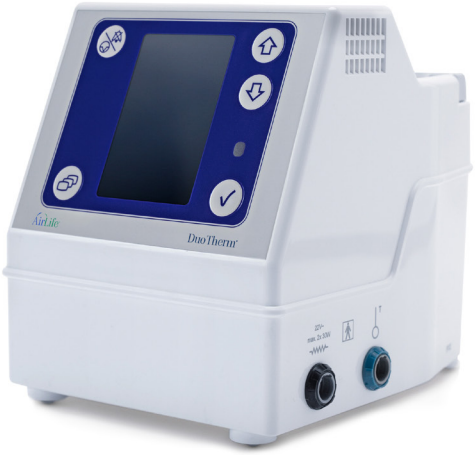
AirLife DuoTherm®
Humidification System



User Manual

1270011.INIFU Rev. 1 2025/05

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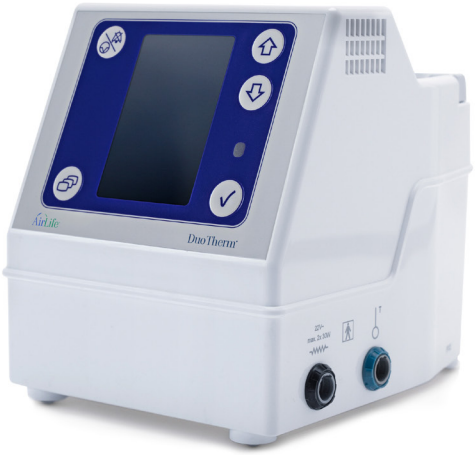
Humidification System



User Manual

1270011.INIFU Rev. 1 2025/05

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

℞ ONLY

Technical and clinical support

productquality@myairlife.com

Customer Service

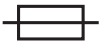
Hours: 6:00 a.m. - 6:00 p.m. MST
1-800-433-2797 from within the United States
info@myAirLife.com

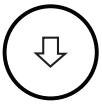
Notice to the user that any serious incident that has occurred in relation to the device should be reported to the manufacturer at, productquality@myairlife.com, and the competent authority of the Member State in which the user patient is established.

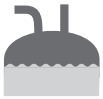
Contents

Symbols

The symbols defined in this table may appear in this document and on the equipment label or labels. Not all symbols are applicable to all components of the system.

Symbols			
Symbol	**Symbol Description**	**Symbol**	**Symbol Description**
	Catalog number		Storage and transport temperature range
	Do not use sharp blade		Serial number
	Humidity limitation range		This side up
	Quantity		Fuse
	Fragile		Follow instructions for use
	Electrical Safety Mark		Keep Dry, Keep Away from Rain
	Manufacturer		Type BF applied part
	Do not throw in trash		Warning
	Surface may be hot; may cause burns		Protective insulation; protection class II
	Caution		Caution: U.S. Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.
IP22	Degree of protection provided by enclosure, no ingress of object > 12mm	LOT	Batch number

Symbols			
Symbol	**Symbol Description**	**Symbol**	**Symbol Description**
	Not made with DEHP		Not made with natural rubber latex
	Do not re-use		MR unsafe
	Atmospheric pressure range		Consult Instructions for Use
	Maximum water level		Use-by date
	Keep away from sunlight		Date of Manufacture
	Warm-up indicator		Humidity level setting
	Temperature probe		INV (invasive mode)
	Therapy pause		Heated wire adapter plug in
	Mute		Enter edit menu/confirm
	NIV (non-invasive mode)		Scroll up
	Expiratory heating level setting		Scroll down

Symbols			
Symbol	**Symbol Description**	**Symbol**	**Symbol Description**
	Free mode		Requires service
	Chamber temperature set point		Configuration menu
	Patient temperature set point		

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.

Indications for use

The AirLife DuoTherm® Heated Humidifier is intended to add moisture to, and to warm, the breathing gases for administration to a patient. Gases available for medical use do not contain sufficient moisture and may damage or irritate the respiratory tract, or desiccate secretions of patients whose supraglottic airways have been bypassed. This product is non-sterile, reusable, and intended to be used in professional healthcare environments under the supervision of a licensed healthcare practitioner.

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.

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, respectively. 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.

The AirLife DuoTherm® Pediatric Heated-Wire Circuits are intended to deliver and warm breathing gases before they enter the patient's airway. The Pediatric Heated-Wire Circuits are used with the pediatric patient population, specifically infant (29 days to 2 years) and children (2 years to 12 years) with an ideal body weight of 6 to 42 kg that requires mechanical ventilation, positive pressure breathing or general medical gases, respectively. The Pediatric Heated-Wire Circuits are used for flow rates greater than 2 LPM. The product is single-use, non-sterile, and used in professional healthcare environments under the supervision of a licensed healthcare practitioner.

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.

The AirLife DuoTherm® Adult Heated-Wire NIV Circuit is intended to deliver and warm breathing gases before they enter the patient's airway. The Adult Heated-Wire NIV Circuit is used with the spontaneously breathing adult patient population (>21 years), specifically those with an ideal body weight of 30 kg or above, that benefit from high flow therapy. The Adult Heated-Wire NIV Circuits are used for flow rates greater than 5 LPM. The product is single use, non-sterile, and used in professional healthcare environments under the supervision of a licensed healthcare practitioner.

The Relief Valve is intended to work with the neonate to adult heated wire nasal high flow circuit. It is connected to an oxygen source and a humidification chamber. Its function is to relieve excess pressure in the inspiratory limb of the circuit for the neonate/pediatric/adult patient population when flow is occluded. The product is single use, non-sterile, and used in professional healthcare environments under a licensed healthcare practitioner.

Contraindications

The AirLife DuoTherm® Humidification System is not suitable for, nor intended for, the nebulization of medication using gas-powered jet nebulizers at the humidification chamber.

Note

The AirLife DuoTherm® Humidification System is intended to be used by respiratory therapists (RTs), nurses, and other specifically trained healthcare providers under the guidance of a licensed physician.

1.0 System overview

The AirLife DuoTherm® Humidification System delivers heated, humidified respiratory gases to patients ranging from neonates through adults receiving invasive or non-invasive therapy. Respiratory gases are delivered from the therapy device or oxygen source into the humidification chamber where the gas is humidified and transported through the inspiratory breathing tube to the patient. The humidification system offers preset modes of use as well as the opportunity to adjust temperatures at the humidification chamber outlet and patient end to provide optimal therapy and to regulate the humidity output. The set-point and displayed gas temperatures are referenced to the temperature probe tips.

2.0 Warnings, cautions and notes

This section provides information that must be read and understood to safely use the heated humidification system. This information includes Warning and Caution statements, which are defined below and presented throughout the manual.

WARNING: Warning statements identify conditions or practices that may cause serious, adverse reactions or that are potential safety hazards.

CAUTION: Caution statements identify conditions or practices that may cause damage to the humidification system, other equipment, or lead to a hazardous situation that may result in minor or moderate injury.

NOTE: In addition to the safety related information provided by Warning and Caution statements, Note statements provide supplemental information to clarify instructions, explanations, and descriptions.

2.1 Warnings

- Read this manual and the instructions included with the respective accessories before setting up and using the equipment. Make sure that you thoroughly understand how to safely use the equipment and that you understand the cautions and warnings provided in this document and on the equipment labels.
- The instructions contained in the documentation provided with the equipment must be followed.
- Avoid using the heated humidifier near other equipment that could interfere with its operation.
- Always monitor the heated humidifier and nearby equipment for proper operation.
- The use of accessories, cables, and transducers for something other than that which the humidification system was designed can significantly degrade emission and immunity performance.
- This device may not be altered without the permission of the manufacturer.
- Supervise children and pets during operation of the heated humidifier.
- When used properly, the heater plate and the humidification chamber become hot.

- Do not touch the heater plate or chamber base. The temperatures may exceed 85°C (185°F).
- Portable and mobile RF communication devices (mobile phones and radio devices including their accessories such as antenna cables and external antennas) should not be used at a distance of less than 30 centimeters (12 inches) from the heated humidifier parts and lines specified by the manufacturer. Failure to comply may result in a reduction in the performance characteristics of the device. For addition information and specifications, refer to section "11.0 EMC specifications" .
- Device configuration may only be performed by trained medical professionals. User training can be provided by AirLife authorized personnel.
- The humidity output capacity can be affected if the device is operated outside the specified ambient temperature or ambient humidity range (see section "9.0 Technical specifications" for more information).
- Always operate the heated humidifier within the specified ambient temperature range that is stated in section "9.0 Technical specifications". The operating temperature range is different from the storage and transport temperature ranges.
- 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.
- Small parts are a choking hazard.
- Do not use the humidifier at an altitude above 3,000 meters (9,842 feet). Using the humidifier above this altitude may affect the quality of the therapy or may cause harm to the patient.
- Use only sterile water for inhalation. Using other substances may produce an adverse effect.
- Strangulation can result from a baby or child getting entangled with the breathing tubes or cables.
- Always place the heated humidifier lower than the patient's airway.
- Do not add any attachments or accessories to the heated humidifier that are not listed in the instruction-for-use of the heated humidifier. Adding attachments or accessories that are not specified for use with the heated humidifier may adversely affect its performance, the quality of the therapy, or injure the patient.
- To prevent disconnection of the tubing or tubing system during use, especially during ambulatory use, only use equipment and accessories that are in compliance with ISO 5367 and ISO 80601-2-74.

- To prevent injury to the patient and not diminish the quality of the therapy, do not cover the breathing tubes with a blanket or warm them in an incubator or with an overhead heater.
- Use only AirLife approved consumables and accessories. Consumables and accessories from third party providers have not been validated and may negatively affect patient safety and product performance.
- Disconnect the power cord from the device before maintaining, servicing, inspecting, or repairing it.
- Do not perform maintenance, service, inspections, or repairs while the device is in use with the patient.
- Do not use this device in an oxygen rich environment (an environment with greater than 22% O_2) where it is susceptible to explosion.
- Position the cables and breathing tubes so they do not cause anyone to become entangled.
- Do not allow the device to tilt more than 10° in any orientation.
- Operational shutoff may only be directed by a physician or by the physician's authorized representative.
- 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.
- Completely insert the temperature sensor into the temperature sensor port of the circuit so that the respiratory gas is measured in the middle of the breathing circuit; otherwise, the temperature of the supplied humidified air may rise above 43°C (109°F).

2.2 Cautions

- Before setting up and operating the heated humidifier, make sure the supply voltage corresponds with the operating voltage specified on the device rating plate.
- To avoid overheating the device, a breathing gas flow of at least 1 L/ min is required in the breathing tube system at all times. If the breathing gas supply is interrupted, the device must be turned off. For applications that require the patient's separation from the humidifier, the device needs to be switched to the Therapy Pause mode.
- All maintenance, servicing, and testing must be performed by trained service personnel.
- Do not use a defective humidifier. Disconnect the defective device from the power source and notify hospital maintenance personnel or the supplier.

- Do not immerse the heated humidifier or its accessories in liquids, and do not sterilize them. Refer to section "7.0 Cleaning and disinfecting procedures" for cleaning instructions.
- Do not operate the system without sterile water in the humidification chamber.
- The heated humidifier is IP22 rated for exposure to vertical or near vertical dripping water only. Do not allow any liquids to penetrate the housing.
- Do not sterilize the temperature probe. Refer to section "7.0 Cleaning and disinfecting procedures" for approved methods.
- Use only approved methods for cleaning and disinfecting the device. Refer to section "7.0 Cleaning and disinfecting procedures" for approved methods.
- Before each use, check that the heated humidifier, the supplied system parts, and the accessories being used are free from defects. If the heated humidifier is defective or damaged, remove it from service and notify the hospital maintenance personnel or the customer service department.
- This user manual does not have precedence over the instructions of the physician nor the treatment protocols of the hospital or clinic.
- Environmental conditions can affect system performance. A change in the room climate (for example, heating or ventilation) or the entry of new ventilation parameters can lead to increased condensation in the breathing tube. Note: Operation in an environment outside of the ambient temperature range of 18 to 26°C (64 to 79°F) may affect system performance and may require the device to be acclimatized.
- Avoid using the device in brightly lit areas or in direct sunlight. Bright light can compromise the visual clarity of the display.
- The heated humidifier should not be operated near direct sunlight, radiators, and other heat sources.
- To ensure the automatic refill device functions as intended, the container with the sterile water must be suspended at least 50 centimeters (20 inches) above the heated humidifier.
- Do not manually fill the humidification chamber.
- Do not fill the chamber with sterile water above 37°C (99°F).
- Do not block access to the power switch when using the device.
- 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.
- Monitor for damage to the electrical connections and housing. Do not use the device if damage is found.

