User Manual

Humidifier

H-80 Series

CE 0123

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 Mute Button

 Knob

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 Type BF Applied Part (mask)

 Class II (Double Insulated)

 AC Power

 DC Power

IP22 ≥ 12.5 mm Diameter, Dripping (15° tilted)

 Hot Surface

 Serial Number of the Product

 Manufacturer

 Date of Manufacture

 Service Life

 Authorized Representative in the European Community

 European CE Declaration of Conformity

 Lot number

 Catalogue Number

	SD Card
	Do Not Re-use
	Non-sterile
	Oxygen Inlet
	Air Inlet
	Air Outlet
	WEEE Marking
	Logo of BMC Medical Co., Ltd.

2. Warning, Caution and Important Tip

WARNING!
Indicate the possibility of injury to the user or operator.

CAUTION!
Indicate the possibility of damage to the device.

IMPORTANT TIP!
Place emphasis on an operating characteristic.
Warnings, Cautions, and Important Tips appear throughout this manual as they apply.

3. Intended Use

H-80 series humidifier is for the treatment of spontaneously breathing patients who would benefit from receiving high flow warmed and humidified respiratory gases. This device is for patients by prescription in the home or hospital/institutional environment.

The device is only allowed to be used after the physician provides guidance for the patient and targeted setting of the device; the physician should ensure that the patient understands all functions and methods of operation of the device.

WARNINGS!
• This device is not intended for life support.
• The instructions in this manual are not intended to supersede established medical protocols.
• Do not bring the device or accessories into a Magnetic Resonance (MR) environment, it may cause unacceptable risk to the patient or damage to the device or MR medical devices. The device and accessories have not been evaluated for safety in an MR environment.
• Do not use the device or accessories in an environment with electromagnetic equipment such as CT scanners, Diathermy, RFID and electromagnetic security systems (metal detectors) as it may cause unacceptable risk to the patient or damage to the device. Some electromagnetic sources may not be apparent, if you notice any unexplained changes in the performance of this device, if it is making unusual or harsh sounds, disconnect the power cord and discontinue use. Contact your home care provider.
• Several accessories are available to make your treatment with this device as convenient and comfortable as possible. To ensure that you receive the safe, effective therapy prescribed for you, use only BMC accessories.

IMPORTANT TIPS!
• Read and understand the entire user manual before operating this system. If you have any questions concerning the use of this system, contact your home care provider or health care professional.
• The pictures in the user manual are only for reference, if they are different from the material object, the latter shall prevail.

4. Contraindications

The patients who meet the following conditions can use the device only under the special care of physician and monitoring on schedule.

Absolute Contraindications:

• Cardiopulmonary arrest, the invasive mechanical ventilation of urgent trachea cannula is required

• Shallow autonomous respiration and coma

• Extremely severe Type I respiratory failure

• Ventilation dysfunction (PH < 7.25)

Relative Contraindications:

• Severe Type I respiratory failure

• Ventilation dysfunction (PH < 7.30)

• Paradoxical breathing

• The protective capacity of airway is poor, and there is high risk of aspiration

• The hemodynamics is unsteady, and the vasoactive drugs are required

• The device cannot be worn in the facial or upper respiratory tract operation

• The nasal cavity is seriously blocked

• Intolerant of nasal humidifier

WARNING!

• Do not use the device if you suffer from severe respiratory failure without any autonomous respiration.

CAUTION!

• Contact your health care professional if you have any questions concerning your therapy.

5. Specifications

Device Size

Dimensions: 335 mm × 227 mm × 158 mm

Weight: about 4 kg

Water capacity: To maximum fill line 235 mL

Product Use, Transport and Storage

	Operation	Transport and Storage
Temperature:	18°C to 28°C (64.4˚F to 82.4˚F)	-25°C to +70°C (-13˚F to +158˚F)
Humidity:	≤ 93%, Non-condensing	≤ 93%, Non-condensing
Atmospheric Pressure:	760 hPa to 1060 hPa	760 hPa to 1060 hPa

Heated humidification

Range: Off, 1 ～ 5 gear

Humidifier Output: No less than 33 mg/L, at 37 ℃ target

Maximum Delivered Gas Temperature: ≤ 43℃

Mode of Operation

Continuous

Work Mode

HFlow, LFlow, AutoFlow, SmartFlow

SD Card

SD card can record patient data and fault information

AC Power Consumption

220 V – 240 V ～, 50 Hz / 60 Hz, 2.5 A

Type of Protection against Electric Shock

Class II Equipment

Degree of Protection against Electric Shock

Type BF Applied Part

Degree of Protection against Ingress of Water

IP22

Sound Power Level

< 28 dB (A), When the working mode of the device is HFlow, and the output flow is 25 L/min

Maximum oxygen input flow

80 L/min

FiO_2

Range: 21% ～ 100 %, binning interval 1%

Margin of Error: ± (5% + 5% set value)

FiO_2 Display Accuracy
± (5% + 5% set value)

Temp
Range: 25℃ ～ 45℃

Temp Display Accuracy
± 2℃

Flow
Range: 2 L/min ～ 80 L/min
Margin of Error: ± (2 L + 10% set value)

Flow Display Accuracy
± (2 L + 10% set value)

sPEEP
Range: 0 ～ 20 hPa
Margin of Error: ± (1 hPa + 20% set value)

Humidity Compensation
Range: -3～3，-3、-2、-1、0、1、2、3, the higher the range, the higher the humidification output

Flow Step Interval
Range: 15 L/min ～ 80 L/min

Tube
Length: 1.8 m
Margin of Error: ±10%
The connection should not fall off under the 45 N tension.

Specification of Patient Connector
φ 18 mm cone joint

6. Available Therapies

The device delivers the following therapies:

HFlow – Under this mode, the setting range of flow is 15 L/min-80 L/min.

LFlow – Under this mode, the setting range of flow is 2 L/min-25 L/min.

AutoFlow – Under this mode, the flow cannot be set, output flow is greater than 15 L/min and peak expiratory flow rate and the end-expiratory pressure is not lower than sPEEP setting; applicable to H-80AS.

SmartFlow – Under this mode, the setting range of flow is 15 L/min-80 L/min, the flow rate when inhaling is the set value and the end-expiratory pressure is not lower than sPEEP setting; applicable to H-80AS.

7. Glossary

Auto Off

When this feature is enabled, the device automatically stops outputting flow after the patient removes the nasal cannula.

Delay

After pressing the stop button, the device stops outputting after continuing to work with the flow of not more than 60 L/min for about 90min.

Standby

When this feature is enabled, the patient removes the nasal cannula, the FiO_2 drops to 21%(not applied to H-80M), the flow drops to below 40 L/min, it continues to heat, and the temp of the output gas of the patient does not exceed 43°C, the maximum standby time is 30 min.

Warm-up time

When the flow is 40 L/min and starting temperature 23±2°C, the set temp of 29°C can be reached within 10 min, the set temp of 37°C can be reached within 30min.

LCD Backlight

LCD Backlight can set the two modes. In backlight mode, the backlight is always on; in automatic mode, the backlight can be dimmed for about 30 seconds without button operation, and brightened when there is a button operation.

Trend Chart

The data of temperature, flow, FiO_2 and respiratory rate for 1 day, 3 days, and 7 days can be reviewed.

LPM

Liters Per Minute.

RR

Respiratory Rate. Number of breaths per minute.

min

Means the time unit "minute".

h

Means the time unit "hour".

yy mm dd / mm dd yy / dd mm yy

Denotes date.

