User Manual

BPAP System

G3 B25VT / G3 B30VT

Table of Contents

1. Symbols

1.1 Control Buttons

	Home Button
	Start / Stop Button
	Knob

1.2 Device Symbols

	Follow Instructions for Use
	Consult instructions for use
	Type BF Applied Part (mask)
	Class II (Double Insulated)
	For indoor use only
	AC Power
	DC Power
IP22	≥ 12.5 mm Diameter, Dripping (15° tilted)
	There is high voltage, beware of electric shock
	Hot Surface
	Serial Number
	Manufacturer
	Date of manufacture
	Use-by Date
	Maximum water level
	Logo of BMC Medical Co., Ltd.
	Do not use if package is damaged and consult instructions for use

	Disassembly is prohibited
	Batch code
	Non-Ionizing Radiation
	SD Card
	WEEE Marking
	Air Inlet
	Air Outlet
	Caution
	MR Unsafe
	Complies with RTCA DO-160 section 21, category M.
	Made in China
	Medical Device
	Prescription only
	Catalogue number
	Unique device identifier
	Model Number
	Temperature Limit
	Humidity Limit
	Atmospheric Pressure Limit

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!

Indicate the possibility that such operation may affect the effectiveness or ease of use of the device.

Warnings, Cautions and Important Tips appear throughout this manual as they apply.

3. Indication for Use

The BPAP System is a Bi-level PAP (Bi-level Positive Airway Pressure) device, which is intended to provide non-invasive ventilation for patients with Obstructive Sleep Apnea (OSA) or Respiratory Insufficiency. The integrated humidifier is indicated for the humidification and warming of air from the flow generator device.

The device is intended for adult patients weighing more than 66 lbs (30 kg) by prescription. The device is intended for single patient use in a home environment and for multi-patient re-use in a hospital / institutional environment.

WARNINGS!

• This device is intended for adult use only.

• This device is not intended for life support.

• The instructions in this manual are not intended to supersede established medical protocols.

• To ensure that you receive the safe, effective therapy prescribed for you, use only accessories manufactured or recommended by REACT HEALTH or those recommended by your physician.

• Do not bring the device or accessories into a Magnetic Resonance (MR) environment as it may cause unacceptable risks 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 risks 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 makes unusual or harsh sounds, disconnect the power cord and stop using it. Contact your home care provider.

CAUTIONS!

• This device is restricted to sale by or on the order of a physician.
• The patient is an intended operator.
• The device is intended for use by operators trained or experienced in similar equipment.
• Cleaning and disinfection can be performed by the patient.

IMPORTANT TIP!

• 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 physician.

4. Contraindications

If you have any of the following conditions, tell your physician before using this device:
• Insufficient respiratory drive to endure brief interruptions in non-invasive ventilation therapy
• Acute sinusitis or otitis media
• Epistaxis causing a risk of pulmonary aspiration
• Conditions predisposing to a risk of aspiration of gastric contents
• Impaired ability to clear secretions
• Hypotension or significant intravascular volume depletion
• Pneumothorax or pneumomediastinum
• Recent cranial trauma, cerebrospinal fluid leak or surgery
• Apparent non-cooperation or extreme stress

The following side effects may occur during treatment:
- Dryness of the mouth, nose or throat
- Abdominal bloating
- Discomfort in the ears or sinuses
- Eye irritation
- Skin irritation due to the use of a mask
- Chest discomfort

CAUTION!

• Contact your physician if symptoms of sleep apnea recur. Contact your physician if you have any questions concerning your therapy.

IMPORTANT TIPS!

• An irregular sleep schedule, alcohol consumption, obesity, sleeping pills, or sedatives may aggravate your symptoms.
• Please use a mask which meets ISO 17510:2015.

5. Specifications

Device Size

Dimensions (L x W x H): 265 mm × 145 mm × 114 mm

Weight: 1.7 kg

Water capacity: To maximum fill line 360 mL

Product Use, Transport and Storage

	Operation	Transport and Storage
Temperature	5°C to 35°C (41°F to 95°F)	25°C to 70°C (-13°F to 158°F)
Humidity	15% to 93% Non-condensing	15% to 93% Non-condensing
Atmospheric Pressure	760 cmH_2O to 1060 cmH_2O	760 cmH_2O to 1060 cmH_2O
Altitude	Sea level to 2300 m	Sea level to 2300 m

This device automatically compensates for altitude Pressure up to 760 cmH_2O.

