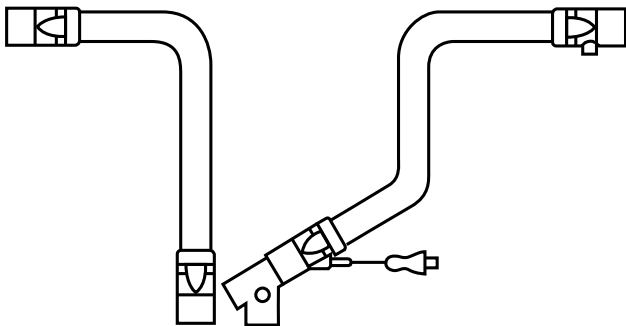




Instructions for Use

Passive Heated Breathing Circuit

VC1114 Series



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MADE IN CHINA

IFU-00040 Rev 2.04
2025-08-04












The Passive Heated Breathing Circuit is intended to convey moistened breathing gas between the humidifier and patient. The user has to ensure, that the physical properties of the circuit are suitable for the humidifier, ventilator and application. The circuit consists out of a connection tube and inspiratory limb. The Passive Heated Breathing Circuit can be used in a hospital or homecare environment in combination with the Fisher and Paykel MR 850 Heated Humidifier. The circuit is intended for single-use only.

Table of Contents

1. Symbols on the packaging
2. Warnings and Cautions
3. Intended Use
4. Device Description
5. Directions for use
6. Cleaning and disposal
7. Operating Conditions
8. Storage and Transport Conditions
9. EMC Compliance
10. Product Specifications
11. Warranty

PLEASE READ ALL INSTRUCTIONS CAREFULLY BEFORE USE

1. Symbols on the Packaging

	Observe the warning and safety instructions in the user's manual.
	Follow the user's manual
	Manufacturer
	Catalog number
	Batch number
Rx only	CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician
	Single Use
	Use-by date
	Do not use the product if the package is damaged.
	Permissible storage temperature
	Air humidity during storage and transport.
	Type BF Applied Part

2. Warnings and Cautions

- Only use the Passive Heated Breathing Circuit in combination with the MR850 Heated Humidifier from Fisher & Paykel Healthcare.
- Retain these instructions for use for future reference.
- Always connect-disconnect the tubes from the humidifier, ventilator and mask by using the grips on the cuff.
- Do not pull the tube when disengaging the tube from the humidifier, ventilator or mask.
- When using electrical products, always follow the standard safety precautions!
- Do not cover the Passive Heated Breathing Circuit with any object including a textile insulation sleeve, a plastic sleeve, a blanket, etc., in order to avoid an elevated airflow temperature that can cause irritation of the airway.
- Do not operate the Passive Heated Breathing Circuit close to other heat sources including lamps, electric blankets, etc., to avoid elevated airflow temperatures.
- Do not use wireless communication devices (such as mobile phones) close (<30 cm or 12 inches) to the Hybernite RT breathing tubes, to avoid interference with the system, which can negatively impact the functioning of the Humidifier/ventilator.
- Do not use other cables and accessories because these could possibly have a negative effect on EMC and result in improper operations.
- Do not use the Passive Heated Breathing Circuit without airflow.
- Do not sterilize the Passive Heated Breathing Circuit.
- Do not disassemble or intentionally damage the Passive Heated Breathing Circuit.
- Do not insert or drop any object in the opening of the Passive Heated Breathing Circuit.
- Do not make the Passive Heated Breathing Circuit subject to pressure, crushing or other mechanical stresses, as it can damage the Passive Heated Breathing Circuit.
- If any tube of the Passive Heated Breathing Circuit is damaged (having holes, kinks, tears, exposed heating wires, etc.) or is not functional, do not try to repair the tube yourself. Immediately replace your Passive Heated Breathing Circuit.

