High Flow Heated Respiratory Humidifiers

HiFRes Series

User Manual

Please read this manual carefully before using the device

User Manual

The following document is the User Manual for the TOPSON HiFRes Series High Flow heated respiratory humidifiers manufactured by Hebei Topson Medical Technology Co., Ltd. (hereafter, called "TOPSON Medical").

Warnings and Precautions

⚠Warnings:

- These warnings are meant to caution the user or operator of this device that there is a substantial risk of injury if these warnings are not followed.
- These instructions in manual are for reference only. They cannot replace the expert medical guidance from a licensed healthcare professional for the proper use of this device.
- Must read through and understand the instructions before using the devices.
- This device is not intended to provide complete ventilation requirements and cannot be used to provide life support.
- Only trained medical professionals are allowed to adjust treatment parameters according to patients' actual situation.
- If there are any discomforts occurring during the use of device, please contact your healthcare professionals immediately.
- Always properly connect device to the mains power supply to ensure device can work normally and safely.
- Regularly check if there are damages or wear-out on cables, enclosure and accessories, please timely replace damaged parts or accessories.
- To avoid electric shocks, must disconnect the device from mains power before cleaning.
- Maintenance and modification of this device can only be carried out by the maintenance personnel designated by TOPSON Medical. Repairs carried out by any service organization that has not been expressly authorized by TOPSON Medical will void the warranty or even result in unnecessary device damages or injury to persons.
- Ineffective therapy, devices damages, hazards to patients may result from excessive ambient temperature and humidity that not specified in manual. Room temperature higher than 18 °c (64 °f) or lower than 30 °c (86 °f) will affect the delivered gases' temperature and humidity.
- Do not use the device in direct sunlight or nearby heating devices, which will lead the device to output gases with excessive and hazardous temperature.
- Must keep the device away from fire source while use the device with oxygen.
- Please prepare a simple breathing apparatus or other machines that can temporarily replace this device, in order to avoid injuries to patients and therapy interruption resulting from sudden device failures.
- Please keep the device away from the electromagnetic interference environment to avoid device malfunction and degradation of essential performances. This device complies to IEC/EN 60601-1-2 so that it will not cause electromagnetic interference to

surroundings.

- If you notice any damages to the device, ingress of water, misused parameters or experience any unusual performance (such as, harsh sounds or unfamiliar odors), quickly disconnect the power supply and stop using the device. Once the device is turned off, contact your healthcare professionals or TOPSON representative.
- Delivery of respiratory gas through nasal channel will generate flow-dependent dynamic positive airway pressure (PAP). This must be taken into account where positive airway pressure could have adverse effects on a patient.
- Use of the heated breathing tube or patient interface for more than a specified time period may cause serious injury to the patient, including infection.
- Only the treatment modes specified in this manual are accessible on this device.
- Must use devices in accordance with the requirements of EN/IEC 60601-1 medical electrical instrument: general requirements for basic safety and essential performance.
- Remove the nasal interface and close the oxygen valve as soon as possible if it happens to power interruption or device failures.
- Only use the water camber, heated breathing tube, patient interface and other accessories provided by TOPSON Medical. Accessories not supplied by TOPSON Medical will cause device malfunction or degradation of performances or even cause injury to patients.
- Never use the device close to or stacked with other equipment. When necessary, should observe the device closely to ensure the device can run properly under used configuration.

Precautions:

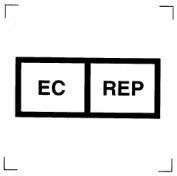
- Only use the device under specified temperature range +18℃ ~+ 30℃.
- Always insert an undamaged filter in the air inlet to ensure device works normally and safely.
- Do not immerse the device in liquid. Do not let any liquid enter into the device or into air inlet.
- Do not cover the device with a blanket in order to avoid overheat hazards, air inlet blockage and device failures.
- Environmental protection: Please properly deal with the wastes, residues and the device or accessories that are about to exceed their service life according to local environmental protection law.
- Please read throughout warnings in section *“4.3 Connect to Oxygen”* prior to connecting device to oxygen source.
- Do not operate this device in the presence of a flammable, anesthetic mixture with air or oxygen or nitrous oxide.
- Inspect the alarm system functionality before using to make sure the device can work

normally and safely.

- Never block the air inlet. Do not place the device on a soft surface where makes it easier to block air inlet, such as a bed or sofa. Prevent the air inlet from ingress of small matters such as fur and hairs.
- Do not block tubing or any accessories (oxygen tubing, water chamber, patient interface, etc.) which consist of gases delivery system.
- Always place the device at a place with good ventilation condition. And keep a distance at least 25cm between the device and the wall or other obstructions in order to avoid air blockages.
- Do not directly pull the power plug at the rear of device to disconnect mains power. If necessary, please pull it out by holding the plug head instead of cable.
- Do not store or use the device where it can fall or be pulled into water. If water has entered the unit enclosure, disconnect the power cord and discontinue use.
- If there is water entering into device, please disconnect from mains power immediately and remove the device from service.
- Do not use the device if: the heated breathing tube is damaged with holes, tears or kinks; the device cannot work normally; screws fall off or loosen; power cord or plug has damages; the device has been dropped or damaged and has been dropped into water, etc.
- The maximum output pressure of device is less than 25cmH2O. For the heated breathing tubing, the leakage rate is less than 25mL/min and the compliance is less than 10mL/KPa per meter length at 6KPa.
- In the specified working environment, the device shall not output gas with temperature exceeding 43℃.

Symbols

Not all symbols are useful

	ON/OFF(STANDBY)		Caution
	AUDIO PAUSE		Class II equipment
	Type BF applied parts	IPX1	Protected against water
	Conforms to the Waste Electrical and Electronic Equipment /the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment		Serial number
	Please read operator's manual before using		Heat Warning
	Manufacturer		Date of manufacture
	CE certificated marking		The authorized EU-representative

1 Overview

1.1 Intended Use

HiFRes serial High Flow Heated Respiratory Humidifiers is intended for the treatment of spontaneously breathing patients who would benefit from receiving high flow warmed and humidified respiratory gases. This includes patients whose upper airways are bypassed by a tracheostomy tube. It is for patients in hospitals and long-term care facilities and this device cannot be used for life-support.

Warnings:

- This device is intended for use by healthcare professionals only.
- Before using any humidifier, users must be thoroughly familiar with the contents of the user manual, including all warnings, cautions, and instructions for use.
- The device is expected to be used with the recommended patient interface or mask.
- The user should ensure that the performance offered by the device is fit for the intended use and that the device is not used in any way or for any purpose other than its intended purpose.

1.2 Working Principle

Air and oxygen are absorbed and blended in the inserted turbine. After measured by oxygen sensor and flow sensor, the air-oxygen mixtures are delivered to the water chamber and humidified in chamber. The humidified air-oxygen is delivered into patient interface through a breathing tube which can maintain delivered gases' temperature. During the whole gas delivery process, the HiFRes serial High Flow Heated Respiratory Humidifiers is capable of controlling and adjusting the working status of turbine, oxygen-limiting valve, heated plate and heated breathing tube through various sensors.

1.3 Contraindications

If the patient has severe respiratory failure without spontaneous breathing, do not use the device. If any of the following conditions apply to you, consult your healthcare professional before using the device.

1. The respiratory driving force is insufficient to tolerate the intermittent treatment of noninvasive ventilation.
2. Patient with acute sinusitis and otitis media.
3. Patient with symptoms may lead to the inhalation of gastric materials.
4. Inability to remove secretions.
5. Hypotension or obvious insufficiency of intravascular blood volume.
6. Pneumothorax or pneumomediastinum.
7. Patient who has cranial trauma or received surgery.