2.3 Notes

- The expected service life of the device is eight years.
- The abbreviation “(i)” means inspiratory, and the abbreviation “(e)” means expiratory.
- The USB interface may only be used for service purposes.
- The heated humidifier must be set up and put into operation as described in this manual.

3.0 AirLife DuoTherm® basic equipment, consumables, and accessories

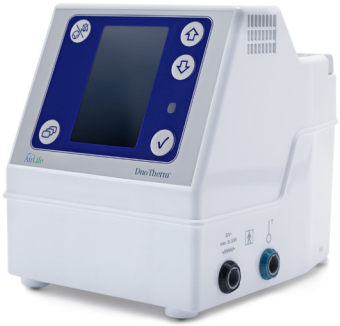
Refer to this section for the various part numbers associated with the heated humidifier.

3.1 Basic equipment

Part number	Description
377HTR	AirLife DuoTherm® Heated Humidifier, 110 to 120 volts

3.2 Included with humidifier

- Heater wire adapter (dual limb)
- Temperature probe (180 cm)
- Power cord
- Quick Start Guide
- Alarm Quick Guide



AirLife DuoTherm® Heated Humidifier (377HTR Series)

3.3 Consumables and accessories

The consumables and accessories required to operate the AirLife DuoTherm® Humidification System are listed below and are available from AirLife. Spare parts can also be ordered from AirLife.

WARNING: Use only AirLife approved consumables and accessories. Consumables and accessories from third party providers have not been validated and may negatively affect patient safety and product performance.

3.3.1. Humidification Chamber

Part number	Description
377CBRE	AirLife DuoTherm® Humidification Chamber

3.3.2 Sterile water for inhalation, USP

Part number	Description
2D0735X	AirLife sterile water for inhalation, USP, flexible bag, 1000 mL
2D0737	AirLife sterile water for inhalation, USP, flexible bag, 2000 mL
CHB0010	AirLife sterile water for inhalation, USP, rigid bottle, 1000 mL
CHB0020	AirLife sterile water for inhalation, USP, rigid bottle, 2000 mL

3.3.3 Manuals

Part number	Description
1270011	Printed Manual, English

3.3.4 AirLife DuoTherm® Power Cords

Part number	Description
377PWR	United States

3.3.5 Heated breathing circuits

Part number	Description
37712CE	AirLife DuoTherm® Neonate Single Limb Circuit Kit, Dual-Wall Heated Wire Circuit with Chamber
37723CE	AirLife DuoTherm® Neonate Dual Limb Circuit Kit, Dual-Wall Heated Wire Circuit with Chamber
37735CE	AirLife DuoTherm® Adult Single Limb Circuit Kit, Dual-Wall Heated Wire Circuit with Chamber
37736CE	AirLife DuoTherm® Pediatric Dual Limb Circuit Kit, Dual-Wall Heated Wire Circuit with Chamber
37747CE	AirLife DuoTherm® Adult Dual Limb Circuit Kit, Dual-Wall Heated Wire Circuit with Chamber
37748CE	AirLife DuoTherm® Pediatric Dual Limb Circuit Kit, Dual-Wall Heated Wire Circuit with Chamber

Part number	Description
37756CE	AirLife DuoTherm® Adult Single Limb NIV Circuit Kit, Large Bore Heated Wire Circuit with Chamber

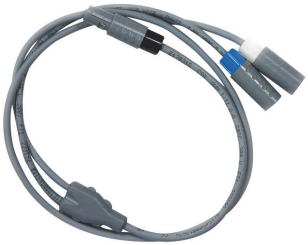
3.3.6 Poles and brackets

Part number	Description
377BR101	AirLife DuoTherm® Pole Clamp
377BR102	AirLife DuoTherm® Mounting Bracket
377BR103	AirLife DuoTherm® Pole and Rail Mounting Bracket
377BR201	AirLife DuoTherm® Water Pole
377BR301	AirLife DuoTherm® Offset Pole and Rail Mounting Bracket
377BR302	AirLife DuoTherm® PB840 Mounting Bracket
377BR303	AirLife DuoTherm® 44 mm Adapter and Mounting Bracket
377BR304	AirLife DuoTherm® Vent Mounting Bracket
377BR305	AirLife DuoTherm® Mounting Bracket with Adapter

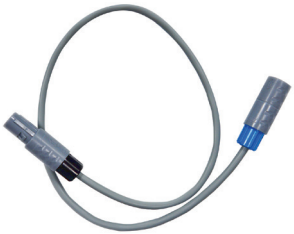
3.3.7 Heater wire adapters and temperature probes

Part number	Description
377ADL	AirLife DuoTherm® Reusable Dual Limb Heated Wire Adapter
377ASL	AirLife DuoTherm® Reusable Single Limb Heated Wire Adapter
377PR5E	AirLife DuoTherm® Reusable Temperature Probe, 160 centimeters
377PR6/ 377PR6E	AirLife DuoTherm® Reusable Temperature Probe, 180 centimeters

AirLife DuoTherm® Reusable Temperature Probe Set (377PR5E and 377PR6 / 377PR6E)



AirLife DuoTherm® Reusable Dual Heater Wire Adapter (377ADL)



AirLife DuoTherm® reusable Single Heater Wire Adapter (377ASL)

3.3.8 Relief valve

Part number	Description
AH115-05E	Pressure Relief Valve, 40cm H_2O

4.0 Installation and setup

Before installing and setting up the system, make sure there is no damage by observing the criteria listed below.

- Replace the housing part whenever you detect cracks or fissures.
- If the air vents are dirty, they should be cleaned.
- If the control buttons are damaged, the circuit board must be replaced.
- If the power switch cover is missing or torn, it must be replaced.
- If the power switch cannot be operated without problems, it must be replaced.
- If the sockets for the heating wire adapter / temperature probe are damaged or blocked, they must be replaced.
- If the front membrane no longer sticks, it must be replaced.
- If the heating plate is scratched, it can be carefully smoothed and cleaned using a fine wire wool scourer or fine sand paper. If the heating plate has significant scratches, the inner part must be replaced.
- If the feet are missing, they must be replaced.
- If the lever for inserting the water chamber cannot be operated, or if it is loose, it must be replaced.
- If the power cord cannot be plugged in, the lower part or the power cable must be replaced.
- If the power cord is damaged, it must be replaced.
- If the USB socket is damaged, the circuit power board must be replaced.
- If the safety information/safety labels are illegible or missing, they must be reattached as shown below.

Figure 1-1. Position of the safety stickers

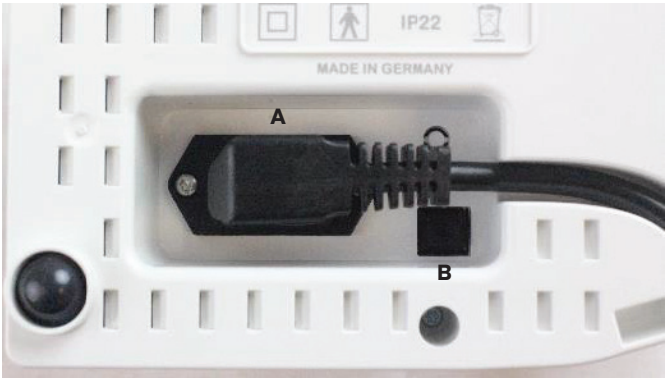
CAUTION: Before setting up and operating the heated humidifier, make sure the supply voltage corresponds with the operating voltage specified on the device rating plate.

4.1 Connecting the components

The power cord is connected to the underside of the humidifier (A). Connect the power cord to an AC outlet or a hospital approved power source with the correct voltage.

NOTE: Firmly insert the plug into the receptacle and firmly insert the cable into the strain relief.

The USB Port (B) is for servicing the humidifier by AirLife authorized personnel.



The connections for the heater wire adapter (C) and for the temperature probe (D) are located on the side of the device. These connectors are color coded and keyed, and the device is marked with appropriate symbols to ensure the proper connections.

Plug the heater wire adapter into the black connector (C).

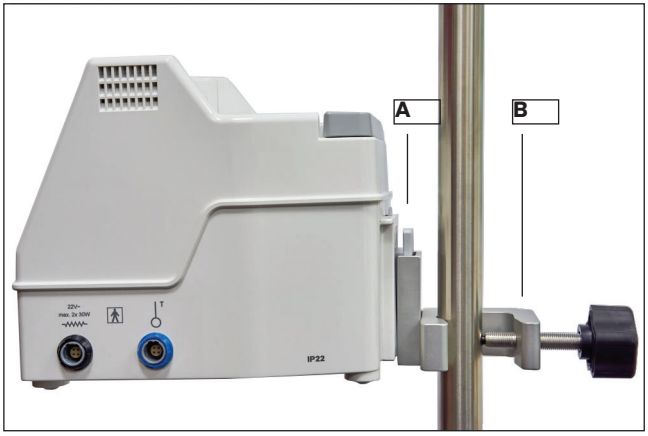
Plug the temperature probe adapter into the dark-blue connector (D).

NOTE: All connectors are color-coded and keyed. When inserted, rotate the connector until the keys align and the connector easily inserts into the receptacle and an audible click is heard.

4.2 Installing/mounting the AirLife DuoTherm® Heated Humidifier

The heated humidifier has feet and can be placed on a flat, solid, and level surface. Alternatively, the device can be suspended with the heated humidifier mounting rail (A) on a suitable mounting bracket (B) (see section 3 for a list of brackets and accessories).

WARNING: Always position the heated humidifier with a humidification chamber lower than the patient's airway.



4.3 Installing the humidification chamber

WARNING: DO NOT clean, sterilize, or reuse the AirLife DuoTherm® 377CBRE humidification chamber. The humidification chamber can be used continuously for up to 14 days on a single patient.

WARNING: DO NOT exceed 364 days of cumulative use of the AirLife DuoTherm® 377CBRE humidification chamber. The humidification chamber is not intended for long-term care.

WARNING:

- Use only 377CBRE humidification chambers with the AirLife DuoTherm® heated humidifier.
- DO NOT use the chamber if the water level is above the maximum water-level line.
- DO NOT use the chamber if the blue caddy is not intact when received.
- DO NOT use the chamber if it has been dropped or damaged.

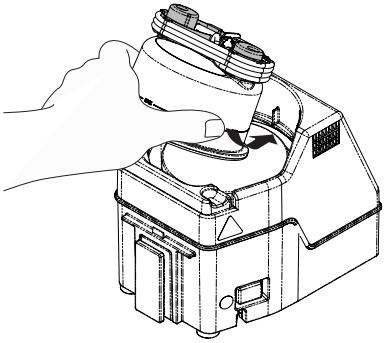
- DO NOT operate the chamber at an angle in excess of 10 degrees.
- DO NOT fill the chamber with water above 37°C (99°F).
- DO NOT soak, wash, sterilize, or reuse the humidification chamber. Avoid contact with chemicals, cleaning agents, or hand sanitizers.
- DO NOT touch the heater plate or chamber base. The temperatures may exceed 85°C (185°F).
- Ensure that there is a water supply connected to the chamber and that water is present within the chamber.
- Set appropriate ventilator alarms.
- The humidification chamber is for Single Patient Use Only. Reuse may degrade performance and result in transmission of infectious substances, interruption to treatment, serious harm, or death.
- High Flow Nasal Cannula (HFNC) therapies require the use of a ventilator or a pressure limiting device such as a relief valve to prevent damage to the system in the event of an occlusion.