- Prior to use, inspect the Passive Heated Breathing Circuit for holes, deformation or any form of damage. When damaged, replace the Passive Heated Breathing Circuit immediately.
- Proper hand hygiene (e.g. hand washing or hand disinfection) is mandatory before and after replacement of the device.
- During use, check the Passive Heated Breathing Circuit frequently for holes, deformation or any form of damage. When damaged, replace the Passive Heated Breathing Circuit immediately.
- Do not reuse the Passive Heated Breathing Circuit. The Passive Heated Breathing Circuit is a single use product. Multiple use could lead to contamination of the product and the patient.
- The Passive Heated Breathing Circuit should always be replaced after 14 days of use.
- Do not clean the Passive Heated Breathing Circuit.
- Dispose of the tube correctly according to your local government regulation.
- This is a prescription device to be used exclusively under medical supervision.
- If too much condensate accumulates, a partial or complete blockage of the circuit can occur. Regularly check the breathing circuit for condensate and empty if necessary.
- When operated in a room with air conditioning, the breathing circuit must not be positioned directly next to the outlet ports of air conditioning units. Avoid drafts.
- Do not use the product with other medicinal substances besides Oxygen.
- Patients undergoing ventilation support are particularly susceptible to airway infections. Single use devices that are not replaced within the prescribed frequency may be a potential source of infection. Proper hand hygiene (e.g. hand washing or hand disinfection) is mandatory before and after replacement of the device.

3. Intended Use

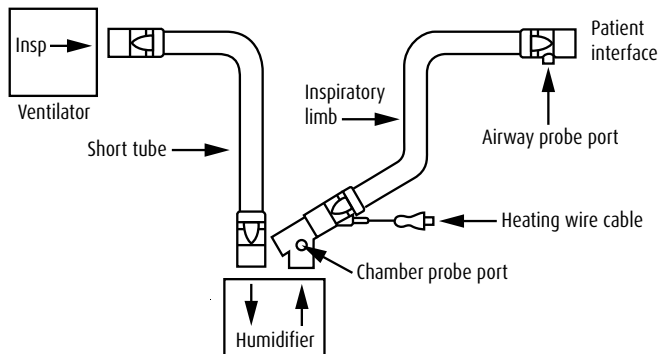
The Passive Heated Breathing Circuit is used to carry moistened gas from the humidifier to the patient requiring mechanical ventilation.

The Passive Heated Breathing Circuit is single-use only.

4. Device Description

Passive Heated Breathing Circuit:

1. Short tube
2. Inspiratory limb



5. Directions for Use

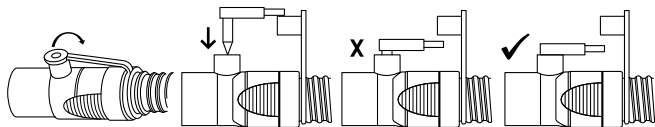
System compatibility

The Passive Heated Breathing Circuit is available for adult (VC1114) and pediatric (VC1114P) patient categories.

All the cuffs of the Passive Heated Breathing Circuit are standard cuffs. As such, the Passive Heated Breathing Circuit can be connected to ventilators and masks that have standard male/female outlet connectors (ISO 5356-1).

How to connect

1. Remove the Passive Heated Breathing Circuit from the packaging.
2. Before setup, check your tubing and connectors for any damage. Also ensure that there is sufficient water in the reservoir of the MR850 Heated Humidifier.
3. Connect the short tube to the ventilator and MR850 Heated Humidifier chamber.
4. Connect the inspiratory limb (blue tube) to the MR850 Heated Humidifier chamber.
5. Remove the port plug before inserting the airway probe.
6. Push the chamber temperature probe and airway temperature probe into the breathing circuit. Ensure that both probes are correctly and securely fitted. Refer to below picture:



7. Connect the heating wires of the MR850 Heated Humidifier to the cables of the tubes.
8. Verify that all connections are properly made.
9. Ensure there is a flow of air through all of the tubing.
10. Connect to the patient interface (e.g. mask, endotracheal tube) and use in accordance with the instructions in your patient interface, ventilator system or MR850 Heated Humidifier operating manual.

