Revision history				
Version	Revision source	Revision description	Reviewer	Date
A0	/	Initial release	Zhao Rongxian	2023/10/17
A1	/	Updated the manufacturer address	Zhao Rongxian	2024/10/30
A1.1	/	Updated the details according to the audit	Zhao Rongxian	2025/3/19

【Product name】 Tube and Chamber Kit

【Product model】 Hi-OT1、Hi-OT2、Hi-OT3

【Product description】

This product is composed of heated breathing tube,chamber ports and water chamber. Non-sterile products.

【Intended use】

The Tube and Chamber Kit is intended to deliver the humidified and heated inspiratory gas as well as decreases condensation of the inspiratory gas. It is recommended to be used in combination with the Hi-800 and Hi-600 High-flow Humidification Device manufactured by Shenzhen Lifotronic and the Hi-800 and Hi-600 High-flow Humidification Device is intended to be used for the treatment of spontaneously breathing adult and pediatric (greater than 5Kg) patients who are with type 1/ type 2 acute respiratory failure with providing high flow warmed and humidified respiratory gases.

【Specifications】

Circuit Length	1.8m +patient interface
Interface Connections	ISO 5356-1 Conical connectors
Gas Ports	22mm male
Maximum Operating Pressure	6kPa
Rated Voltage	24V
Rated Current:	2.4A
Flow Range	From 2 to 60L/min depending on the patient interface
Compressible Volume of Chamber	≥90mL
Operation Environment	Ambient temperature: 18℃~28℃ Relative humidity: ≤80% Atmospheric pressure: 75kPa-106kPa
Transport & Storage Environment	Ambient temperature: -20℃~+55℃ Relative humidity: ≤93% Atmospheric pressure: 75kPa-106kPa
Shelf-life	Three years
Compatibility	Hi-800 and Hi-600 High-flow Humidification Device manufactured by Shenzhen Lifotronic

【Symbol instruction】

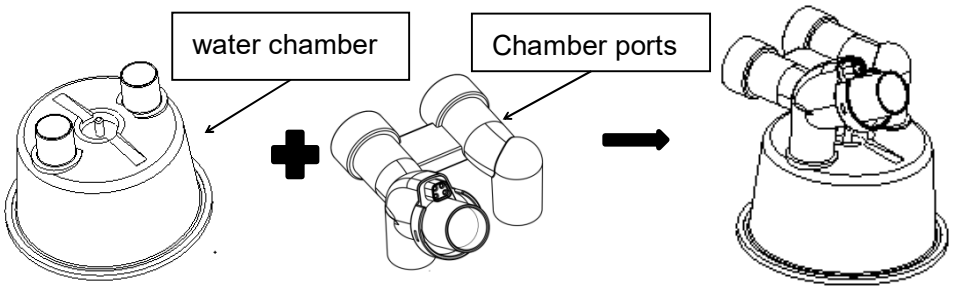
Labels and symbols	Description	Labels and symbols	Description
	Caution! Follow the associated documents		Refer to user manual
	Keep dry		Stacking limit by number
	Manufacturer		Do not re-use,For single patient use.
	Date of manufacture		Batch code
	Do not use if package is damaged		Use-by date
	Authorized representative in the European Community		Indicates this device is in compliance with MDR certification.
	Temperature limit		Humidity limitation
	Atmospheric pressure limitation		Recommended maximum water level
	Medical device		Unique device identifier

【Instructions】

1. Before use, confirm whether the product packaging bag is intact and ensure that the tube is not blocked or damaged；
2. Connect the heated breathing tube to the gas outlet on the water chamber；
3. Connect heated breathing tube to patient interfaces（nasal cannula）once the system has warmed up. Position heated breathing tube below patient interfaces（nasal cannula）so that condensate flows away from the patient.
4. Check whether the product connection is reliable, ensure that it will not be loose during treatment, and check whether there is any leakage in the tube.

【Installation and Connection】

Step1: Install water chamber，install the chamber ports on the water chamber.