8. Model

Model	Product information		
	Work Mode	**Maximum flow (L/min)**	**Adjustment mode of FiO_2**
H-80M	HFlow LFlow	80	Manual
H-80A	HFlow LFlow	80	Automatic
H-80AS	HFlow, LFlow SmartFlow AutoFlow	80	Automatic

9. Package Contents

After unpacking the system, make sure you have everything shown here (Different models of the product may contain different components):

No.	Articles	Qty.	Notes
1	Main Device	1	
2	Air Filter	2	
3	Power Cord	1	
4	Water Chamber Adapter	1	Optional
5	Water Chamber	1	Optional
6	LH2 Heated Breathing Tube	1	Optional
7	Nasal Cannula (Patient interface)	1	Optional
8	SD Card	1	Optional
9	Accompanying Documents	1	

The product's service life is five years if the use, maintenance, cleaning and disinfection are in strict accordance with the user manual.

WARNINGS!

• This device should only be used with the accessories manufactured or recommended by BMC or with those recommended by your prescribing physician or with the medical device registration certificate shall be used in the device. The use of inappropriate accessories may affect the performance of the device and impair the effectiveness of therapy.

• Do not pile up the long tube at the head of the bed, as it may wrap around the head or neck of the patient during sleep.

• Do not connect any equipment to the device unless recommended by BMC or your health care provider.

• The device cannot be used in the environment with the temperature, humidity and atmospheric pressure exceeding those specified in environmental conditions. Otherwise, it may affect the treatment effect or damage the patient.

• When accessories or other elements or components are added to the respiratory ventilation system, the expiration pressure at the connector of patient will rise.

IMPORTANT TIPS!

• If any of the above parts are missing, contact your home care provider.

• Contact your home care provider for additional information on the available accessories of this device. When using optional accessories, always follow the instructions enclosed with the accessories.

• Accompanying documents include user manual, quick operation manual, warranty card and certificate.

• If the user requires SD card, please contact contact BMC to obtain, otherwise, the device may not work properly.

• The pictures in this manual are only for reference, if they are different from the material object, the latter shall prevail.
• Nasal cannula is applied part.

10. System Features

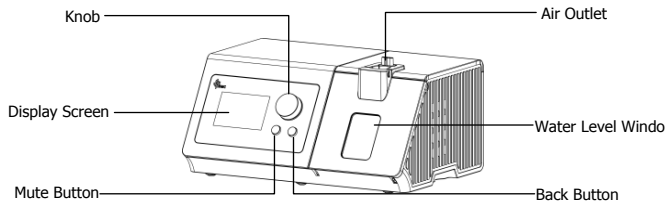

Fig. 10-1

Name	Function
Knob	Start treatment and adjust device settings.
Back Button	Return to the previous operation.
Mute Button	Press this button to mute the alert. However, if the problem causing the alert is not solved, the alert will sound again two minutes later.
Display Screen	Display menus for operation, messages, monitoring data, etc.
Air Outlet	Deliver the gas; connects to the tube.
Water Level Window	Observe the water level in the water chamber.

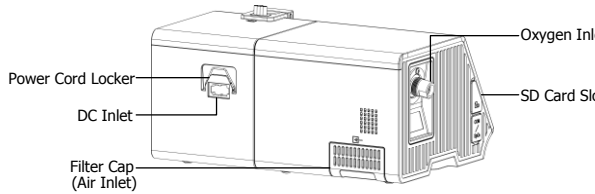

Fig. 10-2

Name	Function
SD Card Slot	Insert the SD card into this slot.
Power Cord Locker	Used to fix the power connector.
DC Inlet	An inlet for the DC power supply.
Filter Cap (Air Inlet)	Place the cap on the air filter, which is used to filter dust and pollen in the air entering the device.
Oxygen Inlet	An inlet for the oxygen.

11. First Time Setup

11.1 Placing the Device

Horizontally place the device on a firm and flat surface or trolley and ensure its height to be lower than the head of the patient. Take out the matching LH2 Heated Breathing Tube, nasal cannula and water chamber.

WARNINGS!

• If the device has been dropped or mishandled, if the enclosure is broken, or if water has entered the enclosure, disconnect the power cord and discontinue use. Contact your home care provider immediately.

• If the room temperature is warmer than 86˚F (30°C), the airflow produced by the device may exceed 109.4˚F (43°C). The room temperature must be kept below 86˚F (30°C) while the patient uses the device.

• To avoid explosion, this device must not be used in the presence of flammable gases (e.g. anesthetics).

• The device can be only used with the nasal cannula, tube and water chamber specified in this manual. Otherwise, the risk of scald or burning may be caused.

• The nasal cannula, tube and water chamber cannot be used exceeding the specified service life, otherwise, it may result in infection and other serious problems.

• If the device is used with oxygen, please strictly follow the guidance in Section 11.8 "Connecting the oxygen" in this manual.

CAUTIONS!

• If the device has been exposed to either very hot or very cold temperatures, allow it to adjust to room temperature (approximately 2 hours) before beginning setup.

• Make sure the device is away from any heating or cooling equipment (e.g., forced air vents, radiators, air conditioners).

• The device is not suitable for use in high humidity environments. Make sure that no water enters the device.

• Make sure that bedding, curtains, or other objects (such as pests) are not blocking or entering the filter or vents of the device.

• Keep pets, pests or children away from the device and avoid small objects being inhaled or swallowed.

• Do not place the device in the place where it may be carelessly touched or the operator may be stumbled by power cord.

• Tobacco smoke may cause tar build-up within the device, leading to the malfunctioning of the device.

• Air must flow freely around the device for it to work properly.

• When the tube, nasal cannula are damaged or bent, please do not use.

• When the room temperature is lower than 50˚F (10℃) or higher than 86˚F (30℃), please do not use the device. When the room temperature is lower than 64˚F (18℃) or higher than 82˚F (28℃), it may affect the humidifying ability of the device.

11.2 Installing the Air Filter and Filter Cap

(1) Attach the air filter to the filter cap, as shown in Fig. 11-1.

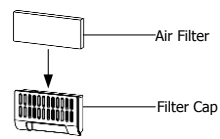

Fig. 11-1

(2) Install the filter cap containing the air filter to the device, as shown in Fig. 11-2.

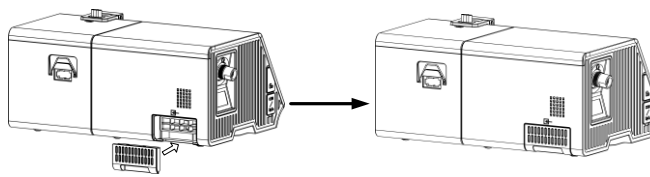

Fig. 11-2

CAUTIONS!

• The air filter must be in place when the device is operating. The filter cover can protect the device from liquid being sprinkled on the device by accident.

• Installing the air filter and filter cap, device must be unplugged.

11.3 Connecting to Power

(1) Insert the plug of the power cord into the DC inlet on the back of the device, as shown in Fig. 11-3;

(2) Press the power cord locker, and fix the power cord and power connector. The function of the locker is to prevent the power cord falling off from the power port, as shown in Fig. 11-4;

(3) Insert the power cord plug into the power supply socket.

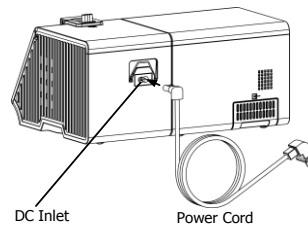

Fig. 11-3

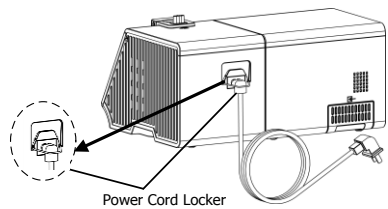

Fig. 11-4

Note: The length of the power cord is 1.8m without the function of preventing electromagnetic interference.

WARNINGS!

• The device is powered on for use when the power cord is connected. The **Knob** presses the blower On / Off.

• Use of the device at an AC voltage beyond the stated range (see Section 5 "AC Power Consumption") may damage the device or cause device failure.

• Connect to appropriate power for proper operation of the device.

• Inspect the power cord often for any signs of damage. Replace a damaged cord immediately.

IMPORTANT TIPS!

• After interruption and restoration of the power supply, the device will restore its pre-interruption working status automatically.