6. Cleaning and Disposal

The product is delivered in a clean status and is ready for use, unless the package has been opened or damaged. This is a single use product. Dispose of the product once the patient therapy has been completed or after maximum 30 days of usage.

Upon disposal clearly mark or damage the product to ensure that the product is not reused. Disposal of the device shall be made in accordance with applicable hospital or national regulations for biologically hazardous waste.

7. Operating Conditions

Ambient Temperature: 18°C – 26°C, 64.4°F - 78.8°F

Relative humidity: 5% – 95%

Atmospheric pressure: 800 - 1200 hPa

Maximum operating pressure: 60 hPa

Humidifier output:

- Invasive ventilation @3 l/min to 60 l/min ≥ 33 mg/l
- Non-invasive ventilation @ 3 l/min to 80 l/min ≥ 10 mg/l

A-weighted sound pressure level for Adult and Pediatric population <50 dB

8. Storage and Transport Conditions

The device and its components should be transported and stored in their original packaging and protected from direct sunlight and dust.

Temperature during storage and transport should not exceed 40°C (103°F) or be below 0°C (32°F) at a relative humidity from 5 % to 95%, non-condensing

9. EMC Compliance

Radiated RF Emission levels

Phenomenon	Immunity test levels	
	Professional healthcare facility environment	Home healthcare environment
Emissions	Compliance	
Radiated RF Emissions CISPR 11	Group 1	
Radiated RF Emissions CISPR 11	Class B	

Immunity levels

Phenomenon	Immunity test levels	
	Professional healthcare facility environment	Home healthcare environment
Immunity Test	Compliance ¹	
Electrostatic Discharge IEC 61000-4-2	+ 8 kV contact	
	+ 2 kV, + 4 kV, + 8 kV, + 15 kV air	
Radiated Immunity IEC 61000-4-3	3 V/m 80 MHz-2,7 GHz 80% AM at 1 kHz	10 V/m 80 MHz-2,7 GHz 80% AM at 1 kHz
Power Frequency Magnetic Field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	

¹ Complies without any deviations from IEC 60601-1-2 and normative references.

Proximity fields from RF wireless communication equipment, Immunity test levels:

Frequency Range and Level: RF wireless communication equipment		
Frequency (MHz)	Modulation	Immunity Level (V/m)
Test	Compliance ²	
385	Pulse Modulation: 18Hz	27
450	FM + 5Hz deviation: 1kHz sine	28
710 - 745 - 780	Pulse Modulation: 217Hz	9
810 - 870 - 930	Pulse Modulation: 18Hz	28
1720 - 1845 - 1970	Pulse Modulation: 217Hz	28
2450	Pulse Modulation: 217Hz	28
5240 - 5500 - 5785	Pulse Modulation: 217Hz	9

¹ Complies without any deviations from IEC 60601-1-2 and normative references.

² Compliance with immunity test levels specified in IEC 60601-1-2, without deviations.

10. Product Specifications

Patient category	Product	Specification	Short tube	Inspiratory limb	Expiratory limb
Adult	TUB006SHBT (Included with VC1114)	Length	0.6m / 2ft	1.6m / 5ft 0.25"	n.a.
		Internal diameter	19mm	19mm	
		Flow resistance, R@80l/min, R@30l/min, R@7.5l/min	<0.06hPa/l/min	<0.06hPa/l/min	
		Compliance, C@60hPa	<5ml/hPa	<5ml/hPa	
		Leakage @60mbar	<10ml/min	<10ml/min	
Pediatric	VC1114P	Length	0.6m / 2ft	1.7m / 5ft 6.75"	n.a.
		Internal diameter	15mm	15mm	
		Flow resistance, R@30l/min, R@15l/min, R@3l/min	<0.12hPa/l/min	<0.12hPa/l/min	
		Compliance, C@60hPa	<4ml/hPa	<4ml/hPa	
		Leakage @60mbar	<10ml/min	<10ml/min	

11. Warranty

The Passive Heated Breathing Circuit is a respiratory consumable product and must be checked before first use otherwise warranty claims are excluded.