⚠Caution:

- There are potential side effects of drying the mouth, nose or throat.
- If there are any discomforts occurring during the use of device, please contact your healthcare professionals immediately.

1.4 Model Coding and Specifications

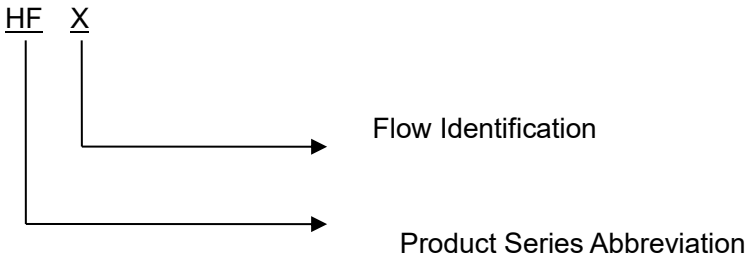


Table of model differences

Function Items		Models		
		HF8	HF7	HF6
O_2 control	Measurement of O_2 concentration	●	●	●
	O_2 Limit alarm	●	●	●
	Settable O_2 range	21%-100%	21%-100%	—
	O_2 -Air Control Mode	Software	Software	Buoy-type oxygen inhalator
Flow control	Settable flow range	2-80L/min	2-70L/min	2-60L/min
	Measurement	●	●	●
Temperature control	Settable temp range	31℃～37℃ 7 levels	31℃～37℃ 7 levels	31℃～37℃ 7 levels
	Measurement	●	●	●
Review function	History Review	●	●	●
Timing function	Accumulated therapy time	●	●	●
	Total use time	●	●	●
	Preset signal therapy duration	●	●	●
	Night Mode	●	●	●

Note: ● indicates with this configuration; — indicates no such configuration.

1.5 Service Life

The service life of host is 5 years.

2 Host Appearance

Pictures for reference only, goods in kind prevail!

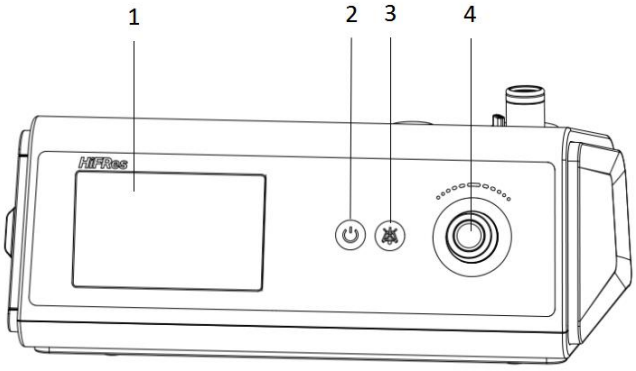


Figure 2-1 Front view of host

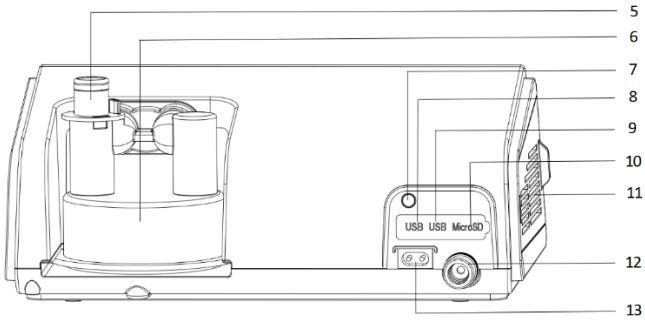


Figure 2-2 Rear view of host

No.	Item name	Description
1	Touch Screen	Touch the screen to adjust running parameters.
2	ON/OFF(STANDBY)button	Press this button to start and stop therapy.
3	MUTE button	Press this button to cancel the alarm sound.
4	Knob	Clockwise or anti-clockwise rotate it to adjust parameters; and press it to confirm selection.
5	Tube connector	Connection adaptor for heating breathing tube, host and water chamber.
6	Auto-Fill Water chamber	Water can be added automatically to provide humidification function.

7	Oxygen inlet port	This inlet is suitable for HF6 device. It used to connect oxygen output end of Buoy-type oxygen inhalator to provide oxygen.
8	SpO2 port	SpO2 module can be connected to device through this port.
9	USB port	Read the device information through this USB port.
10	Micro SD card slot	Micro SD memory card in inserted in this port.
11	Air inlet	Air filter and PM2.5 filter shall be inserted in this place prior to use.
12	High-pressure oxygen inlet port	This inlet is suitable for HF7 and HF8 device. It is used to connect oxygen tube.
13	Power port	Connect device to mains power with power cable.

3 Packing list

The device shall be packaged and accompanied with following items or accessories. If any of them cannot be found in package, please contact your healthcare professional or provider.

Item	Quantity	Notes
User manual	1 (pc)	
Air Filter	1 (bag)	
PM2.5 filter	1 (pc)	
Power cord	1 (pc)	
Transportable Trolly	1 (pc)	
Water chamber	1 (pc)	Maximum volume is 150ml
Heated breathing tube	1 (pc)	Model: HT1(1.8 m length）
Oxygen tube	1 (pc)	
Patient interface	1 (pc)	Optional configuration: 1. Nasal cannula S 2. Nasal cannula M 3. Nasal cannula L 4. Tracheostomy Interface

Attention:

- It is recommended that only use the accessories provided by TOPSON Medical.
- Use of accessories not recommended by TOPSON Medical will void the warranty or

even result in unnecessary damages or injury to persons

- For the configuration differences of HF8, HF7 and HF6, please refer to 1.4.

4 Before Use

4.1 Installation precautions

- The device shall be placed on a firm flat surface or fixed on a supporting system.
- The device shall be positioned at a place where convenient for user to perform operations and the notifications displayed are clear and legible on screen.
- Keep a distance of at least 25cm between the device and the wall. And Make sure the air inlet will not be blocked by clothing, curtains or other matters.
- Make sure the environment is well-ventilated and away from any heating or cooling devices (e.g. forced vents, heaters, air conditioners) to ensure the device can work normally and safely.

4.2 Step-by-Step Instructions

Properly install the device in accordance with following steps:

Insert the filters:

- Push the cover of air inlet at left side of device outside to remove the cover;
- Insert the white PM2.5 filter and black air filter into the white holder;
- Align the cover with the slide guide to push it inward.

Install the water chamber:

- Remove the port caps from the chamber by pulling the tear tab upwards then remove the bracket holding the water supply tube.
- Fit the tube adapter over the two vertical ports on the chamber and push on fully then clip the water supply tube into position.
- Fit the water chamber to the device by pressing down the heating plate and sliding the chamber on, carefully aligning with the chamber port ends.
- Push the chamber on firmly until it clicks into place.

Connect water bag:

- Attach the sterile water bag to the hanging bracket at least 20cm above the device,

and push the bag spike into the fitting at the bottom of the bag.

- Open the vent cap on the side of the bag spike. The chamber will now automatically fill to the required level and maintain that level until the water bag is empty.
- To ensure continual humidification, always ensure that the water chamber and/or water bag are not allowed to run out of water.

Connect breathing tube:

One end of the heating tube has gray plastic sleeve. Left sleeve and inserted it into outlet port of tube adaptor until the buckle is inserted tightly.