• To remove power, disconnect the power cord from the power outlet.

11.4 Inserting the SD Card

First, push the cover of SD card on the device aside downward, and then insert SD card into SD card socket according to the direction shown in Fig. 11-5.

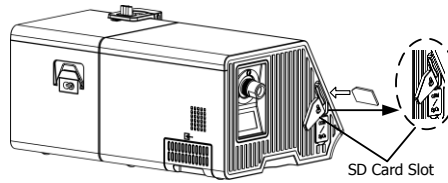

Fig. 11-5

If the SD card is inserted correctly, a symbol indicating correct insertion will appear in the Main Interface on the screen of the device.

If the SD card is inserted incorrectly, a symbol indicating incorrect insertion will appear in the Main Interface on the screen of the device.

CAUTIONS!

• If the SD card is not inserted, there will not be a symbol appear in the Main Interface on the screen of the device.

• To avoid data loss or any damage to the SD card, the SD card can only be removed after the main device stops delivering air.

11.5 Installing the water chamber

(1) **Install adapter:** Install adapters on two vertical interfaces of water chamber according to the direction shown in the figure and press them tightly with force, as shown in the Fig. 11-6.

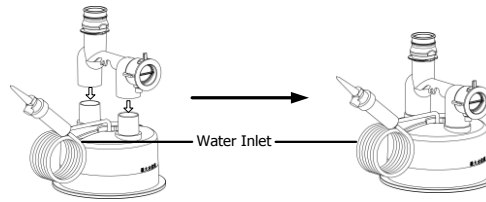

Fig. 11-6

Note: Before installing the adapter, place the water inlet in the position shown in Fig. 11-6 to ensure that the water inlet can be fixed in the slot of the cover after installing the water chamber.

(2) **Open the cover of water chamber:** Open the cover of water chamber along the direction shown in the Fig. 11-7.

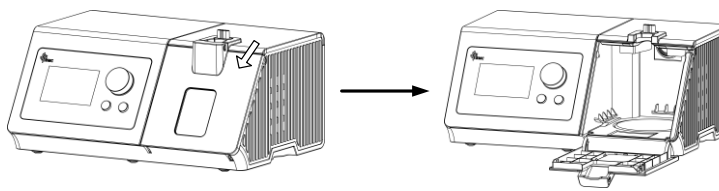

Fig. 11-7

(3) **Install water chamber:** Connect the interface of the adapter with corresponding interface of the device, stick the water inlet in the water inlet slot of the device, then install the water chamber in place (buckles at both sides of the adapter of water chamber will be stuck in the slot of corresponding position of the device, and make a "click" sound), as shown in the following Fig. 11-8.

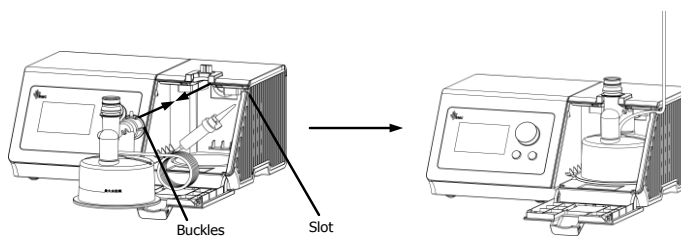

Fig. 11-8

(4) **Close the cover of water chamber:** Close the cover of water chamber along the direction shown in the Fig. 11-9, and buckles on both sides of the cover of water chamber will be stuck in the slot of corresponding position of the device.

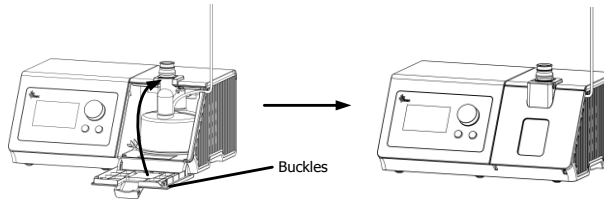

Fig. 11-9

WARNINGS!

• In order to prevent scalds, please do not start the device before installing the water chamber.

• The water chamber will be heated in working, so please power off until the water chamber is cooled and then take it out.

• If the device needs to be moved, the water in the water chamber should be drained off, and it is prohibited to tilt the water chamber for fear of water flowing into the device.

• Please immediately replace the water chamber if it is damaged.

• The water chamber adapter is one-time use of accessory for use by single patient only.

• Do not use the water chamber if it has been run dry.

CAUTIONS!

• The humidifying effect can reach to optimum after preheating under room temperature condition for above half an hour.

• The information of alarming journal will be maintained when the device is powered down, but the instantaneous time of power down will not be recorded.

11.6 Connecting the water bag

Hang the sterile water bag above the device and insert the water inlet needle into the injection hole under the water bag. As shown in Fig. 11-10. Open the air inlet cover beside the needle and the water chamber will start to automatically add water to the fixed water level.

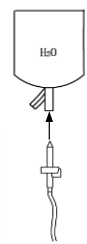

Fig. 11-10

CAUTIONS!

• It is suggested not to fully use up the water in the water bag, and it had better be replaced before being used up.

• Check that water flows into the chamber and is maintained below the fill line. If there is any abnormality, please replace the water chamber in time.

• All the buttons except the mute button and the indicator light on the top shell of water chamber can be illumined by touching any operation button of the device so as to observe the water line in the water chamber.

• To ensure continual humidification, always ensure that the water chamber and water bag are not allowed to run out of water. It is necessary to replace the water bag in time. The following table shows the usage time (hours) generally supported by the 2 L water bag at room temperature and corresponding flow rate as a reference. Make sure to replace the water bag before running out of water during use.

Flow setting and service time (2 L sterile water bag)													
Liter per minute	2	5	10	15	20	25	30	35	40	45	50	55	80
Hour	378	151	75	50	37	30	25	21	18	16	15	13	12

11.7 Assembling the Tube and Nasal Cannula

(1) **Connect the tube**: Connect the connector of the tube to the air outlet of the device and lock, and the specific steps are shown in Fig. 11-11.

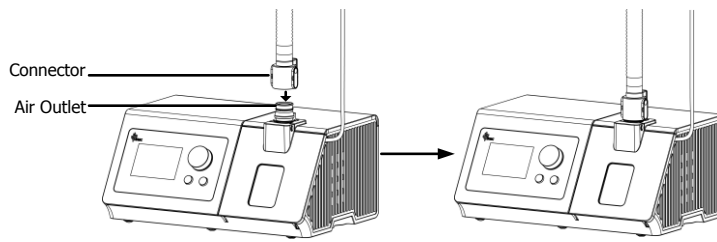

Fig. 11-11

(2) **Connect the nasal cannula**: Connect the other end of the tube to the nasal cannula according to the instruction manual of the nasal cannula.

WARNINGS!

• Prevent the body skin from directly contacting with the breathing tube for a long time.

• Do not make any changes to the breathing tube and nasal cannula.

• Please check whether the breathing tube is damaged or has foreign matter before using, if any, please clean or replace the breathing tube.

• Do not place the breathing tube and nasal cannula in any environment which prevents them from heat dissipation or being directly heated, for example, packaged in the quilt, or placed in the heat insulation rescue table or incubator of the newborn, or beside the air outlet of heater for heating or air conditioner of hot air mode, which may cause extremely serious injury.

CAUTION!

• Please keep the breathing tube in work away from EEG, EKG/ECG, EMG and other electronic lead wires to reduce the signal interference.

11.8 Connecting the oxygen

For H-80M model: please first connect the output end of the medical gas low pressure hose with the flow meter, then connect the flow meter with the oxygen tube, and connect the oxygen tube to the oxygen inlet of the device, finally connect the input end of the medical gas low pressure hose to the oxygen source, as shown in Fig. 11-12.

