-invasive Mode	Airway Temp: 31~38 °C Chamber Temp: 31~36 °C Flow Rate: 5~60 L/min	
Non-Heater Wire Mode	Plate Temp:45/60/70 °C Flow Rate: 5~60 L/min	
Display Range of temperature probe	10℃~70℃	
Accuracy of temperature probe	±0.5℃ (In 25~45 ℃ temp. range)	
Heater Plate Thermal Cutout	95±5℃	
Single/Dual/Non heated wire compatible	Yes	
Noise level	<50dB	
Humidity performance	Invasive: >33mg/L Non-Invasive: >10mg/L Non-Heater Wire: >10mg/L	
Alarm parameter	Safety Temp alarm High Temp alarm Low Temp alarm	
Display	Dual 3 digit, 7 segment LED	
Dimensions (H*W*D)	110*145*157 mm	
Weight	Enclosure	1.1 kg
	Complete System (+Filled chamber)	1.4 Kg
Standards And approvals	Standard class	Class I, Type BF
	IP standard	IP X1
	Comply with	IEC 60601-1, IEC 60601-1-2, ISO 8185
Power Cable	2m	

Appendix I. EMC

- **Warning:** Use only the recommended manufacturer accessories. Using other accessories may lead to excessive emissions or low immunity of the system.
- **Warning:** The measurements can be affected by mobile and RF communications equipment. It should be assured that the humidifier is used in the specified electromagnetic environment.
- **Warning:** To prevent EMC effect on the device, it should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the equipment should be observed to verify correct performance in the configuration in which it is intended to be used.
- **Warning:** Do not use cellular phone in the vicinity of this equipment. High level of electromagnetic radiation emitted from such devices may result in strong interference with the humidifier performance.

EMC Declaration for Respimo-M2

Guidance and manufacturer's declaration – Respimo-M2 emissions		
The Respimo-M2 is intended for use in the electromagnetic environment specified below. The customer or the user of the Respimo-M2 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 2	The Respimo-M2 must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	The Respimo-M2 is suitable for use in all establishments.
Harmonic emissions IEC 61000-3-2	N.A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N.A	

Guidance and manufacturer's declaration – electromagnetic immunity			
The Respimo-M2 is intended for use in the electromagnetic environment specified below. The customer or the user of the Respimo-M2 should assure that it is used in such an environment.			
Immunity test	**Port**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	Enclosure	±8 kV contact ±2 kV, ± 4kV, ± 8kV, ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
	Patient coupling	N.A	
	Signal input/output parts	N.A	
Electrical fast transient/burst IEC 61000-4-4	Input a.c. power	N.A	
	Signal input/output parts	N.A	
Surge IEC 61000-4-5	Input a.c. power	N.A	
	Signal input/output parts	N.A	
Voltage dips, IEC 61000-4-11	Input a.c. power	N.A	
		N.A	
Voltage interruptions IEC 61000-4-11	Input a.c. power	N.A	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	Enclosure	30 A/m 50 Hz or 60 Hz	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 test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The Respimo-M2 is intended for use in the electromagnetic environment specified below. The customer or the user of the Respimo-M2 should assures that it is used in such an environment.			
Immunity test	**Port**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	Input a.c. power	N.A	
	PATIENT coupling		
	Signal input/output parts		

Radiated RF IEC 61000-4-3	ENCLOSURE	3 V/m, 80 MHz - 2,7 GHz, 80% AM at 1 kHz	
Proximity fields from RF wireless communications equipment IEC 61000-4-3	ENCLOSURE	Refer to the following table (table 9 of EN 60601-1-2: 2015)	

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band [a)] (MHz)	Service [a)]	Modulation [b)]	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380- 390	TETRA 400	Pulse modulation [b)] 18 Hz	1.8	0.3	27
450	430- 470	GMRS 460, FRS 460	FM [C)] ±5 KHz deviation 1 KHz sine	2	0.3	28
710	704- 787	LTE Band 13, 17	Pulse modulation [b)] 217 Hz	0.2	0.3	9
745						
780						
810	800- 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b)] 18 Hz	2	0.3	28
870						
930						
1720	1700- 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4 25; UMTS	Pulse modulation [b)] 217 Hz	2	0.3	28
1845						
1970						
2450	2400- 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b)] 217 Hz	2	0.3	28
5240	5100- 5800	WLAN 802.11 a/n	Pulse modulation [b)] 217 Hz	0.2	0.3	9
5500						
5785						

a) For some services, only the uplink frequencies are included.
b) The carrier shall be modulated using a 50% duty cycle square wave signal.
c) As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.