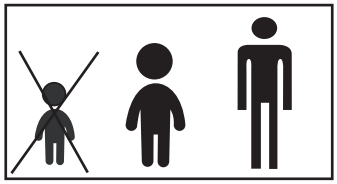
AirLife DuoTherm®

REF **HFT377HI**

AirLife DuoTherm® Adult High Flow Therapy Circuit

Dual-Wall, Single Limb Heated Wire Circuit with Humidification Chamber and Filter



Symbols Glossary			
REF	Catalogue Number	Rx ONLY	Caution: U.S. Federal law restricts this device to sale by or on the order of a Licensed Healthcare Practitioner.
LOT	Lot Number		Manufacturer
QTY	Quantity		Use-by-Date
LATEX	Not made with natural rubber latex	PHT DEHP	Not made with DEHP
	Follow Instructions for use	Single Use	Do not re-use
	Caution	MR	MRI Unsafe
	Warning	%	Humidity Limitation
	Keep away from sunlight	STORAGE TEMP	Storage Temperature

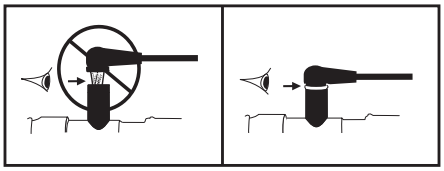
AirLife
2710 Northridge Dr. NW, Suite A
Grand Rapids, MI 49544 USA
www.myAirLife.com
Made in Mexico

AirLife®

Contents:

- Humidifier Dry Line, 22 mm ID x 22 mm ID
- Humidification Chamber
- Gown Clip
- Cable/Tubing Clips (3ea)
- B/V Filter, 22 mm ID x 22 mm OD
- Inspiratory Line, 22 mm ID x 22 ID (Blue)

Figure 1: Temperature probe installation



Intended Use:

The AirLife DuoTherm® Circuit, when used with a Humidification System, is intended to add moisture and warmth to breathing gases administered to patients that require assistance breathing or mucosal humidification. Gases that are available for medical use do not contain sufficient moisture and may damage or irritate the respiratory tract.

Indications for Use:

The AirLife DuoTherm® Adult Heated-Wire Circuits are intended to deliver and warm breathing gases before they enter the patient's airway. The Adult Heated-Wire Circuits are used with the adult population and pediatric population, specifically those with an ideal body weight of 30 kg or above, that requires mechanical ventilation, positive pressure breathing or general medical gases, respectively. The Adult Heated-Wire Circuits are used for flow rates greater than 3 LPM. The product is single-use, non-sterile, and used in professional healthcare environments under the supervision of a licensed healthcare practitioner.

Warnings:

- Risk of burns or patient injury - avoid prolonged contact of breathing circuit with patient's skin.
- DO NOT stretch or milk breathing tube. Doing so may affect performance and patient safety if heating wires are dislodged.
- DO NOT reuse the circuit on more than one patient. Reuse may result in transmission of infectious substances, interruption to treatment or serious patient harm.
- Using circuit for more than 30 days, or humidification chamber for more than 14 days, may affect the performance and safety.
- Route the circuit tubing to avoid pinch points and crush damage. Damage to tubing and/or interruption of gas delivery to patient may occur.
- This product is for use only by trained professionals under a doctor's supervision.
- DO NOT add attachments or accessories to the device that are not listed in the instructions for use, otherwise the device might not function correctly affecting the quality of therapy or injuring the patient.
- Operation in an environment outside of the ambient temperature range of 18 to 26°C (64 to 79°F) may affect system performance or may cause harm to the patient.
- To prevent inadvertent disconnections and partial or complete loss of respiratory gas delivery, only use this device with equipment, accessories, and patient/airway interfaces with connectors that are compliant with ISO 5367. Ensure all connections are firmly secured, especially during ambulatory use.
- Strangulation can result from a patient getting entangled within the breathing circuit.
- To avoid contamination of the circuit, do not allow the breathing tube to contact the floor during setup.
- DO NOT use this product with High Frequency Oscillatory Ventilation (HFOV) equipment.
- Position the device with humidification chamber lower than the patient. This directs any liquid water buildup in the tubing away from the patient.
- DO NOT place material on or around heated wire tubing. Objects such as heavy tapes, towels, or bed linens may over-insulate the circuits, impede normal heat convection, and cause damage to tubing or interruption of gas delivery to the patient.
- During installation, position the breathing circuit so that the risk of tripping or of stepping on the breathing circuit is minimized.
- Secure all connections and check for leaks. Perform pressure, leak and occlusion tests prior to connecting to patient.
- DO NOT use heated breathing circuit in conjunction with a heat and moisture exchanger (HME). There is a risk of pressure buildup and of insufficient ventilation as a result of water accumulating in the HME.

- DO NOT exceed the maximum peak flow rate specified in the technical specifications. Doing so may eject liquid water into the circuit and harm the patient.
- DO NOT modify the heated circuit. Modification may damage or impair the proper functioning of the device which may lead to patient injury.