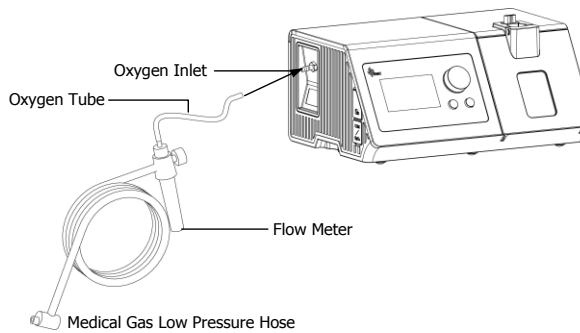

Fig. 11-12

For H-80A and H-80AS models: connect the output end of the medical gas low pressure hose to the oxygen inlet of the device and ensure the medical gas low pressure hose to be firmly connected with the connector, then connect the input end of the medical gas low pressure hose to the oxygen source, as shown in Fig. 11-13.

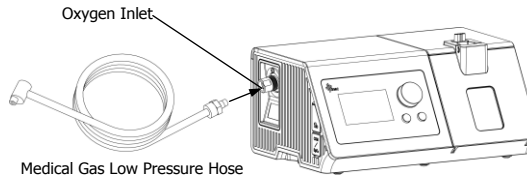

Fig. 11-13

WARNINGS!

• It is recommended to use the breathing tube and nasal cannula provided by BMC matching with the device.

• The oxygen supply must comply with the local standards of medical oxygen.

• When the oxygen is used, please first open the device, start the ventilation, and then connect oxygen; When shut down, please first disconnect the oxygen and then stop ventilation to prevent the oxygen from accumulating in the device (when the device stops running, but oxygen continues to be supplied, the oxygen sent into the tube will gather in accessories of the device, which may lead to a fire hazard.

• Oxygen supports combustion. Device and oxygen source should be kept away from heat sources, open fires, any oil or other combustible material. Do not smoke near device and oxygen sources.

• The device and oxygen source must be at least two meters away from any source that can emit sparks (such as: electrical device).

• It is prohibited to directly connect the manual mixed oxygen type (H-80M) with the oxygen source which is not calibrated or of high pressure.

• The oxygen can only be transported through the oxygen inlet of the device. In order to ensure oxygen to correctly flow into the device, the oxygen tube must be correctly installed on the device.

• For the manual mixed oxygen type (H-80M), please do not connect oxygen whose flow is higher than the set target flow to the device, because excessive oxygen will be discharged to the surrounding environment.

• The concentration of oxygen transported to the patient will be affected by the airflow, oxygen flow, patient interface and airway blockage. If the peak inspiratory flow of the patient exceeds the output flow of the device, the FiO_2 inhaled by the patient will be diluted due to inhaling the ambient air and lower than the value displayed on the device.

• When the device does not work, oxygen must be closed for fear of accumulating in the device.

• The gas storage bag cannot be used as oxygen sources.

• The oxygen source can be wall oxygen, oxygen cylinder, Oxygen Making Machine, etc., of which the scope of oxygen inlet pressure of automatic type (H-80A and H-80AS) is 280 kPa - 600 kPa. The oxygen inlet flow of manual type (H-80M) is ≤ 80 L/min.

11.9 Starting Treatment

Connect the device to a power outlet, press **the Knob** ⛀, and the device will start delivering air. Please wait until preheating is completed, then wear the nasal cannula to start the treatment.

CAUTION!

• The knob and back button will be lighted when any operation button is pressed.

WARNINGS!

• Be sure to follow your physician's instructions on adjusting the settings. To order any accessories not included with this device, contact your equipment supplier.

• DO NOT connect any ancillary equipment to this device unless recommended by BMC or your physician. If you suffer from chest discomfort, shortness of breath, stomach bloating, or severe headache when using the device, contract your physician or qualified medical personnel immediately.

• When accidents occur during normal use, the device should be stopped immediately and appropriate emergency and corrective measures shall be taken.

12. Routine Use

12.1 Connecting the Tube and Nasal Cannula

Connect the power cord, install the water chamber, and connect the water bag, tube and nasal cannula properly according to the instructions in the First Time Setup (Chapter 11). If necessary, please connect oxygen according to Section 11.8.

CAUTIONS!

• Before each use, examine the tube for any damage or debris. If necessary, clean the tube to remove the debris. Replace any damaged tube.

• Please do not stack too-long breathing tube at the bedside, because it may entangle the head or neck of patient asleep. The breathing tube shall not be covered with bed sheet or affected by the heating source (such as: electric blanket), otherwise, the breathing tube may deform and cause danger.

12.2 Adjusting the Tube

Lie down on your bed, and adjust the tube so it is free to move if you turn during sleep.

12.3 Turning on the Airflow

Press **the Knob** ⛀ to turn on the airflow. And the "WARM-UP..." is displayed in the status bar. The prompt "Warm Up Finished" is displayed after preheating, and it disappears after being displayed for 10s. The patient interface and head band are adjusted, so that the patient feels comfortable, and the screen will display treatment pressure and other information.

12.4 Using the heated humidifying

After the device is powered on, the heated humidifying function can be adjusted by "temp" setting.

CAUTIONS!

- If the temperature difference between the environment and set target temperature is too large (above 20°C) or too small (below 5°C), the target temperature may not be reached, or the tube may be excessively dry. Please appropriately adjust the environment temperature or target temperature at this moment.
- The water chamber cannot be run dry.

12.5 Turning the Device Off

After taking off the patient interface, press **the Knob** ⛀ and hold for two seconds. The device will check whether the oxygen source is closed. If the oxygen source is not closed, it will prompt to close the oxygen source. If no problem is found, it will enter the "**Delay"** procedure. This will blow off the vapor left in the tube. The screen will display the remaining time and the device will automatically stop at the end of the countdown. If it is required to skip the "**Delay"** procedure and immediately stop the device, then press **the Knob** ⛀ and the device will stop delivering air. Disconnect the power cord from the power outlet to power off the device.

13. Parameter settings

13.1 Parameter setting steps

13.1.1 Accessing the Main Interface

Connect the power cord and LH2 Heated breathing tube properly. The screen displays the Main Interface shown in Fig. 13-1. The monitored value and set value of FiO_2, flow and temperature can be displayed on the interface.

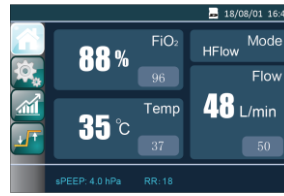

Fig. 13-1

The first icon on the left side of the screen indicates the Main Interface, the second icon indicates the Setup Interface, and the third icon indicates the Trend Chart Interface, and the fourth icon indicates the Alarm Interface. As you turn **the Knob**, the cursor switches among the four icons, and the interface displayed on the screen changes accordingly.

13.1.2 Bringing up the parameter settings of the Main Interface

When the page as shown in the Fig. 13-1 is displayed on the display screen, press **the Knob**. Enter the parameter settings interface of the Main Interface, and the background color of the first option of the parameter setting interface becomes blue, as shown in Fig. 13-2.

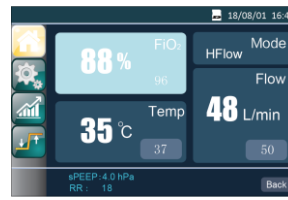

Fig. 13-2

13.1.3 Selecting Options

As you turn **the Knob** clockwise, the cursor moves among the FiO_2, temp and flow options. When the cursor is on a certain option, press **the Knob**, and the option value can now be adjusted and displayed in blue, as shown in Fig. 13-3.

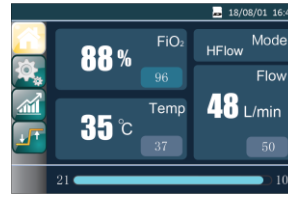

Fig. 13-3

13.1.4 Adjusting Options

The working parameters can be changed by turning **the Knob**. As shown in Fig. 13-3, the "**FiO_2**" option is selected. As you turn **the Knob** clockwise, the value of the FiO_2 option increases. As you turn **the Knob** counterclockwise, the value of the FiO_2 option decreases. The "**FiO_2**" option is still displayed in blue, as shown in Fig. 13-4.