⚠ CAUTION:

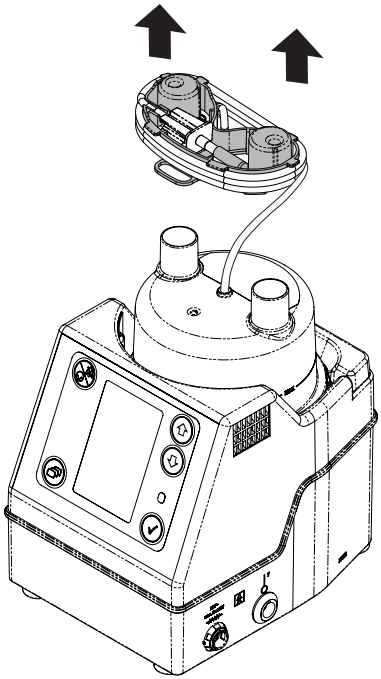
- The AirLife DuoTherm® 377CBRE chamber can only be used with the AirLife DuoTherm® Humidification System and breathing tubes.
- Follow your facility's policy and procedure for ventilation and aerosol therapy. Administering aerosolized medications through the humidification chamber or circuit tubing may adversely affect device performance, including temporary changes in gas temperature of delivered humidity level to the patient. Administering aerosolized medications using gas-powered jet nebulizers may cause temporary temperature alarms and accumulation of condensation in circuit tubing.
- Using the chamber above the maximum operating pressure may lead to cracking, water leakage, and could lead to a loss of ventilation or respiratory therapy.

To install the humidification chamber:

1. Unpack the humidification chamber and check it for damage before use. DO NOT use a damaged humidification chamber.
2. Insert the bottom edge of the humidification chamber under the front, bottom lip on the heated humidifier, and lock the humidification chamber into place under the movable mounting lever. The lever is locked when you hear a click.

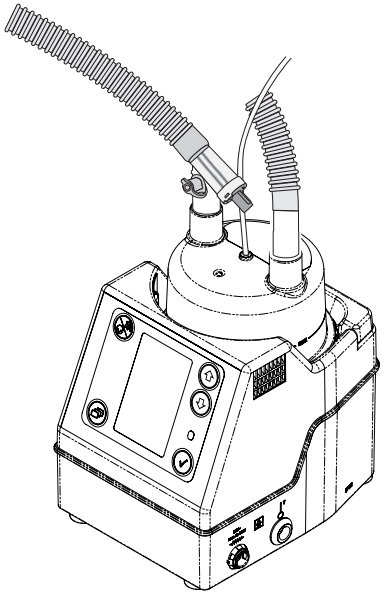


3. Remove the blue caddy from the humidification chamber connection ports and unwind the feed set, leaving the spike in its airtight protective cap.



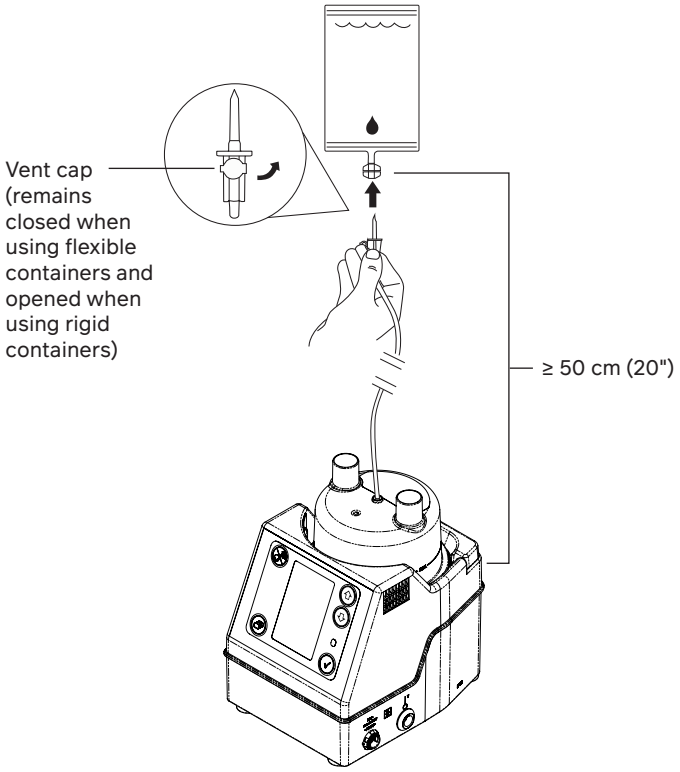
4. Connect the inspiratory limb and dry line to the 22 millimeter connection ports on the chamber.

   NOTE: The ports are not flow direction dependent and either may be used.



5. Perform a ventilator pressure and leak test on the breathing system and check for occlusions before use.

6. When the chamber is ready for use, remove the spike from the blue caddy and discard it. Connect the water spike to the USP sterile water for inhalation source (flexible bag or rigid bottle).



NOTE:

- Ensure that the water source is at least 20 inches/50 centimeters above the humidification chamber.
- Use USP Sterile Water for Inhalation in either flexible bags or rigid containers (see section 3.2 for approved consumables).
- When using flexible bags, ensure that the vent cap on the water spike is closed.
- When using rigid containers, ensure the vent cap is open.

7. Check the water level to ensure that the chamber has filled properly and that the fill level remains below the “MAX” water level indicator during use. We recommend that you DO NOT turn off the water level alarms on the heated humidifier.

CAUTION: To ensure the automatic refill device functions as intended, the container with the sterile water must be suspended at least 50 centimeters (20 inches) above the heated humidifier.

4.4 Connecting the breathing tube

WARNING: DO NOT clean, sterilize, or reuse AirLife breathing tubes. The breathing tubes can be used continuously for up to 30 days on a single patient with exception of NIV breathing tubes can be used continuously for up to 14 days on a single patient only.

As shown in Section 4.3, the dry line is used to connect the breathing therapy device to the hose port of the humidification chamber air supply.

1. Inspect breathing tubes for damage before use.
2. Connect the dry line between the breathing therapy device and the humidification chamber.
3. Connect the inspiratory manifold of the breathing tube to the remaining humidification chamber port.
4. [Dual-limb breathing tubes only.] Connect the expiratory limb of the breathing tube to the ventilator expiratory port.
5. Connect the blue end of the temperature probe set to the heated humidifier.
6. Firmly insert the T-shaped temperature probe into the chamber temperature probe port (Figure A).
7. Firmly insert the L-shaped temperature probe into the patient temperature probe port (Figure B).

Figure A

Figure B

8. Ensure the probes are fully inserted into the temperature probe ports of the breathing tube.
9. Plug the black end of heated wire adapter into the heated humidifier.
10. Plug the light blue end of heated wire adapter into the light blue inspiratory heated wire connection (Figure C). These connections are keyed and locking. When inserting, rotate the heated wire adapter until the keys align and easily slides onto the heated wire connection until an audible click is heard.
11. If the heated breathing tube being used is equipped with a heated expiratory limb, plug the white end of heated wire adapter into the white expiratory heated wire connection (Figure D).

NOTE: Both sensors must be firmly and securely inserted into the respective openings (A and B). The cable of the temperature probe can be secured with the provided clips of the breathing tube (E).

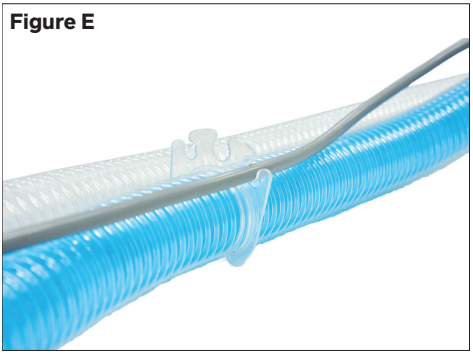
NOTE: The heated humidifier is only ready to operate if the inspiratory heated wire adapter is connected.

NOTE: The cable of the temperature probe can be secured in the provided clips of the breathing tube (E).

Figure C

Figure D

Figure E

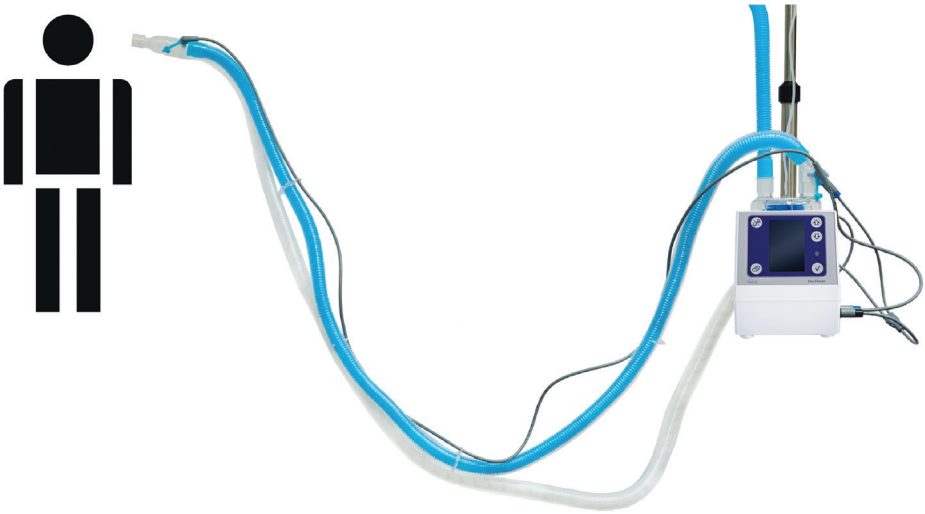


WARNING: To prevent injury from entanglement, route the cables and breathing tubes so they do not hang loosely.

Before connecting the patient to the breathing tube, make sure that:

- The treatment device is working properly.
- The treatment parameters are set correctly.
- The breathing gas is flowing freely in the breathing tube.

Set up the device as shown below.



4.5 Turning on the AirLife DuoTherm® Heated Humidifier

1. Make sure that the humidification chamber, sterile water for inhalation source, heated wire(s), and temperature probes are connected and that there is water in the humidification chamber.
2. Turn on the heated humidifier using the switch located on the side of the unit.

   NOTE: The heated humidifier saves the last settings and uses the settings for restarting (for example, after a power failure). The humidifier may be quickly reset to the factory default settings of INV, 3-Drops by simultaneously pressing the up and down buttons for 3 seconds.

When the device is turned on, the system initialization phase begins:

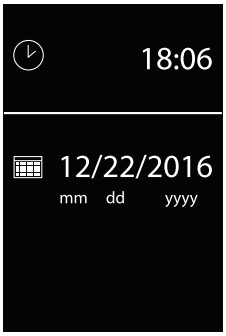
- The company name, software version, and hours used appear on the screen.
- A self test routine begins (during which, no entries can be made).
- A warm-up phase starts and lasts for no more than 30 minutes.
- The water vapor saturation of the respiratory gas is steadily increased until the set temperatures are reached.

During the initialization phase, no entries can be made. After initialization, the operating display appears.

The version number of the software and the hours used are only for illustration purposes.

4.6 Setting the time and date

1. Simultaneously press and hold the ⎙ button and the ⇩ button for three seconds to display Parameter 2 List.
2. In Parameter 2 List, press ⚒ and hold it for three seconds to display the date and time settings.



3. Use the ⇧ and ⇩ buttons to choose a setting, and then press ✓ to confirm your choice. The chosen setting appears gray.
4. Change any marked values by using the ⇧ and ⇩ buttons.
5. Confirm the new value by pressing ✓.
6. Press ⎙ to exit the Time and Date Setting menu.

Note: Setting the appropriate time and date ensures that the data logging and troubleshooting tools are accurately time stamped. The time and date setting do not influence device operation.

4.7 Turning off the AirLife DuoTherm® Heated Humidifier

At the end of treatment, turn off the heated humidifier by using the switch located on the side of the unit.

WARNING: Wait for at least 30 minutes before dismantling, packing, or transporting the device to allow the heating plate to cool down.

