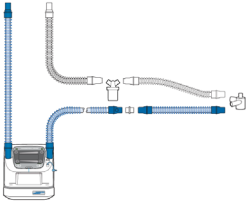

REF 260189

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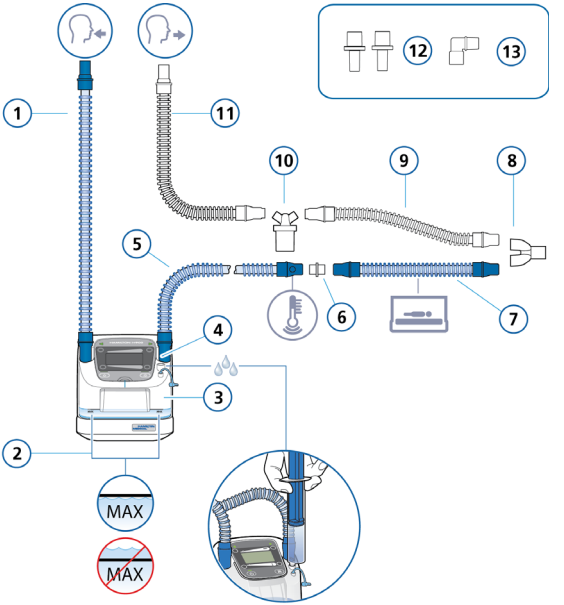
HAMILTON MEDICAL

Breathing circuit diagram



1 Ventilator inspiratory limb (blue) to humidifier

2 MAX filing level mark. *Do not exceed this level.*

3 Humidification chamber

4 Water fill port and stopper. *Ensure the cap is closed during operation.*

5 Heated inspiratory limb (blue) with temperature probe to patient

6 Straight connector 10M/10M

7 Unheated inspiratory limb (short, blue) to patient

8 Y-piece, 10M/10M/15F

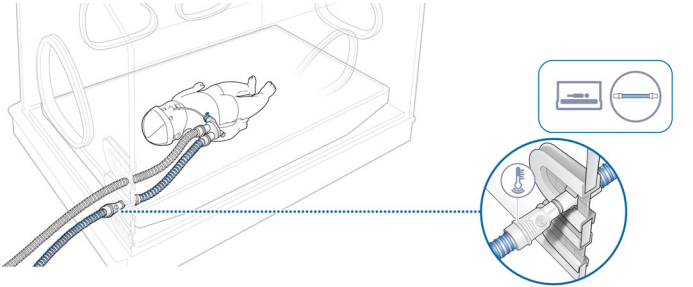
9 Expiratory limb (long, white) from patient

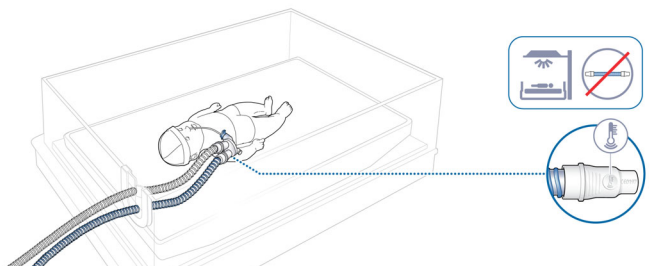
10 Water trap, 10M/10M

11 Expiratory limb (short, white) to ventilator

12 Straight connector, 10M/15M

13 Adapter, 90°, 22M/15F/22F





EN

HAMILTON-BC8010-A breathing circuit set, dual limb, heated, with humidification chamber

Instructions for use

REF 260189

Conventions

⚠ WARNING

Alerts the user to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of the device.

⚠ CAUTION

Alerts the user to the possibility of a problem with the device associated with its use or misuse, such as device malfunction, device failure, damage to the device, or damage to other property.

NOTICE

Emphasizes information of particular importance.

1 Overview

The HAMILTON-BC8010-A breathing circuit set (PN 260189) can only be used with the HAMILTON-H900 humidifier. For an overview of the breathing circuit set and its components, see page 2.

1.1 Intended use

The HAMILTON-BC8010-A breathing circuit set is intended to be used together with compatible Hamilton Medical respiratory gas humidifiers during invasive and noninvasive mechanical ventilation of pediatric and neonatal patients.

The breathing circuit set is intended for use by qualified, trained personnel under the direction of a physician and within the limits of its stated technical specifications.

2 Safety information

⚠ WARNING

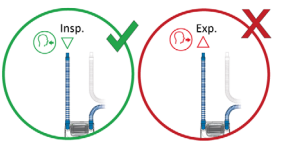
- The breathing circuit set including the humidification chamber must be cleaned, disinfected, and autoclaved before use.
- Follow the instructions in the *HAMILTON-BC8010-A Reprocessing Guide* (PN 624915) to clean and sterilize the product.
- Inappropriate reprocessing may cause malfunction of the product. The use of ETO gas may lead to increased cancer rates in patients and users. Hamilton Medical does not warrant the proper functioning of breathing circuit sets if they are cleaned or reused by the user in an inappropriate manner.