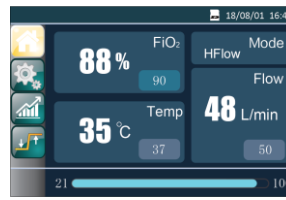

Fig. 13-4

13.1.5 Confirming Adjustments

Press **the Knob**, after setting the parameter, and the parameter will be confirmed, as shown in Fig. 13-5.

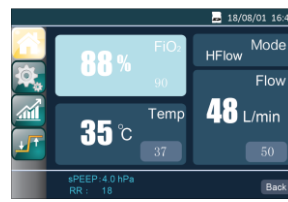

Fig. 13-5

13.1.6 Exiting the parameter settings of the Main Interface

Turn **the Knob** and make the cursor stay on the icon "**Back**", as shown in Fig. 13-6. Press **the Knob**, the screen displays the Main Interface, as shown in Fig. 13-7.

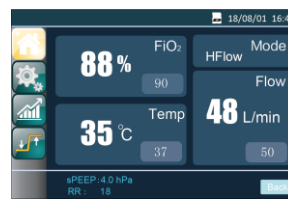

Fig. 13-6

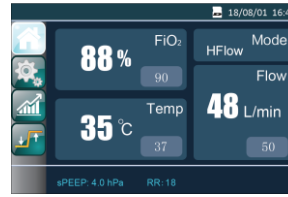

Fig. 13-7

13.1.7 Accessing the Setup Interface

When the cursor stays on the icon , the screen displays the Setup Interface. Access the Setup Interface by pressing **the Knob** . The first option on the Setup Interface is then displayed in blue, as shown in Fig. 13-8.

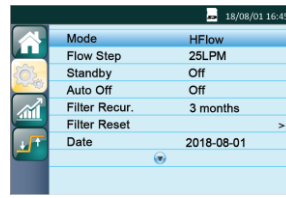

Fig. 13-8

13.1.8 Selecting Options

As you turn **the Knob** clockwise, the cursor moves downwards from one option to another. As you turn it counterclockwise, the cursor moves upwards. When the cursor stays on one option, press **the Knob** , the option will enter the adjustable state, and the background color of the option which enters the adjustable state is yellow, as shown in the "**Flow Step**" column in the Fig. 13-9.

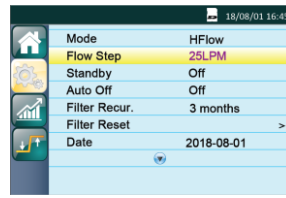

Fig. 13-9

13.1.9 Adjusting Options

Turn **the Knob** to change the working parameter. The option "**Flow Step**" is selected from the menu in the above figure, at this moment. As you turn **the Knob** clockwise, the value of "**Flow Step**" on menu will increase, as shown in the figure below. As you turn **the Knob** counterclockwise, the value will decrease, and the background color of the "**Flow Step**" option is still yellow, as shown in Fig. 13-10.

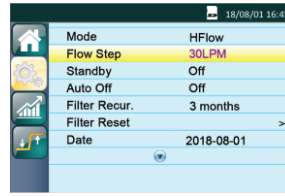

Fig. 13-10

13.1.10 Confirming Adjustments

Press **the knob** after selecting the parameter, the parameter will be confirmed, and the background color of the option will become blue, as shown in Fig. 13-11.

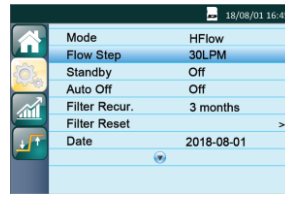

Fig. 13-11

13.1.11 Turning Pages

When the cursor is on "**Date**", the last option shown in Fig. 13-11, the remaining options will appear on a new page if you continue to turn **the Knob** clockwise, as shown in Fig. 13-12.

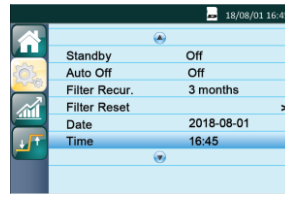

Fig. 13-12

Note: are page turning symbols.

13.1.12 Exiting the Setup Interface

(1) Returning to the Initial Setup Interface

Turn **the Knob** to make the cursor stay on icon "**Back**", and then press **the Knob**, the screen displays the Initial Setup Interface, as shown in Fig. 13-13.

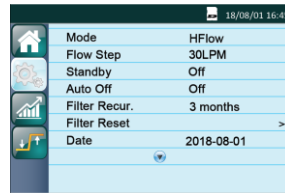

Fig. 13-13

(2) Returning to the Main Interface

Turn **the Knob** to make the cursor stay on "**Home page**", and then press **the Knob** to exit the Setup Interface. The screen will display the Main Interface shown in Fig. 13-13.

13.1.13 Accessing the Trend Chart Interface

When the cursor is on the icon , the screen displays the Trend Chart Interface. Access the interface by pressing **the Knob** , as shown in Fig. 13-14. The flow, temp, FiO_2, RR of the first day, the third day and the seventh day can be selected from the interface for reviewing. Turn the **the Knob** to select the data of the first day, the third day and the seventh day for reviewing.

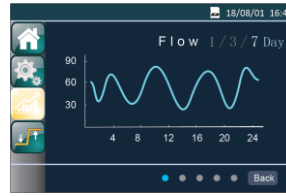

Fig. 13-14

When the page as shown in the Fig. 13-14 is displayed on the display screen, press **the Knob** and the data reviewing will be adjustable, as shown in the Fig. 13-15, and turning **the Knob** to switch among the flow, temp, FiO_2 and RR.

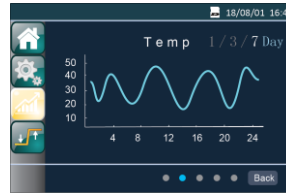

Fig. 13-15

13.1.14 Exiting the Trend Chart Interface

Turn **the Knob** to make the cursor stay on "**Back**", as shown in Fig. 13-16. And then press **the Knob**, the background color of icon will become blue, and the initial trend parameter interface will be displayed on the screen, as shown in Fig. 13-17.

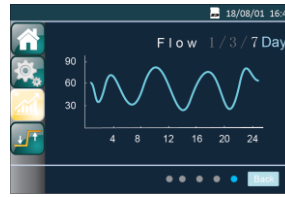

Fig. 13-16

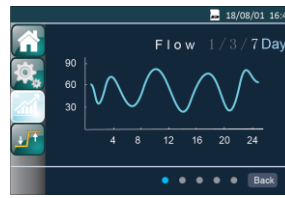

Fig. 13-17

13.2 Options of the Patient Menu and Corresponding Descriptions

Option	Range	Description
FiO_2	21% ～ 100%	Set FiO_2 by adjusting this option. As you turn **the Knob** to the nearest point, the numbering increases or decreases by 1%. The default setting is "**21%**". **Note:** This function is applicable to H-80A and H-80AS.
Temp	29°C ～ 37°C	Set temp by adjusting this option. As you turn **the Knob** to the nearest point, the numbering increases or decreases by 1°C. The default setting is "**31°C**". **Note:** Under the LFlow mode, the temp is set to 34°C, nonadjustable.
Flow	2 L/min ～ 80 L/min	Set flow by adjusting this option. As you turn **the Knob** to the nearest point, the numbering increases or decreases by 1 L/min. The default setting is "**25 L/min**". Different specifications of the Nasal Cannula can achieve different flows, please choose a Nasal Cannula.
Mode	HFlow / LFlow / AutoFlow / SmartFlow	A total of four modes can be selected, turn **the Knob** to switch. The default setting is "**HFlow**". **Note:** AutoFlow and SmartFlow are only applicable to H-80AS.
sPEEP	0 ～ 4	Set the end-expiratory pressure of the patient by adjusting this option. As you turn **the Knob** to the nearest point, the numbering increases or decreases by 1. The default setting is "**1**". **Note:** This function is avaliable under the work mode of AutoFlow and SmartFlow.
Humidity Compensation	-3～ 3	Set the Humidity Compensation. There are 7 points, as you turn **the Knob** to the nearest point, the numbering increases or decreases by 1. The default setting is "**0**".
Flow Step	15 L/min ～ 80 L/min	Set the flow step by adjusting this option. As you turn **the Knob** to the nearest point, the numbering increases or decreases by 5 L/min. The default setting is "**25 L/min**".
Standby	On / Off	The device can still keep certain output temperature and humidity after the nasal cannula is removed. Turn **the Knob** to switch. The default setting is "**Off**".
Auto Off	On / Off	This feature enables the device to automatically discontinue the therapy and shut off when the nasal cannula is removed. Turn **the Knob** to change the setting of this feature. The default setting is "**Off**".

