



HYBERNITE

Superday

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Instructions For Use

Hybernite ROC 2300 Rainout Control System

The Hybernite Rainout Control System helps to prevent moisture condensation in the breathing tube of adult patients requiring continuous positive airways pressure or mask ventilation. The system consists of a heated breathing tube and an independent power supply. The Hybernite Rainout Control System can be used in the sleep lab and in the home.

Hybernite Rainout Control System

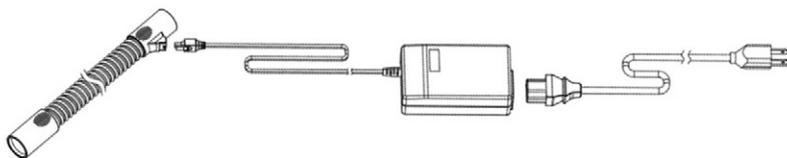


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PLEASE READ ALL INSTRUCTIONS CAREFULLY BEFORE USE

1. Warnings and Cautions

- Always use the Hybernite Rainout Control System in combination with humidification to avoid elevated airflow temperatures.
- Retain these instructions for use for future reference.
- Always connect-disconnect the heated breathing tube from the humidifier and mask by using the grips on the cuffs.
- Do not pull the tube when disengaging the tube from the humidifier.
- When using electrical products, always follow usual safety precautions!
- Do not place or drop the Hybernite power supply into water or other liquid.
- If the Hybernite power supply does fall in water, do not attempt to retrieve it. Unplug the power supply immediately.
- Do not use the Hybernite Rainout Control System when the room temperature exceeds 86°F (or 30°C) in order to avoid an elevated airflow temperature and potential irritation of the patient airway.
- Do not cover the heated breathing tube 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 your Hybernite Rainout Control System close to other heat sources including lamps, electric blankets, etc., to avoid elevated airflow temperatures.
- Do not use the Hybernite Rainout Control System without airflow.
- Do not heat or sterilize the Hybernite heated breathing tube.
- The Hybernite Heated Breathing tube is for single patient use only.
- Do not use (microwave) ovens, fans or any other appliances to dry the heated breathing tube after washing. See cleaning instructions.
- Do not use brushes or objects to clean the inside of the heated breathing tube as it may damage the tubing.
- Do not disassemble or intentionally damage the heated breathing tube.
- Do not insert or drop any object in the opening of the heated breathing tube.
- Do not place materials or objects on the tube as it can damage the heated breathing tube.
- Only use replacement parts (heated breathing tube, power supply) recommended by Plastiflex Healthcare for your Hybernite Rainout Control System.
- Only use the Hybernite Heated Breathing Tube with the included power supply. Do not use with any other power source.
- Do not clean the power supply using water or any other liquid.
- If the tube is damaged (having holes, kinks, tears, exposed heating wires, etc.) or not functional, do not try to repair the tube yourself. Immediately replace your heated tube.
- Immediately replace your power supply when the power cord, lead or connectors are damaged.
- Dispose of the tube correctly according to your local government regulation.
- Upon permanent disposal, mark the tube so that it is not used by any other patient.
- Replace the tube immediately when damaged, and as often as recommended by your physician or respiratory therapist.
- In the USA, Federal law restricts this device to sale by or on the order of a physician
- The heated breathing tube should always be replaced after 12 month's usage.

