

FL-9000 Respiratory Humidifier

Product Data Sheet



PRODUCT: FL-9000 Respiratory Humidifier**DESCRIPTION / FUNCTION**

Flexicare's FL-9000 is a Respiratory Humidifier designed to provide warmed and humidified inspired respiratory gases to ventilated adult patients and those receiving respiratory support, as part of a complete system including a Humidification Chamber and either an adult heated wire breathing circuit or limb, or an adult non-heated breathing circuit or limb.

The FL-9000 Respiratory Humidifier is used in patients who require mechanical ventilation or positive pressure breathing assistance via an endotracheal tube, tracheostomy tube, face mask, nasal cannula or other similar device.

PRECAUTIONS / WARNINGS

- Do not use if packaging is opened or damaged.
- Inspect the humidifier and all accessories for any deficiencies or damage prior to each use.
- The use of breathing circuits, humidification chambers and other accessories which are not approved by Flexicare may result in sub-optimal performance and place the patient at risk.
- Ensure that the invasive mode is selected for patients with bypassed airways.
- Always position the humidifier lower than the patients head.
- DO NOT use as part of patient monitoring or life support systems.
- Ensure that the humidification chamber does not overflow as water could enter the breathing circuit.
- Regularly monitor the water level in the humidification chamber in accordance with manufacturer's instructions.
- DO NOT fill the humidification chamber with water in excess of 37°C.
- Ensure that both temperature probe sensors are correctly and securely fitted.
- In case of an alarm, immediately switch off the humidifier and disconnect from the patient unless the cause is identified and rectified, or assessed to be of no hazard to the patient.
- Use suitable monitoring apparatus to avoid risk of injury.
- DO NOT touch the heater plate as surface temperatures may exceed 85°C.
- Always check the gas supply is flowing through the humidifier before connecting to the patient.
- DO NOT use a heated wire breathing circuit in the presence of flammable anaesthetic.

- The saturation of gas at the humidification chamber outlet may exceed 44mg/L if operating temperatures greater than 37°C are selected.
- DO NOT use liquid antiseptic, abrasives or sharp instruments to clean the surface.
- DO NOT immerse or autoclave.
- To avoid risk of electric shock, this equipment must only be connected to a mains supply with protective earth.
- Always disconnect from the power supply before servicing.
- DO NOT modify this equipment without authorisation of the manufacturer.
- Resetting the overheat protector should only be carried out by qualified service technician.
- High frequency, shortwave or microwave emissions may affect the function of the humidifier.

SPECIFICATIONS / KEY FEATURES

- Dimensions – W135mm x D170mm x H156mm (without chamber fitted)
- Weight – 2.9kg (without chamber fitted)
- Display – 4 digits, 14 segment LED
- Range - 5°C to 80°C
- Accuracy - $\pm 0.3^\circ\text{C}$ (in 25-45°C temperature range)
- Heater plate thermal cut out - $115\pm 3^\circ\text{C}$
- Operating mode: auto mode for invasive and non-invasive ventilation with option to manually set default temperatures.
- Continuous operation
- Two signal ports: DIN Connector (heated wire) and Jack Socket (temperature probe)

PRODUCT RANGE

Product Code	Product Description
FL9000	FL-9000 Respiratory Humidifier UK 230v with 3 pin plug
FL9000EU	FL-9000EU Respiratory Humidifier European 230v with 2 pin plug
FL9000U	FL-9000U Respiratory Humidifier USA 110-120v with NEMA 5-15P 3 pin plug
FL9000AUS	FL-9000AUS Respiratory Humidifier Australia 230v with 3 pin plug
FL9000CH	FL-9000CH Respiratory Humidifier China 220v with 3 pin plug
FL9000 INDIA	FL-9000 INDIA Respiratory Humidifier India 230v 3 pin plug
Replacement Leads	
FL9000-01	Single Heated Wire Circuit Adapter Lead
FL9000-02	Dual Heated Wire Circuit Adapter Lead
FL9000-03	Humidifier Temperature Probe Lead (1.5m)
Accessories	
FL2000-01	Rail Bracket Accessory
FL2000-02	C Clamp Accessory
FL2000-03	Mounting Bracket Accessory
FL2000-04	Mounting Kit Accessory
FL2000-05	Dual Mounting Kit Accessory

MATERIALS

Component	Material
Heater Plate	Anodized Aluminium
Spring Loaded Locking Bar	Polycarbonate/ABS Blend Springs – stainless steel

Plastic Enclosure for Humidification Chamber	Polycarbonate/ABS Blend
Plastic Enclosure	Polycarbonate/ABS Blend
Function, Operation & Warning Indicators	LED's (Red, Yellow, Green)
Display	Four Digit LED
Heated Wire Port	DIN Connector
Temperature Probe Port	Jack Socket
Power Switch	Polyamide (Nylon)

LATEX CONTENT

Flexicare's FL-9000 Respiratory Humidifier does not contain natural rubber latex.

DEHP CONTENT

Flexicare's FL-9000 Respiratory Humidifier does not contain phthalate DEHP.

SINGLE-USE

Flexicare's FL-9000 Respiratory Humidifier is a reusable device.

STERILITY

Flexicare's FL-9000 Respiratory Humidifier is supplied non-sterile.

STORAGE

Store in a cool, dry place out of direct sunlight.

SHELF LIFE

Flexicare declares a shelf life for 5 years from date of manufacture. This is based on the stability of the component devices and the raw material sourced. Expiry date is clearly marked on individual product packaging.

DISPOSAL CONSIDERATIONS

FL-9000 should be disposed via designated collection facilities in accordance with hospital policy, local guidelines and regulations.

PACKAGING MATERIALS

Pouch – Low Density Polyethylene
 Insert Tray – Polystyrene
 Box (476 x 336 x 304mm) – Cardboard