REF 377CBRE

AirLife DuoTherm® Humidification Chamber

Compatible with AirLife DuoTherm® Heated Humidifier

SYMBOL GLOSSARY

REF	Catalogue number	85% 0%	Humidity Limitation
LOT	Lot Number		Manufacturer
QTY	Quantity	MR	MR Unsafe
	Consult Instructions for Use	Single Use	Do not re-use
	Caution	–MAX–	Maximum Water Level
LATEX	Not made with natural rubber latex		Use-by Date
Rx ONLY	U.S. Federal law restricts this device to sales by or on the order of a physician		Keep away from sunlight
PHT DEHP	Not made with Phthalates		Warning
50°C -20°C Storage Temp	Storage Temperature		

Figure 1	Figure 2

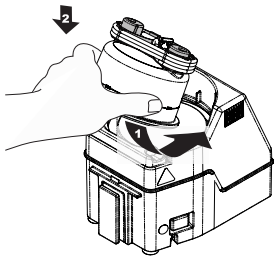
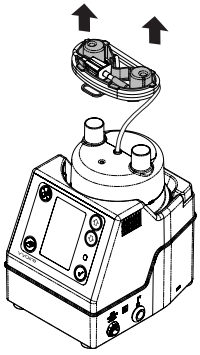
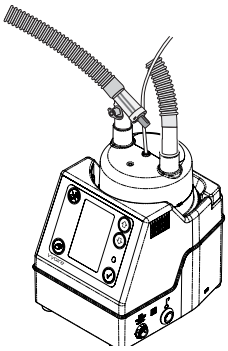
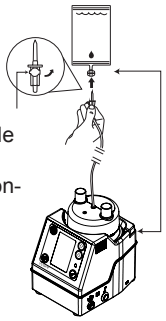

	

Figure 3	**Figure 4**
	Vent Cap: Closed for flexible containers Open for rigid containers  ≥ 50 cm (20”)

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: The AirLife DuoTherm® Humidification Chamber is compatible with the 377HTR AirLife DuoTherm® Series Heated Humidifier and AirLife DuoTherm® 377HTR Series Circuits.

Indications For Use
The AirLife DuoTherm® Humidification Chamber is intended to hold water required to humidify breathing gases delivered to patients ranging from neonates to adults using a heated humidifier. The product is a single-use device, non-sterile, and used in professional healthcare environments under the supervision of a licensed healthcare practitioner.

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 be familiar with the indications for use, warnings and cautions as stated in the IFU.

RX only: Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare practitioner.

Warning
- DO NOT use the chamber if water level is above the maximum water level line. Doing so may result in liquid water entering the breathing circuit tubing.
- DO NOT use the chamber if the blue caddy is not intact when received. Damage to the chamber float mechanism may allow the water level to exceed the maximum fill level.
- DO NOT operate the chamber at an angle in excess of 10 degrees. Doing so may cause liquid water to enter the breathing circuit tubing,
- DO NOT fill the chamber with water in excess of 37°C.
- DO NOT touch the heater plate or chamber base. Temperatures may exceed 85°C. Risk of burns.
- DO NOT turn off water level alarms.
- DO NOT soak, rinse, wash, or sterilize as this can affect performance of the product and cause injury to the patient. The humidification chamber has been designed, tested, and manufactured exclusively for single-use.
- Ensure there is a water supply connected to the chamber and that water is present within the chamber.
- Set appropriate ventilator alarms.
- For Single Patient Use Only. Reuse may degrade performance and result in transmission of infectious substances, interruption of treatment, serious harm or death.
- Position the humidifier with humidification chamber lower than the patient. This directs any liquid water build up in the tubing away from the patient.
- 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 be familiar with the indications for use, warnings and cautions as stated in the IFU.
- Use USP Sterile Water for Inhalation only.
- 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 use the chamber if it has been dropped or damaged. Doing so may increase the risk of device malfunction and patient harm.
- DO NOT use the chamber for more than 14 days.
- DO NOT add attachments or accessories that are not listed in the instructions for use. Doing so may

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Made in Mexico

AirLife®

adversely affect performance, quality of therapy or cause harm to the patient.
- Operation above the maximum flow rates and\or operating pressure may affect the quality of therapy and lead to damage resulting in leakage and loss of ventilation pressure.
- Chamber is not intended for long-term care.
- Do not exceed 364 days of cumulative use.

⚠ Caution
- Chamber may only be used with 377HTR AirLife DuoTherm® Series Humidifier and AirLife DuoTherm® 377HTR Series Circuits.
- Operation or storage under direct sunlight should be avoided.
- Administering aerosolized medications through the humidification chamber or circuit tubing may adversely affect device performance, including temporary changes in gas temperatures 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.
- Do not manually fill the humidification chamber.
- 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.
- The humidification chamber may have hot fluid temperature that exceeds 85°C. Risk of burns.

Technical Specifications	
Interface connections: ISO 5356-1 (22 mm Male)	
Compliance	≤15 mL/kPa (1.471 mL/ cmH_2O)
Resistance to flow @ 60 L/min	<0.82 cmH_2O @ 60 L/min
Compressible Volume (ml)	• Empty / dry: 427 mL Normal use, Nominal water level: 300 ± 5% mL
Maximum Operating Pressure	13.2 kPA (2 psi)
Maximum Peak Flow	200 L/min for 3 seconds
Gas Leakage	≤10 mL/min at 60 cmH_20
Maximum continuous average flow rate to maintain minimum humidity levels per ISO 80601-2-74	60 L/min
Standard Compliance	ISO 80601-2-74 ISO 5367
Environment Temperature & Humidity	
When operating	18 to 26°C 0-85% RH, N.C.
During Storage and Transport	-20 to 50°C 0-85% RH, N.C.
Patient	
Population	All patient populations
System Compatibility	
Heated Humidifier	377HTR AirLife DuoTherm® Series
Pressure Relief Valve	AH115-05E

Set-up Instructions
1. Unpack the heated humidification chamber and check for visible damage before use. DO NOT use a damaged humidification chamber.
2. Install the chamber onto the humidifier by inserting the front edge of the chamber under the front, bottom lip of the humidifier and then push straight down to lock the back edge of the chamber under movable mounting lever. The chamber is locked in place when you hear a click sound (see figure 1)
3. Always position the humidifier with humidification chamber lower than the patient.
4. Remove the blue caddy (Figure 2) from the humidification chamber connection ports and unwind the feedset, leaving the spike in its air-tight protective cap.
5. Connect the circuit and dry line to the 22 mm connection ports on the chamber (Figure 3). **Note**: Ports are not flow direction dependent and either may be used.
6. Perform a ventilator pressure and leak test on the breathing system and check for occlusions before use.
7. When ready for use, remove the spike from the blue caddy and discard. Connect the water spike to the USP Sterile Water for Inhalation source. Ensure that the water source is at least 50 cm (20") above the humidification chamber (Figure 4).
8. Ensure the vent cap (Figure 4) on the water spike is closed when using Flexible Bags and open when using Rigid Containers.
9. Check the water level to ensure the chamber has filled properly and that the fill level remains below the “MAX” water level indicator during use.

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

Incident Reporting:
Notice to the user that any serious incident that has occurred in relation to the device should be reported to the manufacturer productquality@myairlife.com and the competent authority of the Member State in which the user and/or patient is established.