Heated Humidifier

Humidifier Settings: Off, Auto, 1 to 5 (95°F to 154.4°F / 35°C to 68°C)

Humidifier Output: No less than 15 mgH_2O/L

Environmental Conditions: Maximum airflow, 35°C, 15% relative humidity

Maximum Operating Pressure: 40 cmH_2O

Pressure Drop with Humidifier: < 0.4 cmH_2O at 60 LPM flow

Maximum Delivered Gas Temperature: ≤ 43°C

Cellular Module

Transportation Requirements	Shock, severe vibration and moisture should be avoided in transportation	
Frequency Bands	Bands[1] 2, 3, 4, 5, 8, 12, 13, 20, 28	
Communication Mode	LTE Cat M1/ NB1	
Effective Radiated Power LTE	LTE Cat M1/ NB1: ≤ +23 dBm (2100 mW), Class 3	
FCC ID	XPY2AGQN4NNN	
Security Measures	Authentication	Enforced on all data channels (outgoing and incoming)
	Encryption	Base 128 encoding

[1] The LTE bands supported by Cellular Module are defined above, while the following Table 1 describes the Transmitting and Receiving frequencies.

Table 1 Transmitting and Receiving frequencies

Parameter		Min.	Max.	Unit	Remarks
Frequency range FDD Band 12 (700 MHz)	Uplink	699	716	MHz	Module transmit
	Downlink	729	746	MHz	Module receive
Frequency range FDD	Uplink	703	748	MHz	Module transmit

Band 28 (700 MHz)	Downlink	758	803	MHz	Module receive
Frequency range FDD Band 13 (700 MHz)	Uplink	777	787	MHz	Module transmit
	Downlink	746	756	MHz	Module receive
Frequency range FDD Band 20 (800 MHz)	Uplink	832	862	MHz	Module transmit
	Downlink	791	821	MHz	Module receive
Frequency range FDD Band 5 (850 MHz)	Uplink	824	849	MHz	Module transmit
	Downlink	869	894	MHz	Module receive
Frequency range FDD Band 8 (900 MHz)	Uplink	880	915	MHz	Module transmit
	Downlink	925	960	MHz	Module receive
Frequency range FDD Band 4 (1700 MHz)	Uplink	1710	1755	MHz	Module transmit
	Downlink	2110	2155	MHz	Module receive
Frequency range FDD Band 3 (1800 MHz)	Uplink	1710	1785	MHz	Module transmit
	Downlink	1805	1880	MHz	Module receive
Frequency range FDD Band 2 (1900 MHz)	Uplink	1850	1910	MHz	Module transmit
	Downlink	1930	1990	MHz	Module receive

WARNING!

• All other wireless technology emitters must be kept at least 30 cm (12 inches) away from the Cellular Module.

CAUTION!

• Considering the requirements of network security, the CPU on this equipment only supports the standard of our product software and does not support the operation of other foreign software.

• Non-professionals are not authorized to upgrade software.

Mode of Operation

Continuous

Work Mode

CPAP, S, S/T, T

SD Card

The SD card can record patient data and fault information.

AC Power Consumption

100 V - 240 V ~, 50 Hz / 60 Hz, 2 A Max.

Main Device Input

24 V, 3.33 A

Device Offer to Heated Tubing Communications Port

24 V ⎓ 18 W

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

Pressure Range

Model	Work Mode	Pressure Range
G3 B25VT	CPAP, S, T, S/T	CPAP: 4.0 ~ 20.0 cmH_2O; IPAP: 4.0 ~ 25.0 cmH_2O; EPAP: 4.0 ~ 25.0 cmH_2O; in 0.5 cmH_2O increments.
G3 B30VT	CPAP, S, T, S/T	CPAP: 4.0 ~ 20.0 cmH_2O; IPAP: 4.0 ~ 30.0 cmH_2O; EPAP: 4.0 ~ 25.0 cmH_2O; in 0.5 cmH_2O increments.

Under single fault conditions, ≤ 30 cmH_2O for CPAP mode, ≤ 40 cmH_2O for the rest modes.

Pressure Display Accuracy

±(0.8 cmH_2O + 4%)

Static Pressure Stability

±0.5 cmH_2O

Dynamic Pressure Stability

Pressures (cmH_2O)	10 BPM	15 BPM	20 BPM
6.5	±0.5	±0.5	±0.5
10	±1	±1	±1
20	±1	±1	±1

Device with humidification and 22 mm Tubing or Heated Tubing.

Ramp

The ramp time ranges from 0 to 60 minutes.