5.0 Operation

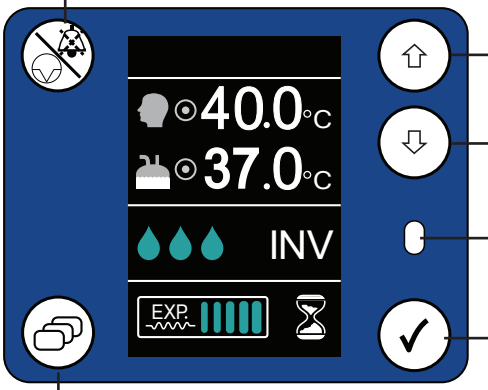
NOTE: Before operating the system, make sure there is no damage by observing the criteria listed in "4.0 Installation and setup" .

The five buttons on the front panel provide navigation through the various modes of operation and setting screens. The illustrations in this section identify the key functions and explain how to use the heated humidifier.

5.1 Home screen operation

Key: LP = Long press (longer than three seconds)
SP = Short press (momentary press)

SP: Mute alarm (120 seconds)
LP: Start therapy pause



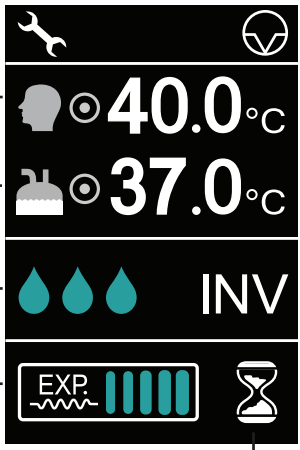
SP: Display of the actual temperatures at the patient outlet and the humidification chamber.
LP both buttons simultaneously: Reset to factory settings. Refer to section 5.2.1 for details.

Ambient light sensor: The backlight changes depending on the ambient light.

LP: Enter the Edit menu

Enter the Configuration menu

5.2 Home screen display



Symbol indicates that the service interval has expired.

Symbol indicates that the device is in therapy pause.

Set-point temperature on the patient outlet and the humidification chamber. By pressing the ⇧ or ⇩ button, the actual temperature at the patient outlet and the chamber is displayed.

Humidification level setting.

Setting option for expiratory heating power setting

Preset parameters for invasive ventilation (INV). Alternatively, can be set to non-invasive (NIV) or individual parameters (FREE).

Timer symbol indicates that the device is still in the warm-up phase. During warm-up mode, certain low priority alarms, e.g. low temperature alarms, are inactive. More information can be found under section "5.5.3 Warm-up time".

5.2.1 Reset to factory settings

The heated humidifier is delivered with the factory setting INV, Humidity setting 3 drops.

- Set-point of the patient-end breathing gas temperature: 40°C (104°F)
- Set-point of the humidification chamber temperature: 37°C (99°F)
- Water level detection: On
- Expiratory power: 5 bars (100%)

During operation, the heated humidifier can be reset to factory settings by pressing ⇧ and ⇩ simultaneously for three seconds. The humidifier will automatically re-initialize and enter warm-up mode to allow for the system to adjust to the new settings.

NOTE: After performing maintenance on the device, reset it to the factory settings.

5.2.2 Therapy Pause

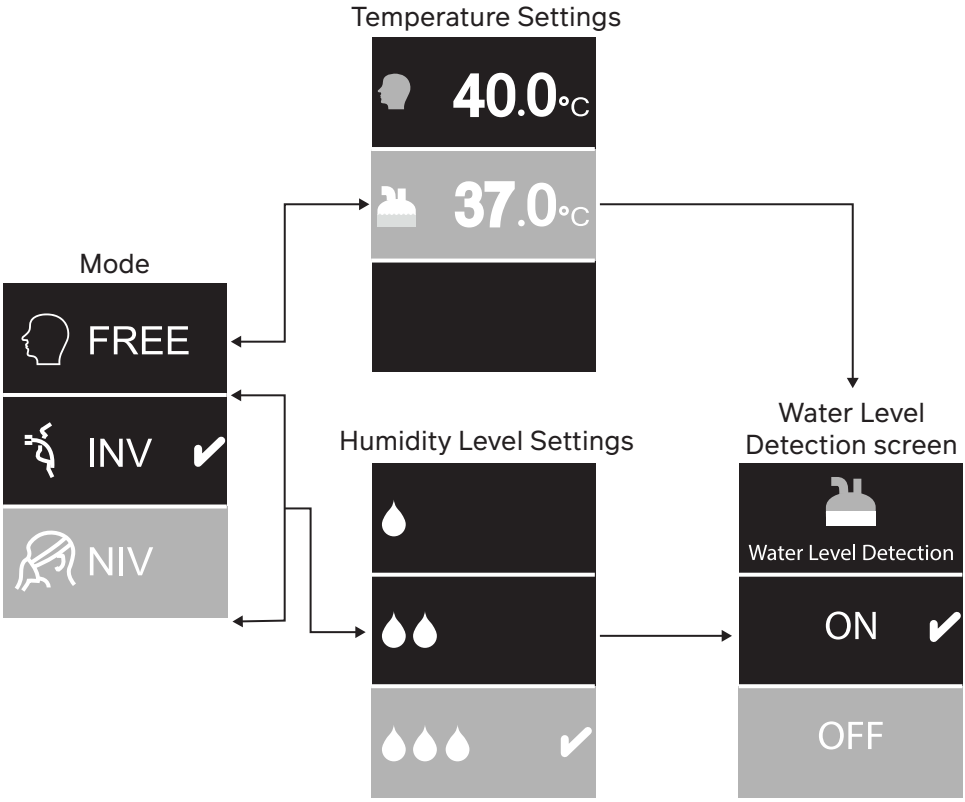
Therapy Pause can be activated from the Home screen and when the warm up phase is complete (when there are no alarms) by pressing for three seconds. In this mode, appears in the upper, right corner of the display.

Therapy Pause lasts for three minutes, and it can be canceled at any time by pressing any key. The heated humidifier resumes normal operation after Therapy Pause is canceled, or after three minutes.

NOTE: During Therapy Pause, the heater plate and the heated wire (if connected) operate at half the power of Normal mode power.

5.3 Operation in Configuration menu

Press the ⏻ button from the Home screen for three seconds to open the Configuration menu where you can make individual adjustments. The following diagram illustrates the sequence of the menu pages.



Use the ⇧ and ⇩ cursor buttons to highlight (in gray) the function that you want to use, and then press the ✓ button to select it. Press the menu ⏻ button to scroll to Humidity Level Settings then to Water Level Detection.

5.3.1 Modes of operation

Operating mode	Humidity level	Humidification Chamber temperature	Patient-end temperature
NIV	1	29°C (84°F)	34°C (93°F)
	2	30°C (86°F)	
	3[1]	31°C (88°F)	
INV	1	35°C (95°F)	38°C (100°F)
	2	36°C (97°F)	39°C (102°F)
	3[2]	37°C (99°F)	40°C (104°F)
FREE[3]		29 to 40°C (84 to 104°F)	29 to 40°C (84 to 104°F)

1. At NIV 3 drop settings, a minimum humidity output of 12 mg/L is achieved.
2. At factory default INV 3 drop settings, a minimum humidity output of 33 mg/L is achieved.
3. In FREE mode, the temperature settings are restricted to a +2 and -5 degree differential between the Humidification Chamber Temperature and the Patient Temperature. This restriction is applied to avoid excessive condensation and low relative humidity, respectively.

5.3.2 Humidity output

Humidity output minimums and test methods are defined by ISO 80601-2-74. The Duotherm® system complies with this standard when operated within the ambient temperature and flow rate ranges specified.

At NIV 3 drop settings, a minimum humidity output of 12 mg/L is achieved.

At factory default INV 3 drop settings, a minimum humidity output of 33 mg/L is achieved.

⚠ **CAUTION:** Deviation of these settings from those of the factory default settings may not meet the ISO 80601-2-74 requirements of 33 mg/L invasive ventilation (INV) or 12 mg/L non-invasive ventilation (NIV) at all combinations of flow rates, ambient temperatures, gas inlet temperatures, and humidity.

5.3.3 Respiratory flow ranges

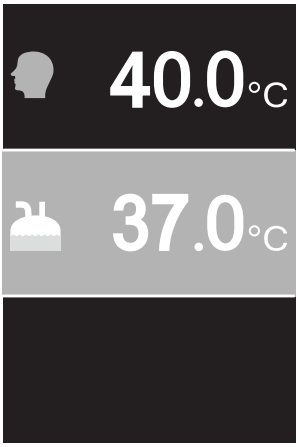
A minimum of 1 LPM of gas flow through the DuoTherm® system is required for proper temperature and humidity control. The DuoTherm® system can maintain a minimum humidity output of 33 mg of H_2O/L of gas for average bulk flows up to 60 LPM. See specific flow rate ranges and ambient condition ranges on the product labeling.

Refer to the breathing tube instructions-for-use for flow rate ranges for the intended setup.

5.3.4 Adjusting temperatures (FREE mode)

The Temperatures menu page is only displayed after the FREE operating mode has been selected. Regardless of the factory setting for invasive and non-invasive ventilation, it is on this menu where you must manually set the patient temperature and chamber temperature. In FREE mode, the device has a +2, – 5 temperature restriction between the patient and humidification chamber temperature.

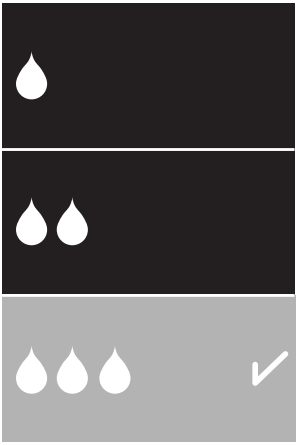
Note: In any operating mode (including INV and NIV), the temperature can be adjusted to the needs of the patient (for example, respiratory gas too moist/too dry). To make an adjustment, press the ✓ button for three seconds to enter the Edit mode. When changing the temperature parameters, the device switches automatically to the FREE operating mode, even with factory settings (INV or NIV).



Temperature Settings

5.3.5 Adjusting humidification level

In non-invasive ventilation (NIV) and invasive ventilation (INV) operating modes, the humidification level can be adjusted in three distinct steps. One drop indicates the minimum humidification level; three drops represent the maximum level. This setting allows adjustment of the humidification level according to the circuit being used and the form of therapy, thereby reducing condensation in the tubing and/or addressing patient comfort needs.



Humidity Level Settings

5.3.6 Adjusting the expiratory heat output

The power supplied to the expiratory limb of dual heated circuits can be modified by entering the Edit Menu with a long press of the ✓ button and using the ⇧ and ⇩ arrow buttons to scroll down to the Expiratory Wire Power symbol. The default and recommended setting is 100%. Reducing the setting will reduce the temperature of the gas exiting the expiratory limb.

The expiratory heated wire output is calculated according to the following formula:

$$P_{exp} = k_{st} \cdot k_u$$

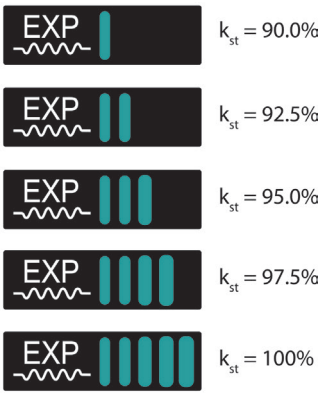
Where:

P_{exp} is the expiratory heated wire output.

k_{st} is the level coefficient (listed in the figure).

k_u is the coefficient that is dependent on the supply voltage (see section "5.5.8 Heated wire output limits").

Settings for k_{st}:



5.3.7 Water fill level detection

The heated humidifier automatically detects and continuously monitors the water level in the humidification chamber. If the water level in the humidification chamber exceeds the maximum fill level or drops below the minimum fill level, an audible and visual alarm is triggered. The system has two selectable options for automatic water level detection:

- ON = Function enabled (Recommended at all times)
- OFF = Function disabled

⚠ **CAUTION:** If the IR sensor is off, high/low water level detection is not provided.