⚠Caution:

- Do not start the device until the water chamber in place. Only use the recommended water chamber. The liquid volume in chamber should be no less than 150mL.
- Do not touch the heater plate, water chamber or chamber base during use. The water in the chamber becomes hot during use. Exercise caution when removing and emptying the chamber.
- When handling the device with water chamber in place, avoid tilting the machine to prevent any chance of water entering the unit enclosure.
- Empty all the water from the water chamber before transporting the device.
- To ensure continual humidification, always ensure that the water chamber and/or water bag are not allowed to run out of water.
- Check that water flows into the chamber and is maintained below the maximum water level line. If the water level rises above the maximum water level line, replace the chamber immediately.
- Do not modify the heated breathing tube or interface in any way.
- Do not allow the breathing tube to remain in direct contact with skin for prolonged periods of time.
- To avoid server burnt injury, do not add heat above ambient levels to any part of the breathing tube or interface e.g. by covering with a blanket or by heating with infrared radiation, an overhead heater, or an incubator.
- Do not use any insulating sleeve or any similar accessories which are not recommended by TOPSON Medical.
- Place the heated breathing tube away from any electrical monitoring wires (EEG, ECG/EKG, EMG, etc.) to reduce the likelihood of any interference with monitored signals.

4.3 Connect to Oxygen

HiFRes Series High-flow heated respiratory humidifiers measures the oxygen concentration at the patient's end through an oxygen sensor: when there is blockage between the oxygen inlet end and the patient's interface, the oxygen concentration delivered to patient will be affected within a certain period of time.

Requirements for oxygen source is provided as below table

Items	HF8	HF7	HF6
Input pressure range	300kPa～600kPa; or 0.3 MPa~0.6MPa; or 43.51psi～87.02psi		Less than 600 kPa; or Less than 0.6Mpa; or Less than 87.02psi.
Oxygen concentration	>95%		>90%

Oxygen connection of HF8 and HF7 device:

Connect the output end of oxygen source to the high-pressure oxygen inlet port on the back of the device through oxygen tube. Make sure you push the oxygen tube firmly onto its connection port.

Oxygen connection of HF6 device:

Connect the oxygen output end of buoy-type oxygen inhalator to oxygen inlet port at the rear of HF6 device with a suitable oxygen tube;

And then connect the oxygen input end of oxygen inhalator to oxygen source.

⚠Caution:

- Please ensure that the oxygen connecting tube is tightly connected to the oxygen source and the oxygen inlet port of humidifier devices.
- No loose or leakage is allowed in order to avoid device exceptions.
- The use of oxygen requires that special care be taken to reduce the risk of fire. Accordingly, for safety it is necessary that all sources of ignition (e.g. electrocautery or electrosurgery) be kept away from the unit and preferably out of the room in which it is being used. Oxygen should not be used while smoking or in the presence of an open flame. The unit should be located in a position where ventilation around the unit is not restricted.
- A spontaneous and violent ignition may occur if oil, grease or greasy substances come in contact with oxygen under pressure. These substances must be kept away from all oxygen equipment.

- Ensure that the device is switched on before connecting oxygen.
- The oxygen concentration delivered to the patient can be affected by changes to the flow setting, oxygen setting, patient interface or if the airpath is obstructed.
- When finished, turn off the oxygen source. Remove the output of the oxygen source from the oxygen inlet port on the back of the device. The oxygen flow must be turned off when the device is not operating, so that oxygen does not build up inside the device.
- Oxygen must only be added through the special oxygen inlet port on the back of the device. The power cord connector should also be well secured.

5 Start Therapy

5.1 Function Overview

After correctly connect device with oxygen source and mains power supply, switch the device on to enter user interface. Must check and make sure there is no damages on the device and accessories before using.

Working Indicators:

- When the device is in non-operation state, the indicators around buttons and knob keep lighting on in blue without flicker.
- While the device is in working state, there is blue light around buttons and knob flickering in cycle of 1second. The indicators light on or off as the change of screen backlight. In other words, the indicators light on as the screen backlight on and light off as the screen backlight off. The brightness of indicators and screen backlight will change synchronously.
- While the device is in alarm condition, the indicators are flickering in red at interval of 500mS.

Warm-up:

In standby state, press the **" STANDBY" button** to start warm-up. During warm-up in progress, a text will appear on the interface writing "warm-up"; the temperature and oxygen concentration will rise in fluctuation and the flow will rise rapidly. These items will pulse until they approach their target settings.

One Key to Enter Low Flow Mode:

In status of standby, warm-up or normal working, press and hold on the knob for 5

seconds to enter low flow mode; exit this mode by pressing knob for 5 seconds.

Transfer Function:

In status of standby, warm-up or normal working, press and hold on the **MUTE button** for 3 seconds to enter the transfer state. At this time, a text writing "Transfer state" will appear on the interface. The device outputs flow and oxygen without heating for 20 minutes. After 20 minutes, the device will automatically return to normal working.

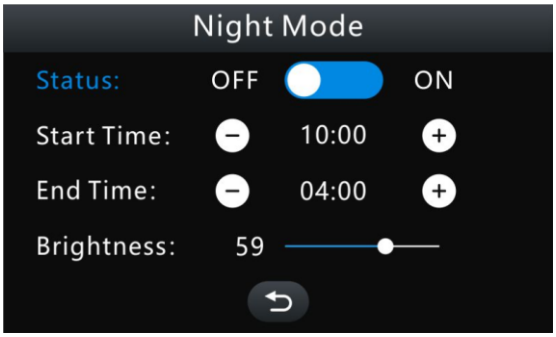
Auto Power Off:

While the oxygen therapy is ongoing, press and hold on the **STANDBY button** for 3 seconds to enter the setting interface of auto power off. Select the delay time to power-off among 30, 60, 90 minutes.

After time setting, a text prompt writing " Auto Power Off " and "Please close the oxygen valve" will display on the interface. Time to power off will start countdown. Also, a sound "Di-Di in loop" will be heard to remind users of auto shutdown, which can be mute by pressing the **MUTE button**.

Night Mode:

Night mode can be enabled in the menu interface of system setting. Select the night mode option on menu interface to set the relevant parameters. Choose ON/OFF to enable or disable this mode; and the start and end time range is 00:00-24:00 in 0.5h increment. Refer to 5.6 for more operation details.



5.2 User Interface

5.2.1 Description of Icons

Icon	Definition	Icon	Definition
	High flow mode		System time
	Low flow mode		Single Therapy Duration has been set.
	Micro SD card is inserted		Audio paused
	Device is working		The USB cable is connected
	Alarming condition		

5.2.2 Therapy Monitoring

Symbol	Definition
	Real-time measured gas temperature at the patient-connection port is measured and displayed in this icon.
	Real-time measured gas flow in the heated breathing tube is measured and displayed in this icon.
	Real-time measured oxygen concentration at the patient-connection port is measured and displayed in this icon.
	Display the real-time therapy duration as the therapy has been started. When the time reaches the preset single therapy duration, there is sound and light alarm signals to remind user of therapy finished. This time will be zeroed after the device is powered off.
	Real-time SpO2 value of the patient is measured and displayed in this icon (only available when the SpO2 module is

	installed).
PR 66	Real-time pulse rate of the patient is measured and displayed in this icon (only available when the SpO2 module is installed).

5.3 Parameter Setting

All the settings or selections can be completed by touching the screen directly or rotating the knob to move cursor and pressing knob to confirm selection.