2. Intended Use

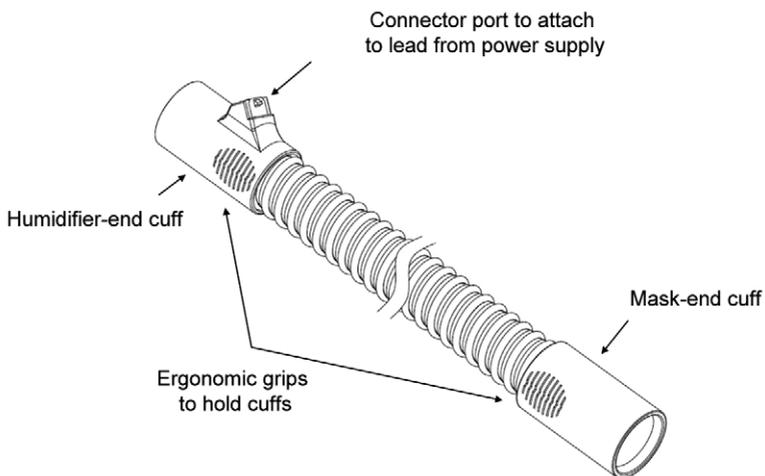
The Hybernite Rainout Control System is used to prevent condensation of humidified air delivered to patients requiring positive airway pressure or mask ventilation.

The Hybernite Rainout Control System is indicated for use in the home or sleep-lab setting by a single adult patient. It can also be used in conjunction with supplemental Oxygen. The Hybernite Rainout Control System is indicated for non-invasive ventilation.

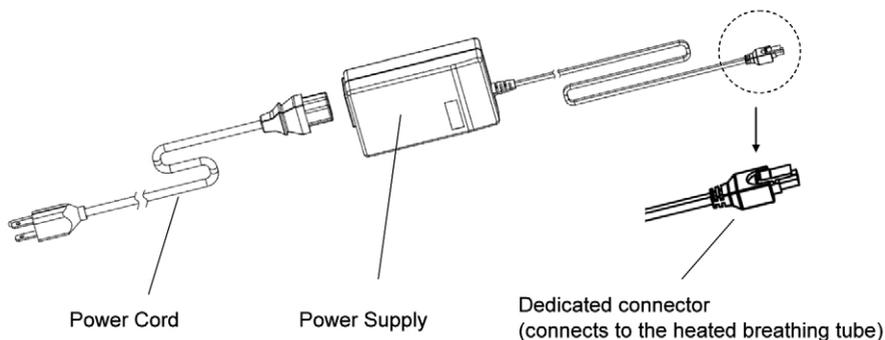
The Hybernite Rainout Control System is intended to help adult patients that have problems with rainout in their tubing when used in combination with heated humidification and who currently do not have an effective solution to prevent rainout. By preventing condensation, the Hybernite Rainout Control System will contribute to your therapy comfort. The Hybernite Rainout Control System is intended for adult patients only.

3. Device Description

Hybernite HBT-300 Heated Breathing Tube



Hybernite V12 Power supply with power cord



4. Directions for use

Humidification System compatibility

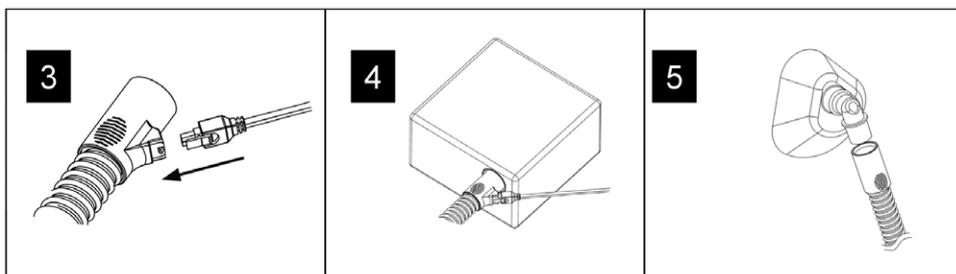
The Hybernite Rainout Control System consists of a heated tube and an independent power supply.

The Hybernite heated breathing tube has standard cuffs on both the humidifier-end cuff and mask-end cuff. As such, the Hybernite heated breathing tube can be connected to heated humidifiers that have standard male outlet connectors.

