

Heated Tubing:

Hybernite ROC 2300 Rainout Control System

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 noninvasive 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.

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 patient interface 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 Switching Power Adaptor into water or other liquid.
- If the Switching Power Adaptor 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 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.
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- 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 dedicated Switching Power Adaptor
- 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.
- Replace the tube immediately when damaged, and as often as recommended by your physician or respiratory therapist.

The heated breathing tube should always be replaced after 12 month's usage.

- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF 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 Hybernite Heated Breathing Tube, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Hybernite Rainout Control System complies to the applicable Radiated RF Emission levels, in order to prevent adverse events to the patients and operator due to electromagnetic disturbances. In order to prevent adverse events to the patients and operator due to electromagnetic disturbances do not modify or change Hybernite Heated Breathing Tube.

CLEANING

Cleaning Instructions:

- Weekly cleaning is advised.
- Press the lever and pull the connector housing to disconnect the connector lead from the heated breathing tube connector port.
- Disconnect the heated breathing tube from the humidifier and mask patient interface by using the grips on the cuffs.
- Wash the heated breathing tube in slightly warm, mild soapy water. 4. Rinse the tube using clean water.
- 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.
- Allow the tube to dry.

Warnings:

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