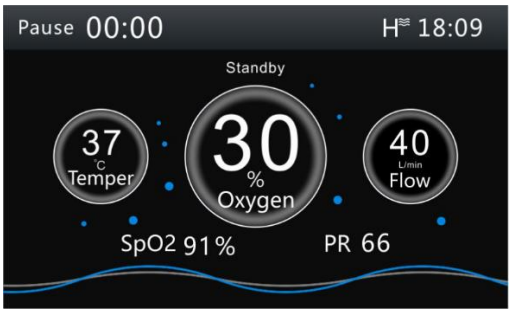


Figure 5-1 Standby interface

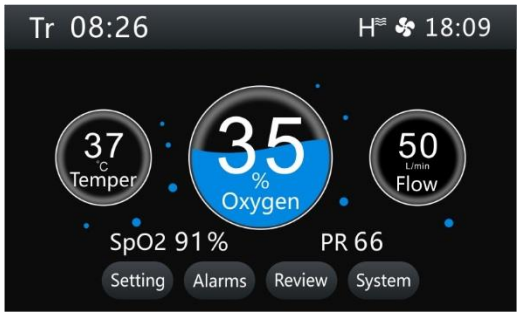


Figure5-2 Interface with menu options

After the device is connected to mains power, the main interface as *Figure5-1* will appear. Touch the screen or press knob to disclose the menu options at the bottom like *Figure 5-2*; tough or press again to hide options.

Select the ***SETTING*** option to configure target settings of Flow, Temp and Oxygen.

5.3.1 Unlock Setting Interface

After select the ***SETTING*** options on the bottom of main interface, an unlocking prompt interface is displayed. Touch the locker icon  or press knob for 5 seconds to unlock the setting interface.	

5.3.2 Temperature Setting

<table>
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- On the unlocked setting interface, choose ***Temperature*** by select the "  " or "  " icon on the bottom.
- On the temperature interface, change the values by select the "  " or "  " icon. *Available temperature range is 31℃~37℃.*
- When ***low flow mode*** is selected, the temperature is default at 34℃.
- The temperature of delivered gases can reach target setting within 30 minutes. The measurement point of displayed temperature is at the patient-end of the breathing tube.

After setting, select  to return to the main interface.

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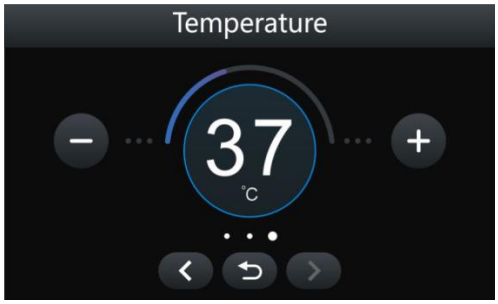

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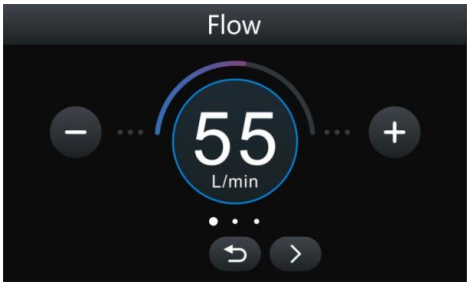
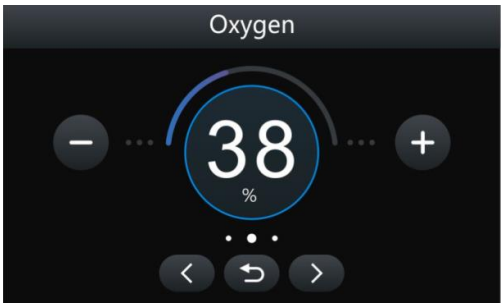
5.3.3 Flow Setting

• On the unlocked setting interface, choose ***Flow*** by select the "›" or "‹" icon on the bottom. • On the flow interface, change the values by select the "+" or "−"icon. *HF8 flow range is 2L/min ~ 80L/min;* *HF7 flow range is 2L/min ~ 70L/min.* *(Note: 2~25L/min in 1L/min increment; 25~80L/min, in 5L/min increment).* *HF6 flow range is 2L/ min-60l /min.* After setting, select ⮌ to return to the main interface.	

5.3.4 Oxygen Setting

• Oxygen concentration can be settable on HF8 and HF7 devices only. • On the unlocked setting interface, choose ***Oxygen*** by select the "›" or "‹" icon on the bottom. • On the Oxygen interface, change the values by select the "+" or "−" icon. *Available range is 21%~100%.* • Oxygen of HF6 device is adjusted through a buoy-type oxygen inhalator. The value displayed fluctuates until the oxygen concentration is steady. After setting, select ⮌ to return to the main interface.	

5.3.5 Recommended settings

Patients' interface type	Recommended temperature	Recommended flow
Nasal cannula S Nasal cannula M Nasal cannula L	31℃~37℃	2L/min~80L/min
Tracheostomy Interface	37℃	10L/min~60L/min

5.4 Alarm Setting

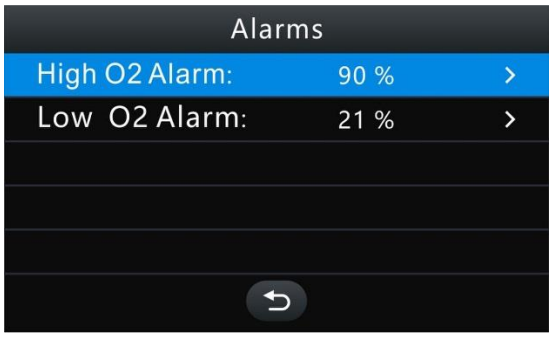


Figure 5-3 Alarm setting

On the main interface, touch screen or press knob to disclose the options at the bottom as *Figure 5-2 Interface with menu options*, and then select the ***ALARMS*** option to enter setting interface like *Figure 5-3.*

Select the ***"HIGH O2 ALARM"*** or ***"LOW O2 ALARM"*** to adjust the O2 alarming threshold. After setting, there is sound and light alarming signals if the O2 is out of range.

After setting, select  to back to main interface.

5.5 Review

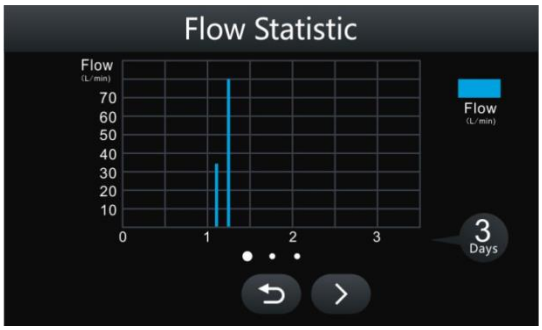


Figure 5-4 Review interface

On the main interface, touch screen or press knob to disclose the options on the bottom as *Figure 5-2 Interface with menu options*, and then select the ***REVIEW*** option to enter interface like *Figure 5-4*.

The statistics of Flow, Temperature and Oxygen in the past are allowed to review and check. Select the ***DAYS*** option at the right corner to change among 1 day, 3 days, 7 days, 30 days.

Select the "  " or "  " icon on the bottom to change among Flow, Temperature

and Oxygen.

After checking, select  to back to main interface.