⚠ **Cautions:**
- DO NOT use this circuit with devices or accessories other than those specified in Technical Specifications Table.
- DO NOT use heated wire circuit without gas flow. Heated circuits must have a minimum gas flow through tubing at all times. Operating circuits with lower flow rates may result in reduced patient humidification and increased condensation in circuit tubing.
- Essential Performance of the heated wire circuit and heated humidifier is to prevent drying of the mucosa and airway secretions in patients requiring supplemental humidification during respiratory therapy. During therapy, measured gas temperatures can fluctuate around set gas temperatures without affecting essential performance.
- DO NOT route circuits underneath patient to avoid/prevent burns or pressure ulcers.
- Portable and mobile RF communications equipment can affect Medical Electrical Equipment.
- Operation in direct sunlight should be avoided.
- Administering aerosolized medications or metered dose inhalers through the humidification chamber and circuit tubing may adversely affect device performance, including temporary changes in gas temperatures and/or delivered humidity levels to the patient.
- Administering aerosolized medications using gas-powered jet nebulizers may cause temporary temperature alarms and accumulation of condensation in circuit tubing.
- Use only USP sterile water for inhalation for filling the humidification chamber. Adding other substances such as drugs or human blood derivatives directly into the humidification chamber may have adverse effects on system performance.
- The medical professional is responsible for the compatibility of the device and accessories used to connect to the patient, ventilator and other equipment before use.
- DO NOT exceed the maximum average continuous flow rate specified in the technical specifications section. Doing so may result in inadequate humidity delivery and drying of mucosa and secretions.
- Covering breathing tubes with a blanket can affect quality of the therapy or injure the patient.
- DO NOT soak, rinse, wash, re-use, or sterilize this product. The breathing circuit has been designed, tested, and manufactured exclusively for single-use.
- Do not use the medical device if the packaging is damaged.
- Supervise children and pets during operation of the respiratory device.
- Do not soak, rinse, wash or sterilize the filter.
- Soaking, rinsing, washing, steam, cold or gas sterilization of this filter device may result in either retention of harmful residual gases in the filter or dangerously increase its breathing resistance.
- Replace filter every 24 hours or more frequently, as required, to avoid increased resistance.

Necessary User Qualifications:
The end-user should receive training on the proper use of the device and be familiar with the indications for use, warnings and cautions as stated in the IFU.

Setup:
1. Inspect contents for damage before use.
2. Connect dry line between device (or gas source) and Humidification Chamber. Install the filter between device outlet and dry line.
3. Connect inspiratory manifold of Inspiratory Line to the remaining Humidification Chamber port.
4. Connect the appropriate Temperature Probe and/or Heated Wire Adapters, per the System Compatibility Chart.
5. Firmly insert T-shaped temperature probe into Chamber Temperature Probe Port (see Figure 1).
6. Firmly insert L-Shaped temperature probe into the Remote Patient Temperature Probe Port (See Figure 1).
7. Ensure probes are fully inserted into temperature probe port of breathing tube (See Figure 1).
8. Connect the Temperature Probe and Heated Wire Adapters to the device (see System Compatibility Table).
9. Connect patient interface, e.g. HFNC, Vented NIV Mask, or Hood, to patient connection port.
10. Route cables through Cable/Tubing Clips.

Test:
- Ensure that all connections are tight. Some connections are deliberately assembled only finger tight and must be firmly secured.
- Test circuit prior to use by occluding patient connection port and pressure test circuit to ensure that there are no leaks. Also, check that there are no occlusions by allowing gas to flow and ensure that gas is emitted from patient connection port.

Safe Disposal:
Dispose of all materials in accordance with local, state, and federal regulations. Decontaminate and dispose of all potentially biohazardous material.

Incident Reporting:
Notice to the user that any serious incident that has occurred in relation to the device should be reported to the manufacturer at, productquality@myairlife.com.

Technical Specifications:

Dimensions	
Length	72 in ± 4 in (183 ± 10 cm)
Minimum Inner Diameter	17 mm
Dual Wall	Yes
Electrical Specifications	
Operating Voltage	~22 V
Power Consumption - Inspiratory	30 W Max
Technical Specifications	
Leakage at 60 cmH_2O	<25 mLPM @ 60 cmH_2O
Compliance	1.10 mL/hPa/LPM @ 60 cmH_2O
Flow Resistance	0.03 hPa/LPM @ 15 LPM 0.06 hPa/LPM @ 30 LPM
Maximum Operating Pressure	13.2 kPa (2 psi)
Minimum Flow Rate	3 LPM
Maximum continuous flow rate to maintain minimum humidity levels per ISO 80601-2-74	60 LPM
Max Rated Peak Flow Rate per ISO 5367	200 LPM for 3 sec
Environment Temperature & Humidity	
When operating	18º to 26°C 0-85% RH
During Storage and Transport	-20º to 50°C 0-85% RH
Patient	
Population	Pediatric/Adult
Recommended IBW	30 - 150 kg

System Compatibility		
Base System	**377HTR AirLife DuoTherm® Humidification System**	**HFT750U AirLife DuoTherm® High Flow Therapy Device**
Temperature Probe	377PR5E; 377PR6 / 377PR6E	HFTCBL
Heater Wire Adapter	377ASL / 377ADL	
Pressure Relief Valve	AH115-05E *	Not applicable

* Use AH115-05E when delivering high flow oxygen therapy with a gas source that does not include an integrated pressure relief valve.

B/V Filter Performance Specifications	
Bacterial Filtration Efficiency (B.F.E.)	**> 99.999%** when tested to ASTM F2101-22 specification
Viral Filtration Efficiency (V.F.E.)	**> 99.99%** when tested to ASTM F2101-22 specification
NaCl Filtration Efficiency	**> 99.0%** when tested to ISO-23328-1 specification
Resistance to Flow	**1.55 cmH_2O @ 60 lpm** when tested to ISO 23328-2 specification