The A-weighted sound pressure level and sound power level

When the device is working at the pressure of 10 hPa, its sound pressure level and sound power level shall not be greater than the values in the following table:

Sound Pressure Level	Uncertainty	Sound Power Level	Uncertainty
26 dB(A)	2 dB(A)	34dB(A)	2 dB(A)

Note: Declared dual-number noise emission values in accordance with ISO 4871:1996.

Maximum Flow

G3 B25VT:

	Test Pressure				
	Pmin	**Pmin +1/4 (Pmax-Pmin)**	**Pmin + 1/2 (Pmax-Pmin)**	**Pmin + 3/4 (Pmax-Pmin)**	**Pmax**
Test Pressures (cmH_2O)	4	10	15	20	25
Measured Pressure at the Patient Connection Port (cmH_2O)	3	9	14	19	24
Average Flow at the Patient Connection Port (L/min)	90	150	150	150	150
When the working pressure is set to the values listed in the table, the average flow rate at the patient end should be greater than 80% of the corresponding flow value in the table.					

G3 B30VT:

	Test Pressure				
	Pmin	**Pmin + 1/4 (Pmax-Pmin)**	**Pmin + 1/2 (Pmax-Pmin)**	**Pmin + 3/4 (Pmax-Pmin)**	**Pmax**
Test Pressures (cmH_2O)	4	11	17	24	30
Measured Pressure at the Patient Connection Port (cmH_2O)	3	10	16	23	29
Average Flow at the Patient Connection Port (L/min)	90	150	150	150	120
When the working pressure is set to the values listed in the table, the average flow rate at the patient end should be greater than 80% of the corresponding flow value in the table.					

Air Tubing

Air tubing	Length	Inner diameter
Tubing	6 ft.(1.83 m)	19 mm
Heated Tubing	6 ft.(1.83 m)	19 mm

The Form and the Dimensions of the Patient Connection Port

The 22 mm conical air outlet complies with ISO 5356-1.

PM2.5 Filter

	Material	Average arrestance
Standard filter	Polyurethane	> 20% for 10 micron
PM2.5 filter	Polypropylene and Poly (ethylene terephthalate)	> 90% for 2.5 micron

Dynamic pressure

Mode: CPAP Tube type: 22 mm

Pa			Test Pressure (V_T=500 mL)				
			Pmin	**Pmin+ 1/4 (Pmax-Pmin)**	**Pmin+ 1/2 (Pmax-Pmin)**	**Pmin +3/4(Pmax-Pmin)**	**Pmax**
			4 hPa	**8 hPa**	**12 hPa**	**16 hPa**	**20 hPa**
f (breaths/min)	**10**	4.29	8.31	12.53	16.64	20.78	4.29
		3.82	7.78	11.87	15.91	19.99	3.82
		4.06	8.05	12.2	16.28	20.39	4.06
	15	4.31	8.49	12.56	16.79	20.85	4.31
		3.83	7.91	11.78	15.81	19.65	3.83
		4.07	8.2	12.17	16.3	20.25	4.07
	20	4.31	8.58	12.72	16.87	20.93	4.31
		3.69	7.66	11.66	15.59	19.29	3.69
		4	8.12	12.19	16.23	20.11	4

Mode: CPAP Tube type: 15 mm

Pa			Test Pressure (V_T=500 mL)				
			Pmin	**Pmin+ 1/4 (Pmax-Pmin)**	**Pmin+ 1/2 (Pmax-Pmin)**	**Pmin +3/4 (Pmax-Pmin)**	**Pmax**
			4 hPa	**8 hPa**	**12 hPa**	**16 hPa**	**20 hPa**
f (breaths/min)	**10**	**Max**	4.32	8.33	12.56	16.68	20.81
		Min	3.8	7.74	11.84	15.88	19.96
		Mean	4.06	8.04	12.2	16.28	20.39
	15	**Max**	4.32	8.52	12.65	16.83	20.89
		Min	3.81	7.89	11.75	15.76	19.61
		Mean	4.07	8.21	12.2	16.3	20.25
	20	**Max**	4.36	8.62	12.86	16.95	20.98
		Min	3.71	7.63	11.75	15.65	19.25
		Mean	4.04	8.13	12.31	16.3	20.12