NOTE:

- Use only an AirLife DuoTherm® humidification chamber to obtain the correct automatic water level detection function.
- Check the water level every two hours (longer intervals may be possible, depending on the ventilation parameters).
- Do not fill the chamber above the maximum level marking or let the humidification chamber run dry during operation.

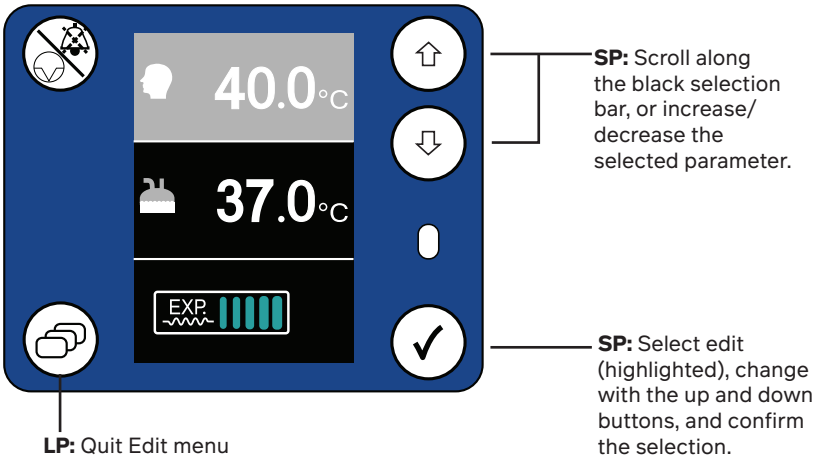
5.4 Operation in Edit menu

From the Home screen, press and hold ✓ for three seconds.

The Edit menu activates to provide the options listed below for changing the set-point temperatures or the expiratory heating capacity.

- Top display section: Set-point for the patient-end temperature.
- Middle display section: Set-point for the humidification chamber temperature.
- Bottom display section: Heating capacity of the expiratory heated wire. The heating capacity can be increased or decreased in five stages, as indicated in the bar graph display.

Key: LP = Long press (longer than three seconds)
SP = Short press (momentary press)



To make a settings change:

1. Select the corresponding line using the ⇧ and ⇩ cursor keys. The selected item appears highlighted in white.
2. Press ✓ to confirm your selection. The selected item is now highlighted in yellow.
3. Use the ⇧ and ⇩ buttons to increase or decrease the marked values.
4. Press ✓ to confirm your selections.
5. Press ⧉ for longer than three seconds to exit the Edit menu.

5.4.1 Reducing condensation in the inspiratory limb

INV and NIV modes maintain a minimum three degree differential between the patient temperature and the humidification chamber at 1, 2, or 3-drop settings. To reduce condensation, decrease the humidity setting to 2-drop or 1-drop settings, or enter FREE mode. To reduce condensation in FREE mode, decrease the humidification chamber temperature and/or increase the differential between the patient temperature and humidification chamber temperature.

5.4.2 Adjusting the humidity

In the preset INV and NIV modes, the 3-drop selection represents the highest humidity setting. Humidity output can be reduced by selecting the 2-drop or 1-drop settings, thus reducing the absolute humidity by approximately 2 mg of H_2O/Liter of gas per drop. In FREE mode, absolute humidity output is proportional to the temperature at the humidification chamber, and relative humidity is proportional to the difference between the temperature at the patient and the humidification chamber.

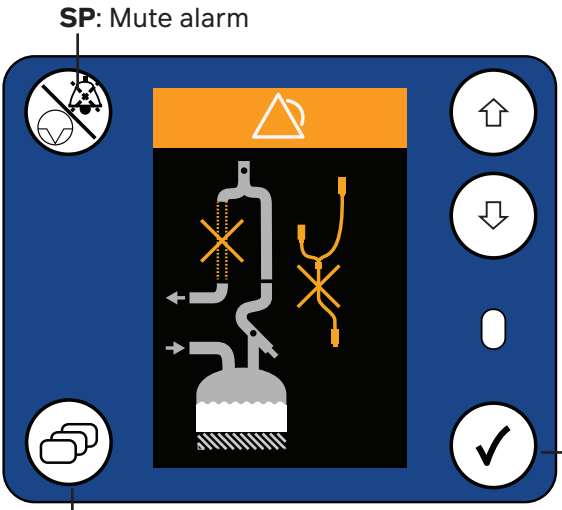
5.4.3 Reducing condensation in the expiratory limb

To reduce condensation in the expiratory limb, the power to the expiratory limb is controlled independently from the inspiratory limb. (The maximum setting is 5 bars.)

Note: Default factory setting is 5 bars (100%).

5.5 Operation in the Alarm mode

Key: LP = Long press (more than 3 seconds)
SP = Short press (momentary press)



5.5.1 Alarm muting

The alarm can be muted for 120 seconds by pressing the Mute Alarm button, and it can be canceled at any time by pressing any key. After 120 seconds of canceling the alarm, or after pressing any key a second time, the alarm sounds again. If the cause of the alarm is not resolved within ten minutes, the unit switches to the OFF mode and the audible/ visual alarm continues until the power is cycled off, then on, to resume normal operation.

5.5.2 Alarm delaying

Alarm messages are also suppressed for a certain time if the following conditions are present:

- After initiation of therapy pause, the alarm delay is activated for three minutes, because during the therapy pause period. The heating power is reduced and the temperatures cannot be immediately achieved after switching to the Normal mode.
- After changing the humidification level, the alarm delay is activated for three minutes to allow for the system to adjust to the setting change.

5.5.3 Warm-up time

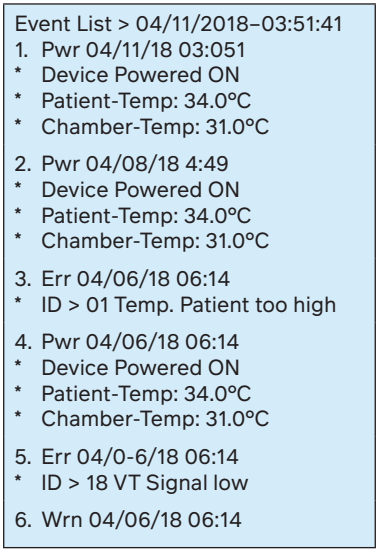
During the warm-up time of 30 minutes, certain alarm messages are suppressed. Meanwhile, the icon ⌛ appears in the lower, right corner of the display. Alarms indicating a deviation of an actual temperature from that of the set-point are not triggered during this period, because the temperatures cannot be achieved immediately after turning on the power.

5.5.4 WARNING:

Portable RF communication devices (radio devices) (including their accessories such as antenna cable and external antennas) should not be used at a distance of less than 30 cm (or 12 inches) from the AirLife DuoTherm® parts and lines specified by the manufacturer. The humidifier must not be used in rooms where EM disturbances of high intensity occur (e.g. MRI). In addition, the function of the humidifier can be impaired by HF surgical equipment. In these cases, the humidifier delivery (an essential performance feature) may be reduced.

5.5.5 Event List

The Event List records alarm related information and can store 200 entries. Each entry includes the name of the alarm along with the date and time that the alarm occurred. When the memory becomes full, the oldest entry is deleted and the new alarm entry is added to the list.



- To view the Event List, press and hold and .
- Use the and buttons to scroll through the Event List.
- To exit the Event List and return to the Home screen, press or or
- The content of the Event List is retained after you turn off the device.

5.5.6 Parameter 1 List

Parameter 1 List contains several system parameters that can help with analyzing device performance.

- To display the list, simultaneously press and hold and for three seconds.
- Record the values in the table.
- To return to the Home screen, press any button.

Parameter 1 List	
patient temperature:	39.8°C
chamber temperature:	29.0°C
heater temperature:	21.5°C
Rinsp:	14.8 Ohm
Rexpi:	24.6 Ohm
Pinsp:	0.0%
Pexpi:	47.8%
Php:	9.2%
Usec:	23.4V
I sense:	1.18A
MAX_INSP:	76%
MAX_EXP1:	76%
tp_init:	39.9°C
tk_init:	29.0°C
thp_init:	21.5°C
warmup:	29 min

Explanation of Parameter 1 List	
patient temperature	Patient-end respiratory gas temperature.
chamber temperature	Chamber gas temperature.
heater temperature	Heater plate temperature.
Rinsp	Resistance of the inspiratory heated wire.
Rexpi	Resistance of the expiratory heated wire.
Pinsp	The power applied to the inspiratory circuit expressed as duty cycle percent.
Pexpi	The power applied to the expiratory circuit expressed as duty cycle percent.
Php	The power applied to the heater plate expressed as duty cycle percent.
Usec	Secondary transformer voltage, applied to external breathing tubes (22V nominal).
I sense	Total current applied to both INSP and EXP breathing tubes.
MAX_INSP	The maximum duty cycle that could currently be applied to the inspiratory breathing tubes.
MAX_EXPI	The maximum duty cycle that could currently be applied to the expiratory breathing tubes.
tp_init	The measured patient temperature at system power-on.
tk_init	The measured chamber temperature at system power-on.
thp_init	The measured heater plate temperature at system power-on.
warmup	The time remaining for the warm-up phase.

5.5.7 Parameter 2 List

Parameter 2 List contains several system parameters that can help with analyzing device performance.

Parameter 2 List	
Ufoto4 (top):	2.37V
Ufoto3:	2.38V
Ufoto2:	0.07V
Ufoto1 (bottom):	0.08V
Ulight:	2.26V
Backlight:	100.0%
Next Service:	09.24
Date:	09/06/2018
Time:	13:32:24

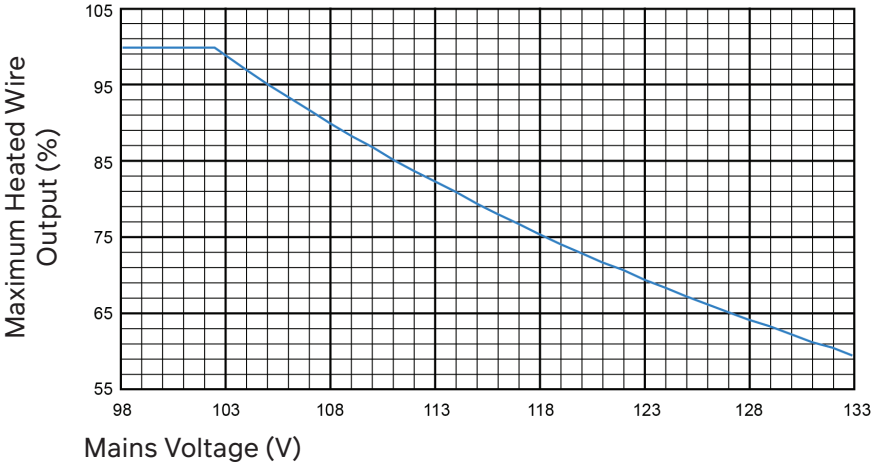
- To display the list, simultaneously press and hold  and for three seconds.
- Record the values in the table.
- To return to the Home screen, press any button.

Explanation of Parameter 2 List	
Ufoto4 (top)	Voltage on the highest IR receive diode for water level detection.
Ufoto3	Voltage of the third IR receive diode for water level detection.
Ufoto2	Voltage of the second IR receive diode for water level detection.
Ufoto1 (bottom)	Voltage on the lowest IR receive diode for water level detection.
Ulight	Measured voltage of the ambient light sensors.
Backlight	Present value of the back lighting in percent.
Next Service	Date when the device must be serviced.
Date	Actual date.
Time	Actual time.

5.5.8 Heated wire output limits

To maintain a maximum output of 30 W, independent of the mains voltage, the mains voltage is continuously measured and the output of the heated wires is regulated. The heated wires are designed to achieve the maximum allowable temperature when permanently activated at a mains voltage of 110 V.