Option	Range	Description
Filter Recur.	Auto/3 months/ 6 months/ 1 year	Set filter replacement prompt, and it can modify the service cycle of the filter.
Filter Reset	——	The service time of the filter returns to zero through this function.
Date	2000-01-01 — 2099-12-31	Set date by adjusting this option.
Time	00:00 — 23:59	Set time by adjusting this option.
Time Format	12-hour / 24-hour	Turn **the Knob** to choose between the two time formats. The default setting is "**12-hour**".
Date Format	yy mm dd / mm dd yy / dd mm yy	Turn **the Knob** to choose among three date formats. The default setting is "**mm dd yy**".
Backlight	Auto / On	The backlight of the LCD screen can be set to "**Auto**" or "**On**." Turn **the Knob** to choose between the two modes. If it is set to "**Auto**," the backlight will turn off automatically after two minutes of inactivity. If it is set to "**On**," the backlight will always be on. The default setting is "**Auto**".
Language	English / 中文（简体）	Turn **the Knob** to choose among the two languages available. The setting is only valid when the device is inserted a SD card with language pack. The default setting is "**English**". **Note:** Only languages included in SD Card can be switched.
Run Time	——	Show the actual total operation time of the device.
Service	——	Specially hidden, activate the specific function through password.
Restore Defaults	——	Restore default settings.
Erase Data	——	Erase use data.
About	——	Show the relevant information about the device, this is only for users to view, can not be modified. Model: the device model; SN: Serial Number of the device; Firmware version: Software version of the device; ID: Contains information such as gallery and language; PIN: Personal identification code.

14. Alarm

This chapter describes device alarms and the responses operators make to different alarms.

After running, disconnect the device from the power supply by unplugging the power cord, an audible alert sounds like "beep beep beep, beep-beep, beep beep beep, beep-beep" and the red indicator light flickers at mute button , which means the alarming system of the device works normally.

CAUTION!

• The mute button will be illuminated only when the device is in the alarm state.

14.1 Grading for Alarming and Description

The grading for alarming and description of this equipment is presented as follows:

Grade	Sign of Grading	Description
High	!!!	Requires operator to make instant response
Intermediate	!!	Requires operator to make instant on-time response
Low	!	Requires operator to be more cautious about the change of the state of equipment

14.2 Visual Alarming

The grading for the visual alarming is expressed by the background of the alarming information on the top of the screen and the color of the LED light under the mute button, which is described as follows:

Grade	Visual	Description
High	Red	Red light flickers—high-grade alarming
Intermediate	Yellow	Yellow light flickers—intermediate alarming
Low	Yellow	Yellow light indicates in a fixed manner—low-grade alarming

14.3 Auditory Alarming

In the case of alarming, the alarming sounds at different grades will occur and are described as follows:

Grade	Auditory	Description
High	●●● ●● ●●● ●●	beep beep beep beep-beep beep beep beep beep beep
Intermediate	● ● ●	beep beep beep
Low	●	beep

In accordance with the requirements of the relevant standards, the volume of the audible alarm signal meets the requirements, and the sound pressure range of the measured auditory alarm signal is described as follows:

Alarm Condition	Measured sound pressure level（dB）	A-weighted sound pressure level averaged over the measurement surface（dB）	Remarks
High priority	52.2	38.5	Maximum volume
Median priority	51.8	39.6	Maximum volume
Low priority	51.8	37.2	Maximum volume

14.4 Alarming Silence

When the breathing machine sounds an alarm, press the mute button and it will become silent for 100 to 120 seconds and then the alarm sound again immediately after the end of the silence; if the mute button is re-pressed during the silence period, the alarm sound will resume.

14.5 Accessing the Alarm Interface

From the Main Interface shown in Fig. 13-1, turn **the Knob** and move the cursor to the icon , and then press **the Knob** can enter the alarm information setting interface, and the first option which is low pressure of parameter setting interface is displayed in blue, as shown in Fig. 14-1.

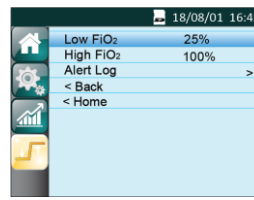

Fig. 14-1

Chose the option which needs to set alarm information, and change and confirm the option parameter, and then return to alarm information setting initial interface. The operation methods of above step is same to parameter setting, please refer to Section 13.1 "Parameter setting steps".

14.6 Alarming Information and Description

Alarm Message	Description	Alarm Delay
Power Failure!!!	An audible alert will sound in 6s if the device is accidentally disconnected from power when it is delivering air. Alarming duration time is no less than 30s. **Note:** (1) The device does not give a sound alarm when power off under standby state. (2) Because the screen loses power after power off, the word prompt cannot be seen, but the red indicator light flickers at the mute button 🔕.	Give an alarm within 6s
Device fault!!!	An audible alert will sound if no airflow comes out of the machine; the screen will display "**Device fault!!!**".	Give an alarm within 30s
Tube disconnected!!!	When the airflow is on, an audible alert will sound if the tube accidentally detached, the screen will display "**Tube disconnected!!!**".	Give an alarm within 40s
Check Water!!!	When the device detects that the water in the water chamber has been used up, the device gives the alarm of checking water, and the screen will display "**Check Water!!!**".	After opening the humidifying function for 2min, immediately give an alarm without delay
High O_2 Pressure!!!	When the device detects that the O_2 pressure is higher than 700 kPa，the device gives the alarm and the screen will display "**High O_2 Pressure !!!**". (applicable to H-80A and H-80AS)	Give an alarm within 15s
FiO_2 Too High!!!	When FiO_2 monitored by the device is higher than the set limit, the device gives the High O_2 alarm; the screen will display "**FiO_2 Too High!!!**". Setting range: Off, 30% ～ 100%	Give an alarm within 40s
FiO_2 Too Low!!	When FiO_2 monitored by the device is lower than the set limit, the device gives the Low O_2 alarm; the screen will display "**FiO_2 Too Low!!**". Setting range: Off, 21% ～ 25%	Give an alarm within 40s
Low O_2 Pressure!!!	When the device detects that the O_2 pressure is lower than 200 kPa and the FiO_2 cannot reach the target setting value, the device gives the alarm and the screen will display "**Low O_2 Pressure !!!**". (applicable to H-80A and H-80AS)	Give an alarm within 80s

