AirLife DuoTherm®

REF **37712CE**

AirLife DuoTherm® Neonate Single Limb Circuit Kit

Dual-Wall, Single Limb Heated Wire Circuit with Chamber Contains 37712CE Circuit, 377CBRE Humidification Chamber

Symbols Glossary			
REF	Catalogue Number	Rx ONLY	Caution: U.S. Federal law restricts this device to sales 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	85% 0%	Humidity Limitation
	Keep away from sunlight	50°C -20°C Storage Temp	Storage Temperature
	Do not throw in trash		

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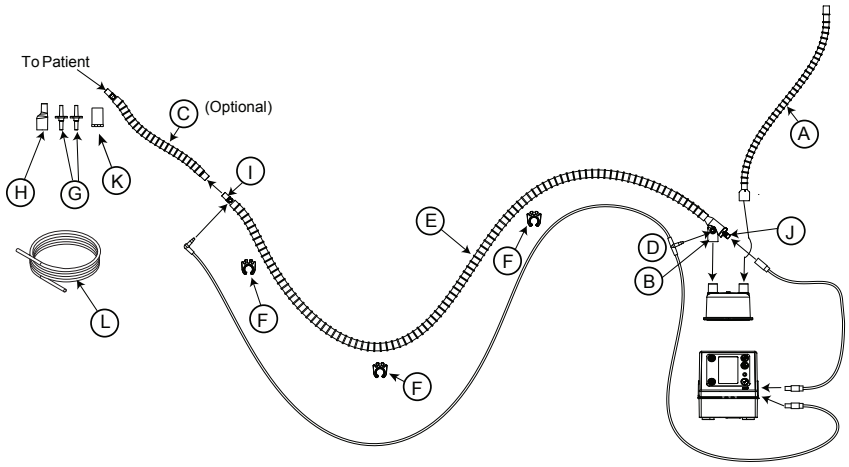
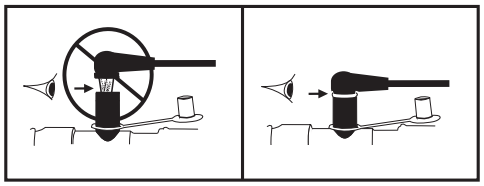
AirLife®



- (A) Humidifier Dry Line, 15 mm OD/11.5 mm ID x 22 mm ID
- (B) Inspiratory Manifold, 22 mm ID
- (C) Unheated Inspiratory Extension Line (Optional)
- (D) Humidification Chamber Temperature Probe Port
- (E) Inspiratory Line (Blue)
- (F) Cable/Tubing Clips
- (G) Pressure Line Adapter, 4.5 mm OD
- (H) High Flow Cannula Adapter
- (I) Remote Patient Temperature Probe Port
- (J) Inspiratory Heater Wire Connector (Blue)
- (K) 15 mm OD Adapter for Insp Line
- (L) Proximal Pressure Line (Optional)

Figure 1: Temperature probe installation



Intended Use:
The AirLife DuoTherm® 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.

Note: This breathing circuit is a compatible accessory to the 377HTR AirLife DuoTherm® Series heated humidifier.

Indications for Use:
The AirLife DuoTherm® Neonate Heated-Wire Circuits are intended to deliver and warm breathing gases before they enter the patient's airway. The Neonate Heated-Wire Circuits are used with a pediatric population, specifically the neonate (birth to 28 days) and infant (29 days to 2 years) pediatric subgroups with an ideal body weight of 0.5 to 8 kg that requires mechanical ventilation, positive pressure breathing or general medical gases. The Neonate Heated-Wire Circuits are used for flow rates greater than 1 LPM. The product is single patient 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.
- This product is intended to be used for a maximum of 30 days.
- Using device for more than 30 days may affect the performance and safety.
- Route the circuit tubing to avoid pinch points and crush damage. Damage to the tubing and or interruption of gas delivery to the patient may occur.
- This product is for use only by trained professionals under a doctor's supervision. The end-user should receive training on the proper use of the device and familiar with the indications for use, warnings and cautions as stated in the IFU.
- DO NOT add any attachments or accessories to humidifier that are not listed in the instruction for use of the humidifier or accessory or humidifier might not function correctly affecting the quality of the 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 baby or child getting entangled within 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 humidifier with humidification chamber lower than the patient. This directs any liquid water build up 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 the 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 leakages. Perform a 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.
- High Flow Nasal Cannula (HFNC) therapies require the use of a ventilator or pressure limiting device such as a relief valve to prevent damage to the system in the event of an occlusion.
- 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 humidifiers, heated wire adapters, or temperature probes 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 (minute volume + background /bias flow) 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 heated humidifier, 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 humidifier 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 or heating them in an incubator or with an overhead heater 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.
- To avoid contamination, keep the circuit packaged until ready to be used. Do not use the medical device if the packaging is damaged.
- Supervise children and pets during operation of respiratory humidifier.

Necessary User Qualifications:
This device is restricted to sale by or on the order of a physician. The end-user should receive training on the proper use of the device and 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 (A) between ventilator (or gas source) and Humidification Chamber.
3. Connect inspiratory manifold (B) of Inspiratory Line (E) to the remaining Humidification Chamber port.
4. When using supplemental patient warming under lights or an incubator,

connect unheated extension (C) to the Inspiratory Line (E). The Unheated Inspiratory Extension Line (C) should be removed when caring for patients in an open, unheated area of care.

5. Firmly insert T-shaped temperature probe into Chamber Temperature Probe Port (D).
6. Firmly insert L-Shaped temperature probe into the Remote Patient Temperature Probe Port (I).
7. Ensure probes are fully inserted into temperature probe port of breathing tube (See Figure 1).
8. Plug temperature probe into the heated humidifier.
9. Plug heater wire adapter into heated humidifier.
10. Plug light blue end of heater wire adapter to light blue Inspiratory Heater Wire Connector (J).
11. If needed, install and use the pressure line (L) for patient pressure monitoring. Utilize adapters (G) in the accessory bag as needed.
12. Use provided accessories and adapters (H) or (K) to adapt to patient interfaces, e.g. High Flow Oxygen Cannula or nCPAP.
13. Route cables and pressure lines through Cable/Tubing Clips(F).

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, and the competent authority of the Member State in which the user and/or patient is established.

Technical Specifications:

Dimensions	
Length	60 in ± 3 in (152 ± 8 cm)
Minimum Inner Diameter	10 mm
Dual Wall	Yes
Electrical Specifications	
Operating Voltage	~22 v
Power Consumption - Inspiratory	30W Max
Technical Specifications	
Leakage at 60 cmH_2O	<25 mL/min @ 60 cmH_2O
Compliance	0.20 mL/hPa/L/min @ 60 cmH_2O
Flow Resistance	Insp: 0.07 hPa/L/min @ 2.5 L/min
Maximum Operating Pressure	13.2 kPA (2 psi)
Environment Temperature & Humidity	
When operating	21º to 26°C 0-85% RH
During Storage and Transport	-20º to 50°C 0-85% RH
Patient	
Population	Neonatal/Infant
Recommended IBW	0.5 - 8 kg
Recommended Minimum Vt	2 mL
Recommended Maximum Vt	50 mL
Minimum Flow Rate (bias flow + minute volume)	1 L/min
Max Rated Peak Flow Rate per ISO 5367	8 L/min
System Compatability	
Heated Humidifier	377HTR AirLife DuoTherm Series
Chamber	377CBRE
Temperature Probe	377PR5E 377PR6/377PR6E
Heater Wire Adapter	377ASL/377ADL
Pressure Relief Valve	AH115-05E