5.6 System Setting

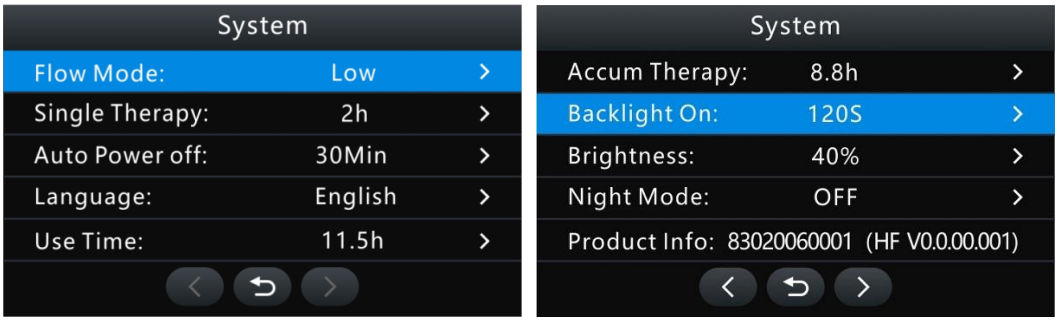


Figure 5-5 System interface

On the main interface, touch screen or press knob to disclose the options on the bottom as *Figure 5-2 Interface with menu options*, and then select the ***SYSTEM*** option to enter interface like *Figure 5-5*.

Select and adjust the parameters through touching screen or rotating knob. The U***SE TIME*** cannot be adjusted, which indicates the accumulated duration of device power-on. The **ACCUM THERAPY** indicates the accumulated duration of every treatment.

⚠Caution:

- The warm-up time required for the gas temperature at the patient end to reach the target temperature from 23±2℃ is less than 30 minutes.
- The gas temperature delivered through heated breathing tube will be affected if tube is covered by things like blanket or used in incubator.
- Low temperature ambient conditions may prevent the device from reaching a 37 °C target temperature setting at high target flow settings. In these cases, consider decreasing the target flow setting.
- For patients whose upper airway are bypassed, the maximum permissible flow is 60L/min. The flow higher than 60L/min will lead to the humidification output lower than 33mg/L.
- When the target flow setting exceeds the recommended flow of the patient interface, the system output temperature will be reduced and the relative humidity will be reduced.
- For pediatric patients, please use low flow mode with flow range of 2L/ min-25l /min.
- The output pressure is lower than 25cmH20 while the device is working normally. When the target flow setting exceeds the recommended flow of the patient interface, the output pressure will increase.

6 Alarm

6.1 Alarm Expression

The device is capable of generating sound and light alarm signals to remind user of taking measures to deal with abnormal conditions happening to device itself or treatment process. This alarm system is to avoid hazardous situations or adverse effects resulting from device exceptions.

HiFRes Series Devices adopt an alarm system with high priority alarm and prompt notifications to distinguish different alarming conditions. The user is obligated to response to alarm as soon as there is alarming sound and light.

Operator's position: it is expected to be 1m away from the device's display screen.

Alarm priority	Sound	Light	LC display
High priority	Di-Di-Di--- Di-Di--- Di-Di-Di --- Di-Di loop alarm with sound > 60 dB (A)	Flashing red light at interval per 500ms around the buttons and knob	Display the alarm reason with texts on a yellow background
Prompt	Di-Di Loop alarm with sound > 60 dB (A)	N/A	N/A

6.2 Alarm List

Alarm/Prompt	Meaning & Remedy	LC display	Priority	Delay
High O2 alarm	The measured oxygen level has exceeded the allowed limit. ***Check that the flow rate has been set correctly.*** ***Adjust the level of oxygen from the oxygen source as necessary.***	Oxygen is too high, please check!	High	/
Low O2 alarm	The measured oxygen level has fallen below the allowed limit. ***Check that the oxygen source is still operational and is correctly connected.*** ***Adjust the level of oxygen from the***	Oxygen is too low, please check!	High	/

	oxygen source as necessary.			
Therapy finished	The preset single therapy time is reached. ***Set another therapy parameter to start again.***	Therapy has finished, please set again!	High	/
Excessive oxygen pressure	The device has detected the pressure of oxygen source is larger than 0.6MPa. ***Adjust the oxygen source to decrease pressure.***	Too much pressure at the oxygen inlet	High	<20S
Tube connector is not installed properly.	The device cannot detect the tube adaptor in place. ***Check the connection of tube adaptor.***	Check for tube connector!	High	<10S
Breathing tube is not connected.	The machine cannot detect the breathing tube in place. ***Check the connection of breathing tube.***	Check tube connection!	High	<10S
Leakages	The device has detected a leak in the system. ***The most likely cause is that the water chamber has been removed or has not been pushed into place correctly.*** ***Check that the heated breathing tube is not damaged and that it is plugged in correctly.*** ***Check that the nasal interface is fitted.*** ***Check that the filter is fitted.***	Check for leakages!	High	<10S
Blockages	The device has detected a blockage in the system. ***Check the heated breathing tube or patient interface for blockage.*** ***Check the air filter and filter holder for blockage.***	Check for blockages!	High	<10S
Power failure	Accidently disconnect the power supply in a non-standby state while the device is power on. ***If power is reconnected in this time, the unit will automatically restart.***	/	Sound prompt	/
Cannot reach target	The device cannot reach the target temperature setting.	Cannot reach target temperature!	High	<30 Minutes

temperature	***The most likely cause for this is that the device is operating at a high flow rate in low ambient conditions. Consider decreasing the target flow setting.***			
Cannot reach target flow	The device cannot reach the target flow setting. ***Check the heated breathing tube or patient interface for blockage.*** ***Check whether the target flow setting is too high.***	Cannot reach target flow!	High	<10 Minutes
No water in chamber.	The chamber has run out of water. ***When a chamber runs dry, the chamber float may be damaged. Replace the chamber and water bag.***	No water in chamber!	High	<20 Minutes
Equipment fault	The device cannot work normally due to communication failure of internal components. ***Restart the device. If the problem persists, contact your TOPSON Medical Healthcare representative.***	Equipment fault!		<5S

6.3 Alarm Limit

Most alarm limits are pre-programmed. The exceptions are listed below. These alarm limits may be changed to other values by authorized personnel. Changes will be preserved during or after any power loss.

Alarm condition	Factory-set alarm limit	Possible preset values
High O2 Alarm	90% O2	30%-100% O2 in 1% increment
Low O2 Alarm	21% O2	21-30% in 1% increment

⚠Caution:

- A hazard can exist if different alarm presets are used on different devices within any single area, e.g. an intensive care unit.
- Alarm limits set to extreme values can render the alarm system useless.

6.4 Alarm Signal Inactivation States

1. The audible and visual alarm signals disappear only when the alarm conditions of high priority are solved or remedied by operators.
2. Press **MUTE** button to pause the audio signals for 120 seconds without affecting the red flashing lights and texts displayed on screen. After 120 seconds, the alarm system will reset to previous state.
3. If another new alarm is generated while an alarm condition is still paused, the audible and visual alarm signals will be activated to remind user of new and old alarms. Press **MUTE** button to pause audio again.
4. While multiple alarm conditions occur at the same time, the corresponding texting notifications are to display on the screen alternatively until they are remedied completely.

⚠Caution:

- If there is alarm occurring, please stop using the device and contact your healthcare professionals to deal with alarm immediately.

6.5 Check Alarm System Functionality

The functionality of the alarm system can be checked at any time when the device is turned on.

Remove the heated breathing tube. You should see the “Check tube connection!” visual alarm signal and hear the auditory alarm signal. If either alarm signal is absent, do not use the device and refer to the 6.2 for a guide on troubleshooting. If problems persist, contact your TOPSON Medical Healthcare representative.

7 Cleaning and Maintenance

7.1 Maintenance

Please do not use the device if there are damages on the device and its accessories. And only repair the device in TOPSON Medical or a service organization designated by TOPSON Medical.

It is recommended that clean and maintain the device once every 6 months, including following items:

1. Check the integrity of device.

2. Check for mechanical damage.

3.Cleaning the device.

4.Replace any damaged parts.

5.Check the essential performances.