Alarm Message	Description	Alarm Delay
Inlet Port Blocked!!	When the device works normally, if the inlet port is blocked, the device will give the inlet port blockage alarm; the screen will display "**Inlet Port Blocked!!**"	Give an alarm within 40s
Low Input Voltage!!	If the device detects that the output voltage supplied by medical power is lower than 22V, an audible alert will sound and the screen will display "**Low Input Voltage!!**".	Give an alarm within 5s
Heated Humidifier Failure!!	The device starts the heated humidifying function, but the temp does not rise after 5min, the device gives an alarm of humidifier failure, and "**Humidifier Failure!!**" is displayed on the display screen.	Give an alarm within 10min
Low voltage!!	The device detects that the output voltage is lower than 22V and sends an alarm of low voltage, and the screen will display "Low voltage !!".	Immediately give an alarm without delay
Can't Reach Target FiO_2!!	When the device detects that the set target FiO_2 can't be reached, it gives an alarm that the target FiO_2 can't be reached, and the screen will display "**Can't Reach Target FiO_2!!**". (applicable to H-80A and H-80AS)	Give an alarm within 70s
Can't Reach Target Temp!!	When the device detects that the set target temp can't be reached over 2 ℃, it gives an alarm then the screen will display "**Can't Reach Target Temp!!**".	Start to judge 30s after starting heating, and continue for 15min. If the judge temperature is still lower than the set target temperature over 2 °C, the device give an alarm
Can't Reach Target Flow!!	When the device detects that the set target flow can't be reached, it gives an alarm that the target flow can't be reached, and the screen will display "**Can't Reach Target Flow!!**".	Give an alarm within 40s
Nasal Cannula Blocked!!	When the device works normally, if the nasal cannula is blocked, the device will give the nasal cannula blockage alarm, and the screen will display "**Nasal Cannula Blocked!!**".	Give an alarm within 15s

Alarm Message	Description	Alarm Delay
Turn Off the O_2 Source!	When the O_2 source is opened before starting the device or O_2 source is not closed at the time of shutdown, the device gives an alarm of turning off the O_2 source, and the screen will display "**Turn Off the O_2 Source!**".	Immediately give an alarm without delay
Tube Damaged!	Give an alarm when the device detects the breathing tube failure, the device gives an alarm of tube damage, and the screen will display "**Tube Damaged!**".	Immediately give an alarm without delay
Please Change Filter!	When the Filter Alert feature is enabled, an audible alert will sound if the preset replacement time reaches but without replacing the air filter; the screen will display "**Please Change Filter!**". The default setting is "**3 months**". **Note:** When the Filter Alert feature is set to automatic, the device automatically judges whether to send out an alarm according to the actual situation of the air filter.	Immediately give an alarm without delay
SD Card Full!	The screen will display "**SD Card Full!**" if the SD card has reached its maximum capacity.	Immediately give an alarm without delay
Reinsert SD card!	The screen will display "**Reinsert SD card!**" if the SD card fails to work.	Immediately give an alarm without delay

14.7 Reposition of Alarming

After the elimination of the alarming faults, the residual alarming information still exists (alarming information is shown on the top of the screen without any visual and auditory alarming), and turn **the Knob** leftwards or rightwards to reduce the residual alarming information.

14.8 Alarming Journal

The alarming journal is designed for the breathing machine to record the latest 6 alarming information. Reserved inside the machine, the alarming journal will not be lost after the power supply interruption and the latest alarming will replace the former one with 6 reserved.

WARNINGS!

• Prior to the use of equipment, the oeprators should examine the current alarming pre-arrangement to check if it is applicable to each case of patient, and such pre-arrangement can only be changed by the professional doctors and must not be modified by the patients at home.

• In the case of the suspension of the power or the power loss for no less than 30 seconds, it will restore the last set alarming value on the next oepration.

CAUTION!

• The information of alarming journal will be maintained when the device is powered down, but the instantaneous time of power down will not be recorded.

14.9 Alarming Verification

Turn on the device, and then check the alarming system of the device at any time.

Tube disconnected alarm test

(1) When the device is working normally, adjust the device to the appropriate patient settings. Remove the tube that connected to the air outlet of the device, and then confirm whether the tube disconnected alarm occurs.

(2) Press the mute button and it will become silent for 100 to 120 seconds. If the alarm state has not been eliminated, and then the alarm sounds again immediately after the end of the silence.

(3) Reinstall the tube.

(4) Turn **the Knob** leftwards or rightwards to reduce the residual alarming information.

Power failure alarm test

(1) Confirm whether an audible alert will sound in 6s when the device is accidentally disconnected from power during it is delivering air.

(2) Reconnect the power supply, and then confirm if the device restarts delivering air.

WARNING!

• Adjust the device to the appropriate patient settings after the test and before use.

15. Cleaning and Maintenance

WARNINGS!

• Regular cleaning of the device and its accessories is very important for the prevention of respiratory infections.

• To avoid electric shock, always unplug the device before cleaning.

• Use the cleaning solution which is nontoxic to human body.

• Follow the manufacturer's instructions on cleaning the LH2 Heated Breathing Tube and on determining the frequency of cleaning.

• Before cleaning, check whether the device has been disconnected from the power supply, whether the power cord has been unplugged, and whether the water chamber has cooled down. Make sure the heater plate has cooled down to room temperature, so you do not get burned.

• Do not open or modify the device. There are no user serviceable parts inside. Repairs and servicing should only be performed by an authorized service agent.

CAUTIONS!

• Overheating of the materials could lead to early fatigue of these materials.

• Do not use solutions containing chlorinated lime, chlorine, or aromatic to clean the device and its accessories. Liquid soap containing moisturizing agents or antimicrobials should not be used either. These solutions may harden cleaned materials or reduce their lifespan.

• Do not clean or dry the device and its accessories when the temperature is higher than 80°C (176˚F). High temperatures could reduce product life.

• Do not immerse the device in any fluids.

• It is unnecessary to clean and maintain before using for the first time.

15.1 Cleaning the Nasal Cannula

For details, refer to the cleaning instructions in the user manual for the nasal cannula.

15.2 Cleaning the Enclosure

Wipe the surface of the device with a soft, slightly damp cloth.

CAUTIONS!

• The device can only be used after the enclosure is dry, so that no moisture enters the device.

• It is recommended to clean the enclosure once a week.

15.3 Cleaning the Tube

For details, refer to the cleaning instructions in the user manual for the tube.

15.4 Replacing the Nasal Cannula

For details, refer to the cleaning instructions in the user manual for the nasal cannula.

CAUTION!

• It is recommended to replace the nasal cannula every two weeks or before being handed over to the next patient for use.

15.5 Replacing the Tube and the Water Chamber

For details, refer to the cleaning instructions in the user manual for the tube or consult the after-sales service personnel.

CAUTION!

• It is recommended to replace the LH2 Heated breathing tube, water chamber and the water chamber adapter every two weeks or before being handed over to the next patient for use.

15.6 Replacing the Air Filter

(1) Open the air filter cap to remove the air filter.

(2) Put the new air filter in the filter area, and then place the filter cap back properly.

CAUTIONS!

• In order to avoid damaging the material, the spare air filter cannot be placed under the direct sunlight, nor in humid environment and environment below the freezing temperature. The air filter shall be replaced at least every 3 months, 6 months or 1 year (the replacement cycle can be shortened according to local air quality, please replace it in case of damage and crack).

• Operating the device with a dirty air filter may stop it from working properly and may cause damage to the device.

• Replacing the air filter and filter cap, device must be unplugged.

15.7 Disinfection

Please always follow the above cleaning requirements to complete the cleaning work during use. When the device is polluted, or before it is used by the next patient, it shall be disinfected according to the following disinfection methods.

Disinfection of the Device:

The device has the one-way protection setting, and the inside of the device need not to be disinfected. Please use a clean, soft and a little damp disposable sterile cloth to scrub the inlet port and outlet port of the device, and wipe away the dirt; then use the alcohol cotton to scrub the inlet port, outlet port and the surrounding.

WARNINGS!

• After disinfection, rinse any disinfected component in clean water thoroughly, so as to

prevent disinfectant residuals from damaging the skin or respiratory tract or causing allergies.
• The device shall not be serviced or maintained while in use with a patient.
• Sterilization of this device and its components other than recommended is not permitted.
• The LH2 Heated Breathing Tube , water chamber and the water chamber adapter cannot be disinfected. LH2 Heated Breathing Tube, water chambers, patient interfaces and the water chamber adapter can only be used by single patient.

CAUTIONS!