For example: Respironics M Series Humidifier and Philips Respironics System One Humidifier

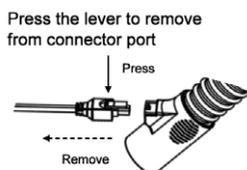
How to connect

1. Remove the packaging from the heated breathing tube.
2. Before setup, check your tubing, connector and power supply for any damage.
3. Connect the connector lead from the power supply to the connector port located in the humidifier-end cuff.
4. Connect the heated breathing tube with the humidifier-end cuff to the outlet of the humidifier.
5. Connect the mask-end cuff to the mask.
6. Ensure there is a flow of air through the tubing.
7. Plug the power cord plug in the wall power socket and place the power supply on the floor.
8. Verify the power supply is functional by checking the LED indicator on the power supply.
9. Apply mask and use as directed by your physician or respiratory therapist in accordance with the instructions in your CPAP or mask ventilator system operating manual.



How to disconnect

Press the lever and carefully pull the lead connector to disconnect the lead connector from the heated tube.



5. Cleaning

Warnings:

1. Do not clean the power supply with water or any liquid.
2. Do not use harsh soaps, detergents, solvents or alcohols to clean the tube.
3. Only reassemble the system when the tube is fully dry.
4. Do not use a dishwasher to clean the heated tube.

Cleaning Instructions:

1. Clean the heated breathing tube every day.
2. Press the lever and pull the connector housing to disconnect the connector lead from the heated breathing tube connector port.
3. Wash the heated breathing tube in slightly warm, mild soapy water.
4. Rinse the tube using clean water.
5. Gently tap the connector cuff to remove the surplus of water from the connector port.
6. Hang-up the heated breathing tube with both cuffs hanging towards the floor.
7. Allow the tube to dry.

6. Operating Conditions

Ambient Temperature: 41°F – 86°F (5°C – 30°C)

Relative humidity: 5% – 95%

7. 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 140°F (60°C) or be below -4°F (-20°C) at a relative humidity from 5 % to 95%.

8. Frequently Asked Questions

Question: What happens if I connect the mask-end cuff to the humidifier and the humidifier-end cuff to the mask?

Answer: The Hybernite Rainout Control System will function similarly as with the correct connection (mask-end cuff to mask and humidifier-end cuff to humidifier). However, to achieve maximum comfort and safety always connect the tubing in the correct direction, as instructed.

Question: Can I use the heated tubing without connecting to the power supply?

Answer: Yes, the tubing will act like a standard CPAP tube. However, rainout might occur.

Question: When do I replace my Hybernite heated breathing tube?

Answer: The heated tubing is intended to be replaced every 3 to 6 months or according to insurance provider recommended schedule.

If damaged, leaking or malfunctioning, replace your Hybernite heated tube immediately.

Question: With what humidifiers or flow generators can I use my Hybernite Rainout Control System?

Answer: The cuffs of the Hybernite Heated Breathing Tube have the same internal dimensions as the cuffs of a standard CPAP tube. You can use the Hybernite heated breathing tube with all humidifiers to which a standard CPAP tube fits.

9. Product Specifications

Heated Tubing

Length	1.83 m
Internal Diameter	19 mm
Flow resistance	$60 \text{ l}\cdot\text{min}^{-1} \leq 0.1 \text{ kPa}$
Tubing Compliance Standards	ISO 5367:2000 ISO 8185:2007
Water resistance	IPx3

Electrical Ratings

Supply Frequency	50-60 Hz
Supply Voltage to power supply	110V - 220V
Supply Voltage and current to tube	12 Volt; 2.0 A
Power Heated Tube	18W max
Electrical Safety Standard	EN 60601-1 Type B Applied Part ()
Water resistance power supply	IPx1

10. Replacement Components

Description

Hybernite HBT 300 Heated Breathing Tube

Please ask your physician, respiratory therapist or home care provider for advice on replacement schemes. The heated tubing should not be used for longer than 6 months.

11. Warranty

- The Hybernite® Heated Breathing Tube warranty is 30 days under normal operating conditions. This is based on 8 hours/day usage.
- The Hybernite® V12 PSU warranty is 1 year at continuous 24 hours per day usage. (At 120 VAC, 60Hz., and rated load current.)



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