⚠Caution:

- If there are faults or alarms that cannot be eliminated, please remove the device from service and contact TOPSON Medical or distributors for maintenance.
- Unauthorized personnel are prohibited to open the device for maintenance.

7.2 Schedule for Changing Accessories

The accessories for the device must be changed frequently to avoid the risk of infection. Parts should be replaced immediately if they are damaged or discolored; otherwise they must be replaced within the periods shown in the following table.

Accessories	Maximum period of use
Nasal cannula S Nasal cannula M Nasal cannula L	7days
Tracheostomy Interface	7days
Water chamber	7days
Heated breathing tube	7days
Filter	3 months or 1000h (or more often if significantly discolored)
PM2.5 Filter	3 months or 1000h (or more often if significantly discolored)

⚠Caution:

- Please use the accessories specified or supplied by TOPSON Medical only.
- The nasal cannula, tracheotomy interface, heated breathing tube and water chamber listed in the table are intended for single-patient use only.

7.3 Cleaning

Clean the Device and Breathing Tube

- Always disconnect the device from power supply before cleaning.
- Use a cloth wetted with warm water or a neutral cleaning agent to clean the device's

enclosure. Must dry the device thoroughly before connecting to power supply.

Replace Filter

After the device has been switched on for 1000 hours, the air filter shall be replaced. Follow the steps below if filter change is due:

- Disconnect the device from power supply.
- Push the cover of air inlet at the left side of device outside to take out the filters.
- Clean the filter holder and cover with a wet clothing socked in warm water or neutral cleaning agent, and then dry them completely.
- Replace the old filter with a new or washed air filter and a new PM2.5 filter.
- Align the cover with slide guide to push it inward.

⚠Caution:

- Gently wash the black air filter with warm water and completely dry it with nature wind. Never insert a wet filter into the device!
- White PM2.5 filter is consumables which cannot be reused after washing.
- Please use the accessories provided by our company to avoid the device damages and undesirable hazards to patients.

8 Storage and Transportation

Store the device in a place where ambient temperature is -20℃~+60 °C (14 - 140 °F) and relative humidity is 10% ~95% (non-condensing), as well as with well-ventilation.

The device can be transported by ordinary means with carton package box. Please prevent the product from direct sunlight, moisture and rough handlings during transport.

9 Disposal Instructions

Device Disposal Instructions

This device contains electronics. Please do not discard with regular waste. Return to Medical or dispose according to local guidelines for disposing of electronics. Dispose according to Waste Electrical and Electronic Equipment (WEEE) directive in European Union.

Consumables Disposal Instructions

Place the interface, 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.

10 SpO2 Module

10.1 Intended Use

SpO2 module is intended for use in continuous noninvasive monitoring of arterial oxygen saturation and pulse rate. When used in combination with the HiFRes High-Flow heated respiratory humidifiers, it will not change the intended use of HiFRes humidifiers. It is intended for adults weighted more than 40 kg.

10.2 Contraindication

The contraindications of HiFRes High-Flow heated respiratory humidifiers apply.

10.3 Connect to Device

SpO2 sensor consists of pulse oximeter probe and connecting cable. It is plug and play, which connect to the HiFRes humidifiers through the SpO2 port at back of unit with its cable. While using, place the oximeter probe on the patient's index finger.

The sampling frequency of blood oxygen saturation is 10Hz and the frequency of real-time display is 1Hz. If the SpO2 module cannot work normally, the HiFRes humidifiers cannot display SpO2 parameters.

⚠Caution:

- The SpO2 module is an auxiliary monitoring device of the high flow heated respiratory humidifiers, which does not maintain vital signs. Therefore, there is no alarm of SpO2 and pulse rate.

10.4 Measurement Limitations

If you encounter difficulties in detecting signals or obtaining accurate measurements, refer to this section to find the problem.

1. Measurement depends on the pulsating characteristics of the arterial blood flow, which may be reduced to a level that cannot be measured under the following conditions:

---Shock

--- Low temperature

--- Use of vasoactive drugs

-Anemia

2. Measurements also depend on the absorption of specific wavelengths of light by oxygenated and reduced hemoglobin. If other substances absorbing the same wavelength

are present, they will cause the measurement to have a false or low SpO2 value. Such as:

--- Carboxyhemoglobin (COHb);

--- Methemoglobin (MetHb);

---Methylene blue;

--- Indigo dyes.

3. Strong light will also affect the measurement. The measurement can be improved by covering the sensor with an appropriate opaque material. At the same time, prevent the pulse oximetry probe from light sources, such as radiant light or infrared light.

4. Make sure your nails block out light.

5. The probe cable should be placed on the back of the hand.

10.5 Specifications

This SpO2 Module has been validated and tested for compliance with ISO 80601-2-61.

The SpO2 accuracy is a root-mean-square difference of less than 3.0% over the range of 70% t0 100% SaO2. (Note: Because pulse oximeter equipment measurements are statistically distributed, only about two-thirds of pulse oximeter measurements can be expected to fall within ±Arms of the value measured by a CO-oximeter.)

Subjects population under clinical investigation is health adults aged from 18-40. Gender is statistically distributed and the population of dark-skin is no less than 30%.

Items	Description
SpO2	Display range：35%～100%; SpO2 range and accuracy：70%～100%， accuracy within±3%. SpO2 range (<70%) is no specified. Measurement resolution：1%
Pulse rate	Display Range：20～250BPM; PR range and accuracy：25～250BPM，accuracy within±3BPM; Measurement resolution：1BPM.
Size	70*33*25mm
Weight	40g
Wave length	Red light：660nm; Infrared ray：940nm±10nm.
Maximum optical output power	The average is less than 1.5mw.

⚠Caution:

- Using the device beyond the specified conditions may result in inaccurate measurement or output.

10.6 Environment Conditions

Items	Working condition	Storage & Transport condition

Ambient temperature	+18℃~+30℃	-20℃~+60℃
Relative humidity	15%~95% (Non- condensation)	15%~95% (Non- condensation)
Atmosphere pressure	70.0~106.0 kPa	70.0~106.0 kPa

While transporting, prevent the products from rough handing, bumping and humidity.

10.7 Safety Tips

⚠ Please use the accessories provided by our company. User is obligated to check the compatibility of device and oximeter probe before using them together.

⚠ Measurement accuracy may be affected by bright light, excessive movement, intravascular staining, thick finger, displacement, etc.

⚠ False measuring results may result from painted nails, false nails, or gray nails.

⚠ Patients with low blood pressure, or severe low systolic blood pressure, severe anemia, or hypothermia can get the wrong measurements.

⚠ In order to avoid failure of data transmission, equipment like computers, TV sets, radios are not allowed to be placed nearby the SpO2 module.

⚠ The SpO2 module can only be used in combination with TOPSON HiFRes series high flow heated respiratory humidifiers.

⚠ It is recommended to displace oximeter probe at least every 3 hours.

⚠ SpO2 module may be affected while using nearby other instruments that meet the electromagnetic emission requirements.

⚠ Always check the compatibility of SpO2 Module and Device to avoid the fault measurements and hazards to patients.

⚠ The SpO2 module has been calibrated to display functional SpO2.

⚠ Do not use the SpO2 module while the magnetic resonance imaging (MRI) device is used.

⚠ If patient is allergic to the materials of SpO2 probe, please stop using the SpO2 module immediately.

⚠ Always disinfect and clean the oximeter probe while it is intended to be used for multiple patients, aiming to avoid cross-infection.

⚠ Do not use the damaged SpO2 module.

⚠ Do not disassemble the SpO2 module. The repair and maintenance can only be performed by an authorized service organization or manufacturer.