Maximum Heated Wire Output
Dependent upon a Mains Voltage of 110



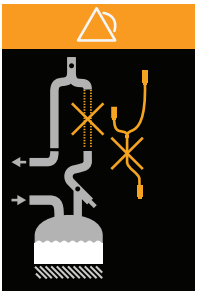
6.0 Alarms

When the device is switched on, a power-on self test is performed to test the alarm system. During this test, a test alarm is sounded and orange lights on the display illuminate. After the test, all alarms are assigned the medium priority. This section provides the remedy for each of the possible alarms.

NOTE: All alarms are stored in the Event List.

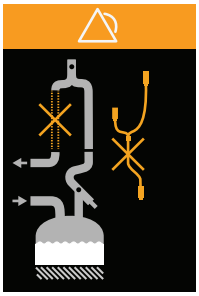
NOTE: If an error is displayed in orange type on a black background when the device starts, contact customer service.

6.1 Inspiratory heated wire missing/defective



Cause	Remedy
Inspiratory heated wire adapter not connected, adapter not fully inserted into breathing circuit, connection is defective, or the heated wire adapter is defective.	Connect, re-insert fully, or replace the heated wire adapter or the breathing circuit.
Inspiratory limb of the breathing tube is defective.	Replace the breathing tube.
Heated wire adapter cable is defective.	Replace the heated wire adapter.
Internal fuses for the heated wire are defective.	Contact customer service.
Defective heated wire connector on the heated humidifier.	Replace the humidifier.

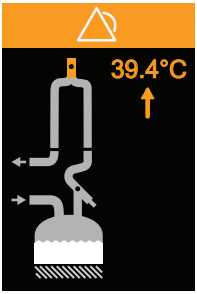
6.2 Expiratory heated wire missing/defective



Cause	Remedy
Expiratory heated wire adapter is not fully connected to breathing circuit, connection is defective, or the heated wire adapter is defective.	Connect, re-insert/fully insert the adapter into the breathing circuit, or replace the heated wire adapter or the breathing circuit.
Expiratory limb of the breathing tube is defective.	Replace the breathing tube.
Heated wire adapter cable is defective.	Replace the heated wire adapter.
Internal fuse for the heated wire is defective.	Contact customer service.
Defective heated wire connector on the heated humidifier.	Replace the humidifier.

6.3 Breathing gas temperature too high

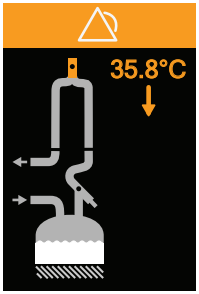
Breathing gas gets warmer than 43°C (109°F) or at least 2°C (or 3.6°F) above the set-point after the warm-up phase and the alarm delay.



Cause	Remedy
Change in gas flow rate.	Mute the alarm and observe whether the temperature reduces to a permissible value.
Temperature probe is defective.	Replace the temperature probe.
Humidifier is defective.	Replace the humidifier.
Flow rate is out of range.	If flow rates must be set outside the recommended ranges and low temperature alarms persist, reducing gas temperature settings may resolve the alarm. Alternately, replace the breathing circuit with a breathing circuit of the appropriate gas flow rate range.

6.4 Low patient temperature

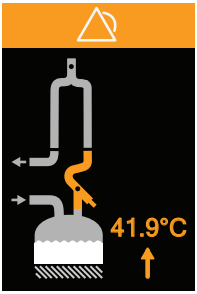
Breathing gas temperature is at least 2°C (or 3.6°F) below the set-point after the warm-up phase and the alarm delay.



Cause	Remedy
Change in gas flow rate.	Mute the alarm and observe whether the temperature reduces to a permissible value.
Temperature probe not fully inserted.	Fully insert the temperature probe.
Temperature probe is defective.	Replace the temperature probe.
Humidifier is defective.	Replace the humidifier.
Humidification chamber inserted incorrectly.	Correctly insert the humidification chamber.
Water build up on temperature probe.	Remove and dry off the temperature probe and reinsert the probe until fully seated.
Flow rate out of range.	If flow rates must be set outside the recommended ranges and low temperature alarms persist, reducing gas temperature settings may resolve the alarm. Alternately, replace the breathing circuit with a breathing circuit of the appropriate gas flow rate range.
Operating outside of the recommended environmental conditions.	Change the operating environment.

6.5 Humidification chamber temperature too high

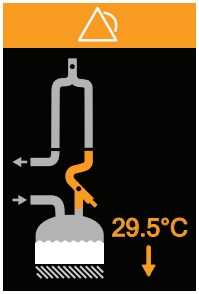
Temperature of the humidification chamber is 5°C (or 9°F) above the set-point for 20 minutes. Immediate alarm occurs when the temperature of humidification chamber is at least 10°C (or 18°F) above the set-point.



Cause	Remedy
Change in breathing gas flow rate.	Mute the alarm and observe whether the temperature reduces to a permissible value.
Temperature probe is defective.	Replace the temperature probe set.
Humidifier is defective.	Replace the humidifier.
Flow rate is too low.	Increase the flow rate of the ventilator or gas source to at least 1 LPM or the minimum flow rate indicated on the breathing circuit specifications.

6.6 Humidification chamber temperature too low

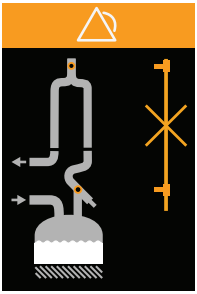
Temperature of the humidification chamber is 5°C (or 9°F) below the set-point for 20 minutes. Immediate alarm occurs when the temperature of humidification chamber is at least 10°C (or 18°F) below the set-point.



Cause	Remedy
Change in the breathing gas flow rate.	Mute the alarm and observe whether the temperature increases to a permissible value.
Temperature Probe not fully inserted into the circuit.	Fully insert the temperature probe into the circuit (chamber-end).
Water build up on temperature probe.	Remove and dry off the temperature probe and reinsert it.
Temperature probe is defective.	Replace the temperature probe set.
Humidifier is defective.	Replace the humidifier.
Humidification chamber not correctly inserted.	Correctly insert the humidification chamber.
Temperature fuse has triggered.	Replace the humidifier.
Bottom of the humidification chamber is uneven.	Replace the humidification chamber.
Gas flow rate is too high.	If flow rates must be set outside the recommended ranges and low temperature alarms persist, reducing gas temperature settings may resolve the alarm. Alternately, replace the breathing circuit with the a breathing circuit of the appropriate gas flow rate range.

6.7 Temperature probe missing/defective

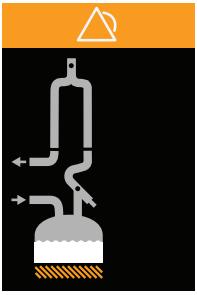
Temperature probe is interrupted or defective.



Possible cause	Measures
Temperature probe is not connected or not plugged into the circuit.	Connect the temperature probe.
Defective temperature probe.	Replace the temperature probe set.
No flow through the system.	Turn on or increase the air flow.

6.8 Heater plate sensor defective

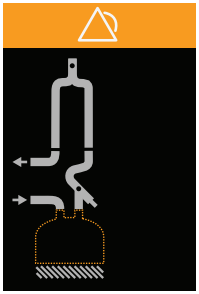
Error in the heater plate.



Possible cause	Measures
Heating element is defective.	Replace the heated humidifier.

6.9 Humidification chamber missing

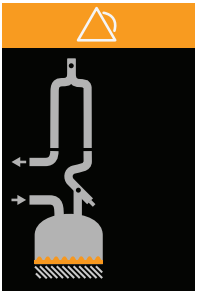
No humidification chamber in the humidifier.



Possible cause	Measures
No humidification chamber in the humidifier.	Insert the humidification chamber into the humidifier.
Humidification chamber is not correctly inserted.	Correctly insert the humidification chamber.
Humidifier is defective.	Replace the humidifier.

6.10 Water fill level too low

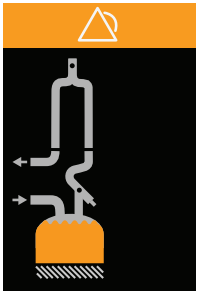
Too little water in the humidification chamber.



Possible cause	Measures
Water reservoir is empty and/or the water level is below the minimum level.	Replace the water reservoir and allow water to fill the chamber and resolve the alarm.
Water reservoir too low in reference to the humidification chamber location.	Increase the height of the water reservoir to more than 50 cm above the humidifier.
Faulty humidification chamber.	Replace the humidification chamber.
Heated humidifier not level.	Level the heated humidifier to within 10 degrees of level.
Water level sensor blocked or dirty.	Remove the humidification chamber and clean the water level sensor.

6.11 Water fill level too high

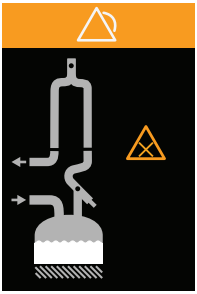
Too much water in the humidification chamber.



Possible cause	Measures
Float is defective.	Replace the humidification chamber.
Error message due to tilted humidifier.	Adjust the humidifier to within 10 degrees of level and ensure the water level is below the max line on all sides of the chamber.
A labeled humidification chamber is used that interferes with the detection sensor for excess water.	Replace the humidification chamber with an AirLife DuoTherm® humidification chamber.
Sensors for water level detection are dirty.	Remove the humidification chamber. Clean the sensors with a clean cloth. Replace the humidifier if the water level is below max line but continues to alarm.
Too much condensate from the breathing circuit system flowing back into the humidification chamber.	• Adjust temperature/humidity levels to reduce condensation. • Manually reduce excess water in the humidification chamber.
Excessive pressure applied to the water reservoir.	Reduce the applied pressure in the water reservoir.
Heated humidifier is not level.	Level the heated humidifer.

6.12 Hardware alarm

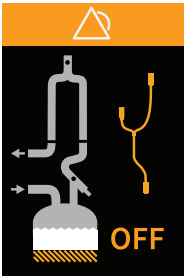
Device-internal error.



Possible cause	Measures
Defective humidifier.	Replace the humidifier.

6.13 Forced shutdown of the humidifier

Forced shutdown of all heaters.



Possible cause	Measures
An error has not been corrected within ten minutes of an alarm.	Cycle mains power off, then on, to resume normal operation. Resolve all alarm conditions within 10 minutes.
Heater plate temperature rises above 108°C (226°F).	Turn off the device and let the heating plate cool down. Contact customer service. Replace the device.

6.14 Warning prompts

Warning prompts appear on the screen without an audible signal, with or without a prompt. Any warning prompts that are not displayed are saved in the event list. Warning prompt situations do not require any action by the user. A warning prompt identifies a situation that does not pose a direct threat, but could possibly impair the functionality of the device.

Error#/Image	**Warning message and cause**	
 Shown in the upper, left corner of the display during normal operation	Message:	Internal battery dead or missing.
	Cause:	The battery power is depleted.
	Program reaction:	Entries in the event list are saved with the incorrect time stamp.
	Remedy:	Call customer service and return the heated humidifier for servicing.
08	Message:	Respiratory gas temperature above 42.5°C (108.5°F).
	Designator:	warning_patienttemp_almost_too_high (80h) [wrn_tp_fast_zu_hoch]
	Cause:	Respiratory gas temperature is greater than 42.5°C (108.5°F).
	Program reaction:	Control of the inspiratory heated wire is shut off.

7.0 Cleaning and disinfecting procedures

This section provides instructions for cleaning the heated humidifier, temperature probe, heated wire adapter, and power cord, and for disinfecting the temperature probe. The cleaning and disinfecting agents listed below have been tested and approved for use with the heated humidifier.

Cleaning agents (choose only one of the following):

- Hydrogen peroxide (4%)
- CaviWipes™, Disinfecting Towelettes[1] (Metrex™ Research)
- Mild detergent (such as dish washing detergent)
- Disinfecting agents:
- CaviWipes™, Disinfecting Towelettes[1] (Metrex™ Research) (intermediate level)
- CIDEX™ OPA[2] Ortho-phthalaldehyde Solution (ASP®) (high level)

The following sections of this manual provide the steps for the cleaning and disinfecting procedures:

- "7.1 Cleaning the system with CaviWipes™ Disinfecting Towelettes"
- "7.2 Cleaning the system with hydrogen peroxide"
- "7.3 Cleaning the system with mild detergent"
- "7.4 Intermediate disinfection of the temperature probe with CaviWipes™ Disinfecting Towelettes"
- "7.5 High level disinfection of the temperature probe with CIDEX™ OPA"

WARNING: Cleaning and disinfecting is required after each time the equipment is used.