• Disinfectants tend to damage materials and reduce the life of components. Try to select the appropriate disinfectant, and follow the disinfectant manufacturer's instructions and recommendations.
• After disinfection, check the disinfected component for any signs of damage. Replace any damaged component immediately.

16. Reordering

Contact your home care provider to order accessories or replacement filters.
The device does not require routine servicing.

WARNINGS!

• If you notice any unexplained changes in the performance of the device, if it is making unusual or harsh sounds, if it has been dropped or mishandled, if the enclosure is broken, or if water has entered the enclosure, discontinue use. Contact your home care provider.
• If the device malfunctions, contact your home care provider immediately. Never attempt to open the enclosure of the device. Repairs and adjustments must be performed by BMC-authorized service personnel only. Unauthorized service could cause injury, invalidate the warranty, or result in costly damage.
• If necessary, contact your local authorized dealer or BMC Medical Co., Ltd. for technical support and documents.

17. Technical Support

Please contact BMC directly if you need the circuit diagram of the device and the list of components for certain purposes such as maintenance or connection to other equipment. BMC will provide the circuit diagram and / or other technical documents in whole or in part according to your needs.

18. Disposal

When the device reaches the end of its service life, dispose of the device and packaging in accordance with local laws and regulations.

19. Troubleshooting

The table below lists common problems you may have with the device and possible solutions to those problems. If none of the corrective actions solve the problem, contact your home care provider.

19.1 Common Problems in Patients and Corresponding Solutions

Problem	Possible Cause	Solution (s)
Dry, cold, runny, and blocked nose; having a cold	The nose reacts to the airflow and cold. Due to fast airflow, the air becomes cold, leading to nasal mucosa irritation and subsequent dryness and swelling.	Increase the humidity setting of the device. Contact your physician, and continue treatment unless the physician suggests the opposite.
Dry mouth and throat	Probably because the patient sleeps with his or her mouth open, and the pressurized air goes out via the mouth, leading to nasal and throat dryness.	Use a chin strap to prevent the mouth from opening during sleep. Contact your physician for details.
Nasal, sinus, or ear pain	Sinus or middle ear inflammation.	Contact your physician immediately.
Facial redness or inflammation in contact with the nasal cannula	Headband too tight	Adjust the headband properly
	Inappropriate type of nasal cannula	Contact the equipment supplier and select another type of nasal cannula
	Allergic to material of the nasal cannula	Consult your physician and equipment supplier
Device noise is too loud	The tube is not connected properly.	Connect the tube to the correct connector. Check whether the breathing tube leaks air. Check whether the water chamber is connected with the device in place
Air delivered from the device is abnormally hot	The air inlet of the device may be partially blocked, leading to insufficient airflow into the device.	Replace the air filter (see 16.6 Replacing the Air Filter), and clean the air inlet.
		Place the device in an area where air flows freely, and make sure the device is at least 20 centimeters away from the wall, curtain, or other things.

19.2 Common Problems in the Device and Corresponding Solutions

Problem	Possible Cause	Solution (s)
The device does not work when it is turned on	Power is not connected properly.	Ensure that the power cord and the device are connected properly.
	There is no voltage.	Check whether a power outage occurs by turning on a light or other means. If you are sure the fuse in the device is broken, contact your equipment supplier for repair.
	Cannot find any cause.	Contact your equipment supplier.
The device produces very low flow	The air inlet of the device may be blocked.	Replace the air filter (see 16.6 Replacing the Air Filter), and clean the air inlet. Make sure the air inlet is unblocked.
After the device is turned on, the screen displays intermittently, or displays nothing at all	The operating system of the device needs to be readjusted or restarted.	Unplug the power cord of the device, and re-plug it 20 seconds later.
The device is in standby, and will not start	The operating system of the device needs to be readjusted or restarted.	Unplug the power cord of the device, and re-plug it 20 seconds later.

20. EMC Requirements

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration - electromagnetic emissions</th></tr>
<tr><td colspan="3">The device is intended for use in the electromagnetic environment specified below. The user of the device should ensure that it is used in such an environment.</td></tr>
<tr><th>Emissions Test</th><th>Compliance</th><th>Electromagnetic Environment - Guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>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</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class B</td><td rowspan="3">The 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</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations
/ flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

Guidance and manufacturer's declaration - electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The user of the device should make sure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV 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 / burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input / output lines	±2 kV for power supply lines ±1 kV for input / output lines	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	±1 kV line (s) to line (s) ±2 kV common mode	±1 kV line (s) to line (s) ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T; 1 cycle 70% U_T; 25 / 30 cycle At 0° 0% U_T; 250 / 300 cycle	0% U_T; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% U_T; 1 cycle 70% U_T; 25 / 30 cycle At 0° 0% U_T; 250 / 300 cycle	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 a battery And batteries that can only be replaced by maintenance personnel using tools
Power frequency (50 / 60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
Note: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The user of the device should make sure 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 ~ 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz	3 V 0.15 MHz ~ 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz	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** $d = 1.17\sqrt{p}$ $d = 0.35\sqrt{p}$ 80 MHz to 800 MHz $d = 0.70\sqrt{p}$ 800 MHz to 2.5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	

Note 1: At 80 MHz and 800 MHz, the higher frequency range applied.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from 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 10 V/m.

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

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

Rated maximum output of transmitter W	150 kHz ～ 80 MHz $d = 1.17\sqrt{p}$	80 MHz ～ 800 MHz $d = 0.35\sqrt{p}$	800 MHz ～ 2.5 GHz $d = 0.70\sqrt{p}$
0.01	0.12	0.04	0.07
0.1	0.37	0.12	0.23
1	1.17	0.35	0.70
10	3.70	1.11	2.22
100	11.7	3.50	7.00

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

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

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.

Recommended separation distances between RF wireless communications equipment

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between RF wireless communications equipment and the device as recommended below, according to the maximum output power of the communications equipment.

Frequency MHz	Maximum Power W	Distance	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
385	1.8	0.3	27	27	RF wireless 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** $E = \frac{6}{d}\sqrt{P}$ Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
450	2	0.3	28	28	
710	0.2	0.3	9	9	
745					
780					
810	2	0.3	28	28	
870					
930					
1720	2	0.3	28	28	
1845					
1970					
2450	2	0.3	28	28	
5240	0.2	0.3	9	9	
5500					
5785					

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

WARNINGS!

• This device should not be used in the vicinity or on the top of other electronic equipment such as cell phone, transceiver or radio control products. If you have to do so, the device should be observed to verify normal operation.

• The use of accessories and power cord other than those specified, with the exception of cables sold by the manufacturer of the equipment or system as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment or system.

• This device may be interfered with by other equipment, even if that other equipment complies with CISPR EMISSION requirements.

21. Limited Warranty

BMC Medical Co., Ltd. warrants that the device shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of one (1) year for main unit and three (3) months for all accessories from the date of sale by BMC Medical Co., Ltd. to the dealer. If the product fails to perform in accordance with the product specifications, BMC Medical Co., Ltd. will repair or replace, at its option, the defective material or part. BMC Medical Co., Ltd. will pay customary freight charges from BMC Medical Co., Ltd. to the dealer location only. This warranty does not cover damage caused by accident, misuse, abuse, alteration and other defects not related to material or workmanship.

BMC MEDICAL CO., LTD. DISCLAIMS ALL LIABILITY FOR ECONOMIC LOSS, LOSS OF PROFITS, OVERHEAD OR CONSEQUENTIAL DAMAGES WHICH MAY BE CLAIMED TO ARISE FROM ANY SALE OR USE OF THIS PRODUCT. SOME STATES DO NOT ALLOW THE EXCLUSION OR LIMITATION OF INCIDENTAL OR CONSEQUENTIAL DAMAGES, SO THE ABOVE LIMITATION OR EXCLUSION MAY NOT APPLY TO YOU.

To exercise the rights under this warranty, contact the local authorized dealers or:

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