⚠ Do not expose the SpO2 module to an environment with temperature and humidity beyond the specifications in this user manual.

⚠ Do not use the SpO2 module if there is any damage on its connecting cable.

⚠ Do not use the SpO2 module in presence of oxidants, such as nitrous oxide.

⚠ Always keep the SpO2 module away from fire and heat source.

⚠ Never make the SpO2 module immerse in water.

⚠ If any accident occurs during normal use, stop using the device immediately and take appropriate emergency and corrective measures.

⚠ The functional tester and patient simulator cannot be used for the accuracy of pulse oximetry probe and pulse oximetry monitor. As Masimo's R correction curve is applied on this device, the accuracy of SpO2 module can also be determined by testing this standard curve.

10.8 Cleaning and Disinfection

SpO2 module cleaning

Wipe the surface and probe of the SpO2 module with a wetted soft clothing, and then dry them.

SpO2 probe disinfection

Clean the SpO2 probe with wetted soft clothing before disinfection. And then disinfect it by wiping with a soft gauze soaked in 75% medical alcohol or 70% isopropanol solution. After disinfection, wipe it again with a wetted soft cloth and let it dry naturally.

⚠Caution:

- Disinfectants may ruin the device’s surface and shorten device’s service life. Always select a proper disinfectant by reading the manual of its, and follow the advices of the disinfectant manufacturer.
- Always check if there is any damage on SpO2 Module after every disinfection processing. Otherwise, do not use it.
- The SpO2 module cannot be sterilized. Make sure the module is not electrified prior to cleaning, and reuse after completely drying it.

10.9 Disposal Instructions

While the SpO2 module exceeds its service life, please deal with it and its package materials in accordance to the relevant local laws and regulations to prevent environmental pollutions.

In general rule, the SpO2 module, package cartoon boxes and plastics shall be sent to the recycling institutions which have the ability and qualification to dispose of the plastic, glass, metal parts, printed circuit boards, wires and cables, electric motors and other materials.

11 Technical Data

11.1 Performance

Items	Settable range	Accuracy
Oxygen	21%～100%	Within ±5%
Flow	High flow mode: 10L/min～80L/min	Within±5L/min at range of 25L/min～80L/min Within±2L/min at range of 2L/min～25L/min.
	Low flow mode: 2L/min～25L/min	
Temperature	31℃～37℃	Within ±2℃

11.2 Environment Conditions

Parameter	Working condition	Storage & Transport condition
Ambient Temperature	+18℃～+30℃	-20℃～+60℃
Relative humidity	15%～95% （Non - Condensing）	15%～95% （Non - Condensing）
Atmospheric pressure	70.0～106.0 kPa	70.0～106.0 kPa
Permissible pressure range of High-pressure oxygen	300kPa～600kPa; or 0.3 MPa~0.6MPa; or 43.51psi～87.02psi	——

11.3 Physical and Electrical

Item	Description
Dimensions	323mm × 225mm × 136mm

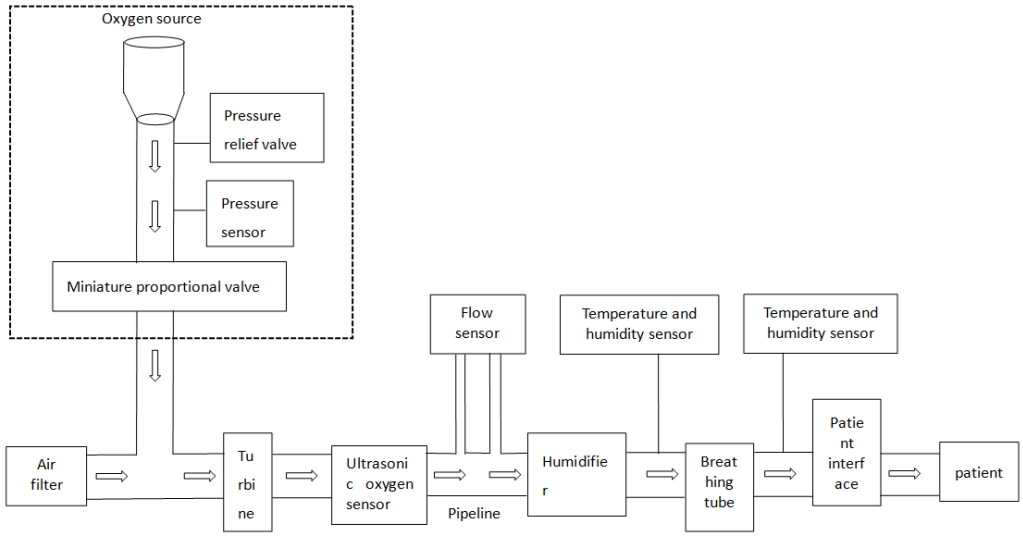
Weight	3.2kg
Power input	AC 100-240V, 50/60Hz

11.4 Electrical Safety Classification

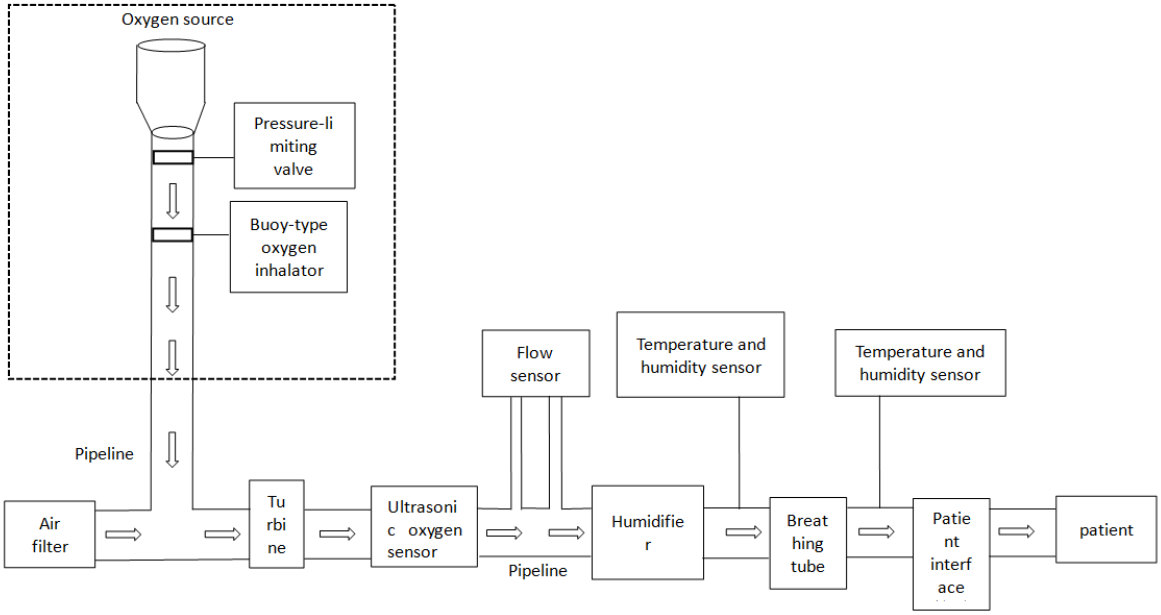
Item	Description
Equipment Classification	Class Ⅱ, Type BF, Continuous operation
IP Classification	IPX1
Degree of safety when used in the presence of a flammable, anesthetic mixture with air or oxygen or nitrous oxide.	Non-AP/APG type.