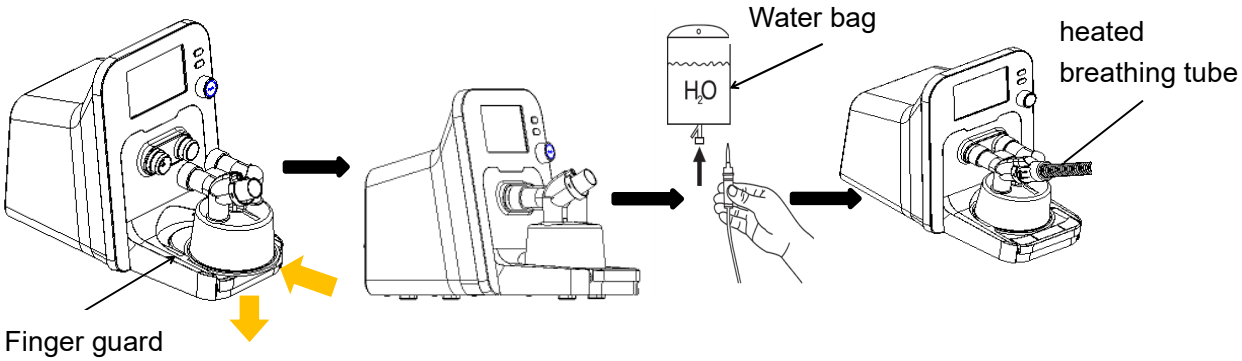


Step2: Fit the water chamber to the main unit by pressing down the finger guard on the High-flow Humidification Device and sliding the water chamber on. Push the water chamber on firmly until the finger guard clicks into place.

Step3: Connect the infusion bag needle on the water chamber to a medical water bag (generally 500mL). It is recommended to use a sterile water with CE Mark.

Observe the liquid level to ensure that it is lower than the highest liquid level. If the water level rises above the fill line,replace the chamber immediately.

Step4: Install heated breathing tube to the chamber ports.



【Precautions】

1. This product is not aseptically provided；
2. Do not use if the packaging bag is broken；
3. Please use within two weeks after opening the package bag；
4. This product is for single use only， please do not use it for different patients to prevent cross-infection；
5. When connecting with the device, you need to ensure that the connection is firm and not easy to loosen；
6. Avoid bending of the tube as much as possible to ensure that the tube is not flattened during use；
7. Stop using this product when the tube is damaged and leaks；
8. Ensure that the tube will not be blocked by patient secretions during treatment;

9. Waste generated after use should be treated in accordance with national and local guidelines for potentially infectious or bio-hazardous materials；
10. This product needs to be assembled to the High-flow Humidification Device produced by Shenzhen Lifotronic Technology Co.,Ltd.
11. Use this product in accordance with the use requirements of high-flow humidification device.Only adequately trained healthcare professionals are allowed to use this machine.

【Hospital Use】

1. This product is intended to be used for a maximum of 14 days.
2. Do not soak, wash or sterilise.

【Disposal Instructions】

Place the breathing tube and chamber in a waste bag at the end of use. Hospitals should discard according to their standard method for disposing of contaminated product.

【Contraindication】

The device has no contraindications, but it is necessary to pay attention to the contraindications related to humidification treatment.

【Clinical benefit】

The High-flow Humidification System is intended to benefit adult and pediatric (greater than 5Kg) patients who are with type 1/type 2 acute respiratory failure with humidified and warmed air/oxygen, after using the High-flow Humidification System, the breathing rate of patients can be reduced by at least 2 times per minute.

【Basic Information】

Notification of Adverse Events

As a health care provider,you may report the occurrence of certain events to Shenzhen Lifotronic Technology Co., Ltd.,and possibly to the competent authority of the Meber state in which the user and/or patient is established.

These events,include device-related death and serious injury or illness.In addition,as part of our Quality Assurance Programs,Shenzhen Lifotronic Technology Co., Ltd.requests to be notified of device failures or malfunctions.This information is required to ensure that Shenzhen Lifotronic Technology Co., Ltd.provides only the highest quality products.

Manufacturer

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European Representative

EC REP

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