- Hamilton Medical cannot be held responsible for the correct functioning of flow sensors that are not cleaned and sterilized according to Hamilton Medical's reprocessing instructions for the autoclavable flow sensor.
- Adding attachments or other parts/assemblies to a breathing system can change the pressure gradient across the ventilator, which can adversely affect ventilator performance and patient safety.
- Discard the product if it fails two subsequent preoperational checks or if there is any sign of damage.
- Follow hospital infection control procedures for all tests and use.
- Connect only a single breathing circuit set at a time. Do *not* connect any circuit as an extension to another one. Doing so can seriously harm or kill the patient.
- Before using the humidifier on the patient, verify that the breathing circuit is correctly connected to the ventilator as follows:

  – The BLUE inspiratory limb is connected to the *To patient* inspiratory port.

  – The WHITE expiratory limb is connected to the *From patient* expiratory port.

  Failure to connect the limbs to the proper ventilator ports can result in delivery of overheated gas to the patient.



- Use caution when positioning the breathing circuit. Place the breathing circuit in such a way that condensation cannot reach the patient.
- Heated limbs must *not* be placed directly on the patient's skin. Attach breathing circuits or tubing holders appropriately to avoid mechanical forces on the ET tube.
- Route the breathing circuit without tension and without any kinks from the ventilator or humidifier to the patient, and protect against unintended influences.
- The humidifier must always be positioned below patient level. Do *not* operate the humidifier at an angle in excess of 10°.
- The breathing circuit set must *not* be covered by any objects, such as sheets, towels, and so on.
- Do *not* touch the hot plate or the bottom of the humidification chamber. The surfaces can reach a temperature of over 85°C. These hot surfaces radiate heat.
- Do *not* use heated breathing circuit sets without existing gas flow. If the gas supply is interrupted, the humidifier must be turned off or be in Standby mode.

- Do *not* add any drugs or medication directly to the water in the humidification chamber. If the HAMILTON-H900 is used in combination with any medical gases or nebulized medications, follow the instructions for use of the supplied application and ensure it is suitable for use with active humidification
- Only fill the humidification chamber with sterile, demineralized water that meets the hospital's hygiene requirements.
- Do *not* operate the device if the water level in the humidification chamber exceeds the marked maximum (MAX).
- Check the water level regularly and refill if needed.
- Regularly check the breathing circuit for condensation, and drain if required.
- Do *not* use this breathing circuit set with humidifiers other than the HAMILTON-H900.
- During high-frequency oscillation (HFO), regularly check the patient condition and ventilation settings, and refer to the HFO device *Operator's Manual*.

⚠ CAUTION

- *(USA only) Federal law restricts this device to sale by or on the order of a physician.*
- *Check the breathing set for damage prior to use. Discard the breathing set if there is any sign of damage.*
- *Handle used products as contaminated goods according to local laws and regulations or hospital internal procedures.*
- *The temperature symbol on the temperature probe must always face up and be visible.*
- *Use the unheated limb extension only inside the incubator.*
- *Always place the heated limb with the temperature probe outside the incubator.*
- *If the ambient temperature is outside the recommended range (18°C to 26°C), physiological humidity levels may not be achieved. Humidification performance is not guaranteed outside of this range.*

NOTICE

- Before use, read the *HAMILTON-H900 Humidifier Instructions for Use*.
- Any incident with the product leading to serious patient injury, death, or a potential threat to public health must be reported to the manufacturer and the relevant authorities.
- The refill water should *not* be warmer than 37°C.
- Before using the breathing circuit set on the patient, a Leak (tightness) test must be carried out. If this test fails, it may be repeated once. After two consecutive failed tests, the breathing circuit set must be replaced by a new one.
- Ensure that the water supply to the humidification chamber is functioning properly.
- Do *not* apply pressure to the water reservoir once the water refill has automatically stopped and the water has reached the maximum level.
- Follow the *Instructions for use* of the corresponding ventilator when using a pressure line.
- Check the stability of all connections, prior to use.

- Set the appropriate ventilator alarms.
- Ensure the humidifier is placed in Standby or turned off before disconnecting any components.
- Incompatible parts can result in degraded performance, which can affect safety.

3 About the breathing circuit and breathing circuit sets

The breathing circuit comprises the limbs with integrated heater wire and integrated temperature probe. The breathing circuit set comprises the breathing circuit and the humidification chamber with water feed line.

4 Connecting the breathing circuit

Note that the limb connectors on the humidifier combine electrical connections with breathing circuit connectors. Ensure proper orientation of electrical contacts on the breathing circuit connectors to match the connecting element on the humidifier.

For an overview of the breathing circuit set and its components, see page 2.

To connect the breathing circuit set to the humidifier and ventilator

Illustrations for connecting the breathing circuit set are provided after the instructions.