11.5 Schematic Diagram

The Schematic Diagram of HF7 and HF8 is provided as below:



The Schematic Diagram of HF6 is provided as below:



12 Warranty

TOPSON Medical (the “Manufacturer”) warrants to the Original Purchaser that the HiFRes High-Flow heated respiratory humidifiers (the “Product”), shall be free from defects in materials and workmanship under normal use, if used in accordance with this User Manual, for a period of two (2) year from the actual date of sale to the Original Purchaser. The applicable period for accessories is limited to a period of 12 month following the date of initial delivery. THERE ARE NO OTHER WARRANTIES.

This warranty does not cover normal wear and tear and maintenance items.

Subject to the conditions of and upon compliance with this Warranty, the Manufacturer will repair or replace at its option without charge (except for a minimal charge for postage and handling) any Pump (not including accessories) which is defective if a claim is made during such two-year period. The following conditions, procedures, and limitations apply to the Manufacturer’s obligation under this warranty:

A. Parties Covered by this Warranty: This warranty extends only to the Original Purchaser of the Product. This warranty does not extend to subsequent purchasers. The Original Purchaser may be a patient, medical personnel, a hospital, or institution which purchases the Product for treatment of patients. The Original Purchaser should retain the invoice or sales receipt as proof as to the actual date of purchase.

B. Warranty Performance Procedure: Notice of the claimed defect must be made in writing or by telephone to the Manufacturer as follows: Rm 003-204, Fangda Science Park, No. 266 Tianshan Street, New and High-tech District, Shijiazhuang, China. Notice to the Manufacturer must include date of purchase, model and serial number, and a description of the claimed defect in sufficient detail to allow the Manufacturer to determine and facilitate

any repairs which may be necessary. AUTHORIZATION MUST BE OBTAINED PRIOR TO RETURNING THE PRODUCT. If authorized, the Product must be properly and carefully packaged and returned to the Manufacturer, postage prepaid. Any loss or damage during shipment is at the risk of the sender.

C. Conditions of Warranty: The warranty is void if the Product has been 1) repaired by someone other than the Manufacturer or its authorized agent; 2) altered so that its stability or reliability is affected (which includes use of service/replacement parts not supplied by TOPSON Medical or its authorized agents, including the battery pack); 3) misused; or, 4) damaged by negligence or accident. Misuse includes, but is not limited to, use not in compliance with the Operator's Manual or use with non-approved accessories. Removal or damage to the Product's serial number will invalidate this warranty.

D. Limitations and Exclusions: Repair or replacement of the Product or any component part thereof is the EXCLUSIVE remedy offered by the Manufacturer. The following exclusions and limitations shall apply:

1. No agent, representative, or employee of the Manufacturer has authority to bind the manufacturer to any representation or warranty, expressed or implied.
2. There is no warranty of merchantability or fitness or use of the Product for any particular purpose.
3. The Product can only be used under the supervision of medical personnel whose skill and judgment determine the suitability of the Product for any particular medical treatment. The Manufacturer disclaims responsibility for the suitability of the Product for any particular medical treatment or for any medical complications resulting from the use of the Product. The Manufacturer shall not be responsible for any incidental damages or consequential damages to property, loss of profits, or loss of use caused by any defect or malfunction of the Product.

This warranty gives the Original Purchaser specific legal rights, and the Original Purchaser may have other legal rights which may vary from state to state.

13 EMC

The device complies with the electromagnetic compatibility requirements of EN/IEC 60601-1-2.

Note

- Using accessories, cables or sensors not specified may increase the instrument's electromagnetic emission, or decreased the instrument's electromagnetic immunity.
- Never use the instrument close to or stacked with other equipment. When necessary, should observe the instrument closely, ensure the instrument can run properly under used configuration.

- Need specific protection for device's EMC, also the installation and maintenance should under the environment that meets the following EMC information.

- This device is intended to be used by healthcare professionals only.
- Portable or mobile RF communication devices may affect the performance of device.
- Basic performance: During EMC testing, the display screen works normally; no false alarms; the device can work normally; SpO2 and pulse rate is accurate during the immunity test.

Cable information

Item	Cable length（m）	Whether Shield
Power Cable	1.5	NO
SpO2 Cable	1.8	NO

Guidance and manufacturer ' s declaration – electromagnetic emission		
The models HF8, HF7, HF6 are intended for use in the electromagnetic environment specified below. The customer or the user of the models HF8, HF7, HF6 should assure that they are used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR11	Group 1	The device 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 CISPR11	Class B	This device 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
Harmonic emissions IEC61000-3-2	Class A	
Voltage fluctuation /flicker emissions IEC61000-3-3	Complies	

Guidance and declaration – electromagnetic immunity
The models HF8, HF7, HF6 are intended for use in the electromagnetic environment specified below. The customer or the user of the models HF8, HF7, HF6 should assure that they are used in such an environment.

Immunity test	IEC60601 test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC61000-4-2	±6KV contact ±8KV air	±6KV contact ±8KV air	Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient /pulse IEC61000-4-4	±2KV for power supply lines ±1KV for input/output line	±2KV for Main power line ±1KV for input/output lines	Mains power quality should be that of a typical home or hospital environment
Surge IEC61000-4-5	±1K differential mode ±2KV common mode	±1KV differential mode ±2KV common mode	Mains power quality should be that of a typical home or hospital environment
Voltage dips, short interruptions and voltage variations of the input power IEC61000-4-11	<5% UT (>95% dip in UT), for 0.5 cycle 40% UT (60% dip in UT), for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 s	<5% UT (>95% dip in UT), for 0.5 cycle 40% UT (60% dip in UT), for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or from a battery
Power frequency (50/60Hz) magnetic field IEC61000-4-8	3A/m	3A/m	Power frequency magnetic fields shall be at levels characteristic of a typical location in a typical hospital or home environment.
NOTE：U_T is the a. c. mains voltage prior to application of the test level.			

Guidance and declaration – electromagnetic immunity			
The models HF8, HF7, HF6 are intended for use in the electromagnetic environment specified below. The customer or the user of the models HF8, HF7, HF6 should assure that they are used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance

Conducted RF IEC61000-4-6 Radiated RF IEC61000-4-3	3Vrms 150kHz to 80MHz 3V/m 80MHz to 2.5GHz	3Vrms 3V/m	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80MHz to 800MHz $d = 2.3\sqrt{P}$ 800MHz to 2.5GHz $\sqrt{P}$is the maximum normal output power of the transmitter,its unit is Watt (W) and d is the recommended separation distance,its unit is meter (m). Measured magnetic field strengths a from fixed RF transmitter should be less than the compliance level in each frequency range . Interference may occur in the vicinity of equipment marked with the following symbol:

Note 1: At 80 MHz and 800 MHz, the higher frequency range applied.

Note 2: These guidelines may not be apply in all situations. Electromagnetic propagation is affected by absorption and reflection of the structures , objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

b Over the frequency range 150 kHz to 80 MHz, the field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the

The HF8, HF7, HF6 is intended for use in electromagnetic environment in which radiated RF disturbances is controlled. The customer or the user of the HF8, HF7, HF6 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the HF8, HF7, HF6 are recommended below, according to the maximum output power of the communications equipment.

Separation distance according to frequency of transmitter (m)			
Rated maximum output of transmitter （W）	150 kHz ～ 80 MHz $d = 1.2\sqrt{P}$	80 MHz ～ 800 MHz $d = 1.2\sqrt{P}$	800 MHz ～ 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73

1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters(m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts(W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the higher frequency range applied.

Note 2: These guidelines may not be applied in all situations. Electromagnetic propagation is affected by absorption and reflection of the structures, objects and people.