WARNING: Before cleaning the heated humidifier, check to ensure that the unit is switched off, the power cord is disconnected, and the unit has cooled down.

CAUTION: Do not immerse the heated humidifier or its accessories in liquids or sterilize them. Detailed instructions for cleaning

1 If the brand-name product is not available in your area, we recommend using a medical grade cleaning wipe specified for intermediate disinfection containing 17% alcohol (isopropyl or isopropanol) and 0.28% quaternary ammonium chloride or equivalent.

2 If the brand-name product is not available in your area, we recommend using a medical grade, high level disinfectant containing approximately 0.55% Ortho-phthalaldehyde or equivalent.

and maintaining the device are included in the sections on maintenance and cleaning.

CAUTION: Do not sterilize the temperature probe.

CAUTION: Do not allow any liquids to penetrate the housing.

CAUTION: Discard and replace temperature probes with signs of deterioration such as corrosion, discoloration, pitting, or cracking.

NOTE: Dilution, exposure times, and change in the composition have a major impact on the cleaning process.

NOTE: Wipe the heated humidifier and cables with a lint-free or low-lint, soft cloth to remove any cleaning residues from the device before using it.

NOTE: Wipe the airway temperature probe with a lint-free or low-lint, soft cloth to remove any cleaning residues from the probe before using it.

NOTE: After cleaning and disinfecting the heated humidifier, store it in a clean environment.

NOTE: In the absence of applicable institutional protocols, AirLife recommends high level disinfection as instructed in section "7.5 High level disinfection of the temperature probe with CIDEX™ OPA". Follow the manufacturer's high-level disinfectant instructions, including the instructions for preparation of the solution, the exposure time and temperature, and rinsing.

NOTE: The maximum number of reprocessing cycles for the temperature probe is 333 cycles or five (5) years of service. Perform the annual inspection per the Service Manual and dispose of temperature probes that do not pass the temperature accuracy test, exhibit signs of deterioration, or met the maximum reprocessing cycle or years of service limit.

7.1 Cleaning the system with CaviWipes™ Disinfecting Towelettes

1. Use a CaviWipes™ towelette to wipe the external surfaces of the heated humidifier, especially the display screen and the front panel buttons.

2. Move the mounting lever to the open position and wipe the inside walls of the heated humidifier where the humidification chamber sits and clean the top surface of the hotplate.
3. While holding the heated wire adapter in one hand, use a fresh CaviWipes™ towelette to wipe in one direction down the length of the wire. If the towelette becomes soiled, use a fresh one to repeat this step until the wire is clean (when no soil appears on the towelette). Do this step a minimum of two times.
4. Inspect the ends of the wire and use a fresh CaviWipes™ towelette to remove any remaining soil from around the plug.
5. While holding the power cable in one hand, use a fresh CaviWipes™ towelette to wipe in one direction down the length of the cable. If the towelette becomes soiled, use a fresh one to repeat this step until the cable is clean (when no soil appears on the towelette). Do this step a minimum of two times.
6. Inspect the ends of the cable and use a fresh CaviWipes™ towelette to remove any remaining soil from around the plug.
7. While holding the temperature probe in one hand, use a fresh CaviWipes™ towelette to wipe in one direction down the length of the cable. If the towelette becomes soiled, use a fresh one to repeat this step until the cable is clean (when no soil appears on the towelette). Do this step a minimum of two times.
8. Inspect the ends of the cable and use a fresh CaviWipes™ towelette to remove any remaining soil from around the plug.

7.2 Cleaning the system with hydrogen peroxide

1. Saturate a lint-free or a low-lint, soft cloth with a hydrogen peroxide solution prepared to 4% v/v.
2. Use the prepared cloth to wipe the external surfaces of the heated humidifier, especially the display screen and the front panel buttons.
3. Move the mounting lever to the open position and wipe the inside walls of the heated humidifier where the humidification chamber sits and clean the top surface of the hotplate.
4. While holding the heated wire adapter in one hand, use a fresh, prepared cloth to wipe in one direction down the length of the wire. If the cloth becomes soiled, use a fresh one to repeat this step until the wire is clean (when no soil appears on the cloth).
5. Inspect the ends of the wire and use a fresh, prepared cloth to remove any remaining soil from around the plug.

6. While holding the power cable in one hand, use a fresh, prepared cloth to wipe in one direction down the length of the cable. If the cloth becomes soiled, use a fresh one to repeat this step until the cable is clean (when no soil appears on the cloth).
7. Inspect the ends of the cable and use a fresh, prepared cloth to remove any remaining soil from around the plug.
8. While holding the temperature probe in one hand, use a fresh, prepared cloth to wipe in one direction down the length of the cable, and gently wipe around the contact points of the probe. If the cloth becomes soiled, use a fresh one to repeat this step until the cable and contact points are clean (when no soil appears on the cloth).
9. Inspect the ends of the cable and use a fresh, prepared cloth to remove any remaining soil from around the plug.

7.3 Cleaning the system with mild detergent

Cleaning procedure:

1. Prepare the cleaning solution according to the manufacturer's specifications.
2. Saturate a lint-free or a low-lint, soft cloth with a mild detergent (such as dish-washing detergent).
3. Use the prepared cloth to wipe the external surfaces of the heated humidifier, especially the display screen and the front panel buttons.
4. Move the mounting lever to the open position and wipe the inside wall of the heated humidifier where the humidification chamber sits and clean the top surface of the hotplate.
5. While holding the heated wire adapter in one hand, use a fresh, prepared cloth to wipe in one direction down the length of the wire. If the cloth becomes soiled, use a fresh one to repeat this step until the wire is clean (when no soil appears on the cloth).
6. Inspect the ends of the wire and use a fresh, prepared cloth to remove any remaining soil from around the plug.
7. While holding the power cable in one hand, use a fresh, prepared cloth to wipe in one direction down the length of the cable. If the cloth becomes soiled, use a fresh one to repeat this step until the cable is clean (when no soil appears on the cloth).
8. Inspect the ends of the cable and use a fresh, prepared cloth to remove any remaining soil from around the plug.
9. While holding the temperature probe in one hand, use a fresh, prepared cloth to wipe in one direction down the length of the cable, and gently

wipe around the contact points of the probe. If the cloth becomes soiled, use a fresh one to repeat this step until the cable and contact points are clean (when no soil appears on the cloth).

10. Inspect the ends of the cable and use a fresh, prepared cloth to remove any remaining soil from around the plug.

Rinsing procedure:

1. With a lint-free or low-lint, soft cloth dampened with utility water, wipe the surfaces of the heated humidifier.
2. While holding the heated wire in one hand, use a fresh, dampened cloth to wipe in one direction down the length of the wire.
3. Repeat the previous step.
4. While holding the temperature probe in one hand, use a fresh, dampened cloth to wipe in one direction down the length of the cable, and then gently clean around the contact points of the probe.
5. Repeat the previous step.
6. While holding the power cable in one hand, use a fresh, dampened cloth to wipe in one direction down the length of the cable.
7. Repeat the previous step.

7.4 Intermediate disinfection of the temperature probe with CaviWipes™ Disinfecting Towelettes[3]

1. Conduct a full cleaning procedure (according to the previous instructions) before continuing with disinfection.

   NOTE: For best results, perform this procedure at a room temperature above 20°C (68°F).

2. While applying the disinfectant, ensure that all surfaces of the temperature probe remain wet for at least three minutes. Reapply the disinfectant with a fresh CaviWipes™ towelette as needed.
3. While holding the temperature probe in one hand, use a fresh CaviWipes™ towelette to wipe in one direction down the length of the cable, and gently wipe around the contact points of the probe. Repeat this step with a fresh CaviWipes™ towelette.
4. Allow the temperature probe to air dry completely before using it or storing it.

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3 If the brand-name product is not available in your area, we recommend using a medical grade cleaning wipe specified for intermediate disinfection containing 17% alcohol (isopropyl or isopropanol) and 0.28% quaternary ammonium chloride or equivalent.

7.5 High level disinfection of the temperature probe with CIDEX™ OPA[4]

NOTE: Follow the high-level disinfectant manufacturer's instructions, including the instructions for preparing and testing of the solution, the exposure time and temperature, and rinsing.

⚠ **CAUTION:** Do not submerge the electrical connectors. The temperature probes can be submerged up to, but not including, the electrical connectors.

1. Conduct a full cleaning procedure (according to the previous instructions) before continuing with disinfection.

   NOTE: For best results, perform this procedure at a room temperature-above 20°C (68°F).

2. While applying the disinfectant, ensure that all surfaces of the temperature probe remain wet for at least 12 minutes, Reapply the disinfectant with a dampened soft cloth as needed.
3. Dampen a lint-free or a low-lint, soft cloth with CIDEX™ OPA.
4. While holding the temperature probe in one hand, use a fresh, prepared cloth to wipe in one direction down the length of the cable, and gently wipe around the contact points of the probe. Repeat this step with a fresh, damp cloth.
5. Allow the temperature probe to air dry completely before using it or storing it.

4 If the brand-name product is not available in your area, we recommend using a medical grade, high level disinfectant containing approximately 0.55% Ortho-phthalaldehyde or equivalent.

8.0 Maintenance

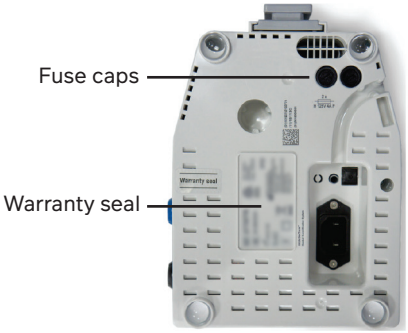
8.1 Conducting a safety inspection and functional test

The heated humidifier does not need calibration. Every 12 months (of hospital operation) conduct a safety-related technical check-up and a functional test of the heated humidifier (see the service and maintenance manual for detailed information).

8.2 Replacing the fuse

Before replacing the fuse, ensure that the power cord is disconnected. With a #2 flat blade screwdriver, push in and rotate the fuse cap counter-clockwise. Replace the fuse according to the following table. Push in and rotate the fuse cap to lock it into position.