1. Hang the patient end of the breathing circuit on the tubing support arm.
2. Holding the humidification chamber in one hand and the breathing limbs to the ventilator in the other, insert the humidification chamber into the humidifier until it clicks into place (Figure 1).
3. Connect the BLUE ventilator inspiratory limb to the *To patient* inspiratory port on the ventilator (Figure 2).

   Ensure that you connect the BLUE inspiratory limb to the *To patient* inspiratory port on the ventilator, and the WHITE expiratory limb to the *From patient* expiratory port on the ventilator.

   Connecting the limbs to the incorrect ports can cause a buildup of heat in the humidification chamber, with the risk of delivering overheated gas to the patient.
4. Connect the WHITE expiratory limb to the *From patient* expiratory port on the ventilator (Figure 3).
5. Manually fill the humidification chamber using a syringe (Figure 4).

   Be sure not to fill the chamber above the marked MAX level.
6. Continue setting up the breathing circuit set components, such as flow sensor and patient interface, as required for your patient.

Figure 1. Insert the humidification chamber

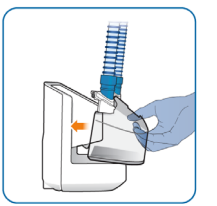


Figure 2. Connect BLUE inspiratory limb to *To patient* inspiratory port on the ventilator

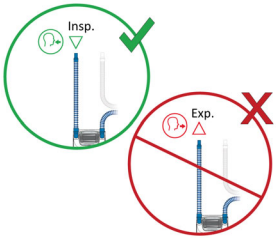


Figure 3. Connect WHITE expiratory limb to *From patient* expiratory port on the ventilator

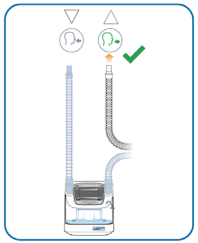
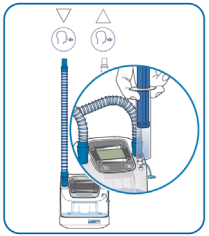


Figure 4. Insert water spike into water supply and open the air release cap on the spike



5 Cleaning, disinfection, and reprocessing

For detailed reprocessing instructions, use the information provided in the *HAMILTON-BC8010-A Reprocessing Guide* (PN 624915). The guide is available online at the Resource Center at: https://www.hamilton-medical.com/Resoucecenter.html.

Registration is free.

A printed copy can be sent to you upon request; contact your Hamilton Medical technical representative.

6 Delivery

The components are delivered clean and ready for clinical use.

7 Disposal

A used component must be handled as contaminated. Follow all local, state, and federal regulations with respect to waste management and environmental protection when disposing of used parts.

8 Technical specifications

Parameter	Specification
Flow range	1 to 30 l/min
Connectors Ventilator: Patient:	Conical according to ISO 5356-1 15F 10ID/15OD
Compliance (at 60 cmH2O)	1.2 ml/cmH2O
Compressible volume	700 ml
Water volume (max)	200 ml
Flow resistance (at 15 l/min) Inspiration: Expiration:	 1.6 cmH2O 1.7 cmH2O

Parameter	Specification
Gas leakage (at 60 cmH2O)	< 40 ml/min
Maximum operating pressure in humidification chamber	10 kPa
Circuit length	1.60 m (approx. 5 ft)
Compatibility	HAMILTON-H900 humidifier
Operating temperature	Recommended: 18°C to 26°C
Atmospheric pressure	61 to 106 kPa
Maximum operating duration	28 days
Conforms to	IEC 60601-1:2005/ A1:2012 ISO 80601-2-74:2017 EN ISO 5356-1:2015 EN ISO 5367:2014 IEC 62366-1:2015 ISO 10993-1:2018 ISO 13485:2016

9 Symbols on device and packaging

See page 11.

Symbols on device and packaging

	Manufacturer		Date of manufacture
	Catalog number		Batch code
	Quantity		Follow the Instructions for use
	Autoclavable		Applicable to neonatal/pediatric patient groups
	Do not use if packaging is damaged		Do not use any blades, knives, or cutters to open; they can damage the product
	MR Unsafe		Medical device
	Use-by date		Humidity limitation
	Atmospheric pressure limitation		Temperature limit
	*To patient* inspiratory port		*From patient* expiratory port
max	Filling level mark on humidification chamber		Restricted use of hazardous substances in electronic and electrical parts
EAC	EurAsian Conformity (EAC) mark		Temperature probe. Marks the location of the temperature probe on the breathing circuit set.

	For use in incubator.		For use in warming bed.
EC REP	Authorized representative in the European Community/European Union	Rx USA only	Prescription only – device restricted to use by or on the order of a physician
CE 0197	CE Marking of Conformity, seal of approval guaranteeing that the device is in conformance with the Council Directive 93/42/EEC concerning medical devices		

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