Heated humidifier part #	Fuse description
377HTR	4 A,125 V, Fast Blow, 10 kA UL Listed Fuse



9.0 Technical specifications

Dimensions	Height:	170 mm
	Width:	145 mm
	Depth:	200 mm
Weight	Heated humidifier:	Approximately 2.3 kg
		Approximately 2.5 kg with accessories
Classification	Unit (protection class cf. IEC 60601) Class II	
	Application parts of Type BF:	Heated breathing tube system
		Temperature probe
	Protection category by enclosure IP22 (protected against solid objects with diameter from 12 mm, protected against access with a finger, protection against falling water drops if the enclosure is tilted up to 15°.)	
Electrical specifications	Operating voltage:	Heated humidifier 110–120V ±10%
	Mains frequency:	50 Hz / 60 Hz
	Power consumption:	315 VA maximum
	Heating plate:	170 W
	Inspiratory tube heater:	22V~, 30 W
Operating data	Warm-up time:	30 minutes (maximum)
	Recommended Average Flow Rate Range to maintain the minimum levels of humidity delivery per ISO 80601-2-74	1 to 60 L/min
	Humidity output:	> 33 mg of H_2O/liter of gas flow in the range of 1 to 60 L/min
	System humidity output:	INV > 33 mg/L NIV > 12 mg/L See "5.4.2 Adjusting the humidity"
	Maximum operating pressure:	13.2 kPa[1]
	Continuous noise:	< 50 dB (1m)
	Sound pressure level of the alarm:	65 dB (maximum)

Humidification system	Humidification Chamber: Maximum gas leakage at max. operating pressure:	< 10 mL/min[2]
	Breathing Circuit: Maximum gas leakage at 60 mbar:	Adults: < 40 mL/min[2]
		Children: <30 mL/min[2]
		Neonates: <30 mL/min[2]
	Internal compliance:	Adults: 0.5 to 5 mL/mBAR[2]
		Children: 0.5 to 4 mL/mBAR[2]
		Neonates: 0.5 to 1.5 ml/mBAR[2]
	Flow resistance	Adults: < 0.06 mBAR/L/min at 30 L/min
		Children: <0.12 mBAR/L/min at 15 L/min
		Neonates: <0.74 mBAR/L/min at 2.5 L/min
Environment	**Temperature**	
	When operating:	+18 to +26°C (+64 to +79°F) +21 to +26°C (+70 to +79°F) neonate
	During storage and transport:	–20 to +50°C (–4 to +122°F)
	Gas inlet temperature:	+18 to +26°C[3] (+64 to +79°F)
	Humidity	
	When operating:	0 to 85% non-condensing
	During storage and transport:	0 to 85% non-condensing
	Atmospheric pressure:	
	When operating:	70 to 106 kPa
	During storage and transport:	50 to 106 kPa
Measurement range	Temperature sensor:	9.5 to 50°C ±2°C (49 to 122°F) patient-side
		5 to 80°C ±2°C (41 to 176°F) humidification chamber
Standards	The heated humidifier complies with IEC 60601-1, IEC 60601-1-2, IEC 60601-1-8, ISO 10993, ISO 80601-2-74, and IEC TR 60601-4-2, ISO 18562.	
	The chamber/circuits comply with ISO 10993, ISO 5356-1, ISO 5367, ISO 80601-2-74, and ISO 18562.	

[1] Unless the user instructions for the humidification chamber used prescribes lower maximum pressures.

[2] Depending on the AirLife DuoTherm® humidification chamber used and the AirLife DuoTherm® breathing tube used.

[3] The maximum gas outlet temperature of the therapy device at 23°C (73°F) room temperature is 32°C (90°F).

10.0 Storage and disposal

- Clean the heated humidifier and the heated wire adapter before storing them, and store them in a plastic bag.
- Clean and disinfect the temperature probe and loosely wind the cable.
- The required storage temperature is from –20 to +50ºC (–4 to +122ºF). Before use, the device must be acclimatized and may only be put into operation after reaching room temperature.

10.1 Disposal

Devices category	Disposal instruction
General Medical Waste	Dispose of waste according to local and state environmental regulations.
Infectious/Bio-Hazardous Medical Waste	Dispose of waste in a container that is clearly labeled, leak-proof, and color-coded according to local standards and state environmental regulations.
Physical Hazardous Medical Waste	Dispose of waste according to local and state environmental regulations. Biohazardous sharps must be collected in a sharps container that is clearly labeled.
Radioactive Medical Waste	Dispose of waste in a shielded container that is labeled with the Radioactive symbol according to local and state environmental regulations.
Electronical And Electronic Waste (WEEE)	Dispose of electronic devices in compliance with WEEE or according to local and state environmental regulations.

11.0 EMC specifications

Guidance and Manufacturer's Declaration – Emissions All ME Equipment and ME Systems		
The AirLife DuoTherm® Heated Humidifier is intended for use in the electromagnetic environment specified below. The customer or user of the heated humidifier must ensure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF Emissions CISPR 11	Group 1	The AirLife DuoTherm® Heated Humidifier uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The AirLife DuoTherm® Heated Humidifier is suitable for use in all establishments including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonics IEC 61000-3-2	PASS	
Flicker IEC 61000-3-3	PASS	

Essential performance of the AirLife DuoTherm® heated humidifier is defined as heating and humidifying breathing gases. During a significant EM disturbance, the device screen may go blank. While the screen is blank heat and humidity is not being added to the breathing gas. In this situation remove or increase separation distance between any device that may be outputting EM energy. The AirLife DuoTherm® heated humidifier will self-correct once the EM disturbance is removed or decreases to the levels shown in the following tables.

It is also suggested that Portable RF communication devices (radio devices) (including their accessories such as antenna cable and external antennas) should not be used at a distance of less than 30cm (or 12inches) from the AirLife DuoTherm® parts and lines specified by the manufacturer.

Guidance and Manufacturer's Declaration – Immunity All ME Equipment and ME Systems			
The AirLife DuoTherm® Heated Humidifier is intended for use in the electromagnetic environment specified below. The customer or user of the heated humidifier must ensure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
ESD IEC 61000-4-2	±8 kV Contact ±15 kV Air	±8 kV Contact ±15 kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30%.
EFT IEC 61000-4-4	±2 kV Mains ±1 kV I/Os	±2 kV Mains N/A	Mains power quality should be that of a typical commercial or hospital environment.

11.0 EMC specifications

Surge IEC 61000-4-5	±1 kV Differential ±2 kV Common	±1 kV Differential ±2 kV Common	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/ Dropout IEC 61000-4-11	>95% Dip for 0.5 Cycle	>95% Dip for 0.5 Cycle	Mains power quality must be that of a typical commercial or hospital environment. If the AirLife DuoTherm® Heated Humidifier needs to run continuously during power mains interruptions, an uninterruptible power supply or backup battery must be used.
	>95% Dip fo 1 Cycle	>95% Dip for 1 Cycle	
	30% Dip for 25/30 Cycles	30% Dip for 25/30 Cycles	
	>95% Dip for 250/300 Cycles	>95% Dip for 250/300 Cycles	
Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8	30 A/m	30A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.
NOTE: UT is the a.c. mains voltage before application of the test level.			

Guidance and Manufacturer's Declaration – Immunity ME Equipment and ME Systems

The AirLife DuoTherm® Heated Humidifier is intended for use in the electromagnetic environment specified below. The customer or user of the heated humidifier must ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Conducted RF IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 6 V[1] in ISM between 0.15 MHz and 80 MHz[2] 80% AM at 1 kHz	3 V 0.15 MHz to 80 MHz 6 V[1] in ISM between 0.15 MHz and 80 MHz[2] 80% AM at 1 kHz	PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz.	10 V/m 80 MHz to 2.7 GHz 80% AM at 1 kHz	PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT

[1] r.m.s. before modulation is applied.

[2] The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz,3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHzto 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

Guidance and Manufacturer's Declaration –
Immunity To RF Wireless Communications Equipment ME Equipment and ME Systems

The AirLife DuoTherm® Heated Humidifier is intended for use in the electromagnetic environment specified below. The customer or user of the heated humidifier must ensure that it is used in such an environment.

Test Frequency	Band[1]	Service[1]	Modulation[2]	Maximum Power	Distance	Immunity Test Level
MHz	**MHz**			**W**	**Meters**	**(V/m)**
385	380 to 390	TETRA 400	Pulse modulation[2] 18 Hz	1.8	0.3	27
450	430 to 470	GMRS 460, FRS 460	FM[3] ±5 kHz deviation 1 kHz sine	2.0	0.3	28
710 745 780	704 to 787	LTE Band 13, 17	Pulse modulation[2] 217 Hz	0.2	0.3	9.0
810 870 930	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation[2] 18 Hz	2.0	0.3	28
1720 1845 1970	1700 to 1900	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation[2] 217 Hz	2.0	0.3	28
2450	2400 to 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation[2] 217 Hz	2.0	0.3	28
5240 5500 5785	5100 to 5800	WLAN 802.11a/n	Pulse modulation[2] 217 Hz	0.2	0.3	9.0

NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

[1] For some services, only the up-link frequencies are included.

[2] The carrier shall be modulated using a 50% duty cycle square wave signal.

[3] As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

12.0 Cybersecurity Information

12.1 Overview

This section of the manual is supplied by AirLife to provide the operator with information to be used for the integration of the AirLife DuoTherm® Humidification System into the operator's infrastructure according to IEC 80001-1-2021, Annex B *Guidance for Accompanying Document Information.* This section was generated based on current knowledge of Health IT-networks and is subject to change as conditions in this area change/advance. Since framework conditions, installations, and the operation of the environment are the responsibility of the operator, AirLife cannot fully guarantee failure-free operation.

12.2 System level description

12.2.1 Environment description

The AirLife DuoTherm® Humidification System is used to deliver heated, humidified breathing gases to a patient's airway when they are mechanically ventilated, receiving continuous non-invasive (NIV) positive airway pressure or high-flow oxygen therapies. The AirLife DuoTherm® System consists of a Heated Humidifier, Humidification Chamber and Heated Circuits, along with its accessories. Optional accessories include Relief Valves, Mounting Brackets and Poles.

The AirLife DuoTherm® System does not connect to IT infrastructure or other devices, with the exception of authorized devices used for in-field updates and maintenance by authorized personnel. The device is intended to be used in an access-controlled environment by authorized and trained personnel only.

12.2.2 Data interfaces

Table 12.1 below lists the local data interfaces enabled in the medical device.

Table 12.1 – Data interfaces

Interface	Services	Purpose
Universal Serial Bus (USB)	Proprietary programming interface and driver	For local programming, maintenance/updates, and exporting logs by authorized personnel

12.2.3 Data flows and protocols

The AirLife DuoTherm® System does not connect to IT health infrastructure and is a standalone product. There are no external information flows present

in this system. Clinical and operational information flows can be found in the remainder of this manual.

12.3 Security and user access

12.3.1 General

This system security plan provides an overview of the security requirements and describes the controls in place or planned for implementation to provide a level of security appropriate for the device to be a resilient and robust medical device that is safe, effective, and secure.

The security safeguards implemented for the AirLife DuoTherm® system meet the policy and control requirements set forth in this System Security Plan. All systems are subject to monitoring consistent with applicable laws, regulations, agency policies, procedures and practices.

12.3.2 Implemented security controls

Security controls implemented in the AirLife DuoTherm® System or recommended to be implemented in the system are described in Table 12.2

Table 12.2 – Data interfaces

Security Control	Description
Restrict physical access to device and accessories	Ensure that physical access to the device is restricted to authorized personnel only, e.g., store and operate the device in an area which is protected by physical access controls.
Temperature reading failsafe mechanism	A control mechanism in the device that ensures the temperature of the breathing gas provided will not exceed a safe temperature for use in human patients, even if the readings from the temperature probes are faulty or have been tampered with.
Require physical confirmation to put device into mode where service settings can be changed	A special keypad sequence is used to put the device into a mode that allows changes to service settings.

12.3.3 Malware / antivirus / allow-list

The AirLife DuoTherm® System does not contain any network interfaces nor a commercial operating system. Antivirus and communications allow listing does not apply to this system. See Section 12.4.2, Table 12.3 for more information on the controls implemented or suggested in the AirLife DuoTherm®.

12.3.4 Security exclusions

The device does not store any sensitive information impacting the manufacturer, patients, nor healthcare delivery organizations. This device does not contain any network interfaces nor a commercial operating system. Therefore, common security controls associated with such data or technologies are not present nor relevant to this device.

12.3.5 System access

12.3.5.1 Types of users

User roles and privileges are described in Table 12.3.

Table 12.3 – Roles and privileges

Role	Internal or external	Privileged (P), Non-Privileged (NP), or No Logical Access (NLA)	Sensitivity level	Authorized privileges	Functions performed
Field Service Representative	External	P	Moderate	Custom administrative access	Install and configure software and updates, export or clear log files, and factory reset device
Unauthenticated User	Internal	NP	Limited	N/A	Functional capabilities of device

12.3.5.2 Device maintenance and updating

The expected service life of the product is eight years.

For disposal information, see Section 10.1 Disposal. There are no additional disposal or decommissioning steps required for this product as no sensitive information or access is stored or retained by the product system.

Customers with security concerns and additional requests for information may email productquality@myairlife.com. A report will be recorded and assigned to a specialist who will investigate incidents or assist in customer needs. The specialist may reach back out to the customer with questions or to clarify the concern.

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