Mode: BPAP Tube type: 22 mm

				Test Pressure (V_T =500mL)				
				Pmin+4	Pmin+2+1/4 (Pmax-Pmin)	Pmin+2 +1/2 (Pmax-Pmin)	Pmin+2 +3/4 (Pmax-Pmin)	Pmax
Pa				8 hPa	13 hPa	19 hPa	26 hPa	30 hPa
				Pmin	Pmin-2+1/4 (Pmax-Pmin)	Pmin-2 +1/2 (Pmax-Pmin)	Pmin-2 +3/4 (Pmax-Pmin)	Pmax-4
				4 hPa	9 hPa	15 hPa	22 hPa	25 hPa
F (breaths /min)	10	IPAP	Max	8.43	13.49	19.47	27.29	31.23
			Min	7.85	12.83	18.52	26.02	29.95
			Mean	8.14	13.16	18.995	26.655	30.59
		EPAP	Max	4.31	9.38	15.5	22.56	26.19
			Min	3.81	8.77	14.79	21.42	24.93
			Mean	4.06	9.075	15.145	21.99	25.56
	15	IPAP	Max	8.46	13.52	19.52	27.32	31.28
			Min	7.84	12.78	18.49	25.96	29.88
			Mean	8.15	13.15	19.005	26.64	30.58
		EPAP	Max	4.34	9.4	15.56	22.59	26.25
			Min	3.74	8.76	14.78	21.38	24.92
			Mean	4.04	9.08	15.17	21.985	25.585
	20	IPAP	Max	8.5	13.59	19.58	27.35	31.35
			Min	7.83	12.69	18.46	25.88	29.78
			Mean	8.165	13.14	19.02	26.615	30.565
		EPAP	Max	4.36	9.46	15.62	22.62	26.33
			Min	3.72	8.74	14.58	21.36	24.88
			Mean	4.04	9.1	15.1	21.99	25.605

Mode: BPAP Tube type: 15 mm

				Test Pressure (V_T =500mL)				
				Pmin+4	Pmin+2+ 1/4 (Pmax-Pmin)	Pmin+2 +1/2 (Pmax-Pmin)	Pmin+2 +3/4 (Pmax-Pmin)	Pmax
Pa				8 hPa	13 hPa	19 hPa	26 hPa	30 hPa
				Pmin	Pmin-2+1/4 (Pmax-Pmin)	Pmin-2 +1/2 (Pmax-Pmin)	Pmin-2 +3/4 (Pmax-Pmin)	Pmax-4
				4 hPa	9 hPa	15 hPa	22 hPa	25 hPa
F (breaths /min)	10	IPAP	Max	8.47	13.58	19.52	27.31	31.33
			Min	7.86	12.79	18.48	25.95	29.88
			Mean	8.165	13.185	19	26.63	30.605
		EPAP	Max	4.35	9.43	15.59	22.58	26.28
			Min	3.78	8.79	14.74	21.4	24.95
			Mean	4.065	9.11	15.165	21.99	25.615
	15	IPAP	Max	8.5	13.61	19.56	27.38	31.38
			Min	7.82	12.71	18.46	25.92	29.83
			Mean	8.16	13.16	19.01	26.65	30.605
		EPAP	Max	4.37	9.48	15.62	22.62	26.32
			Min	3.74	8.75	14.65	21.35	24.92
			Mean	4.055	9.115	15.135	21.985	25.62
	20	IPAP	Max	8.53	13.62	19.64	27.42	31.48
			Min	7.8	12.67	18.41	25.86	29.78
			Mean	8.165	13.145	19.025	26.64	30.63

		EPAP	**Max**	4.39	9.52	15.65	22.68	26.38
			Min	3.71	8.72	14.53	21.33	24.86
			Mean	4.05	9.12	15.09	22.005	25.62

6. Model and Work mode

Fig. 6-1

All models have the same appearance; as shown in Fig. 6-1.

G3 B25VT

The maximum working pressure of the G3 B25VT is 25 cmH_2O.

The G3 B25VT delivers the following therapies:

CPAP – Delivers Continuous Positive Airway Pressure; CPAP maintains a constant level of pressure throughout the breathing cycle. If your physician has prescribed ramp for you, you can turn **the Knob** to reduce the pressure and then gradually increase the pressure to the therapeutic pressure setting so that you can fall asleep more comfortably.

S – A bi-level mode which responds to both your inhalation and exhalation by increasing pressure when you start to inhale and decreasing pressure when you start to exhale. There is no automatic delivery of breathing gas if you do not inhale. IPAP (Inspiratory Positive Airway Pressure) and EPAP (Expiratory Positive Airway Pressure) are preset by a physician.

T – A bi-level mode in which the device automatically starts inhalation and exhalation, and automatically controls the time of inhalation and that of exhalation according to the preset parameter.

S/T – A bi-level mode which responds to both your inhalation and exhalation by increasing pressure when you start to inhale and decreasing pressure when you

start to exhale. If you do not start inhaling within a set time, the device will automatically start the process of inhalation. When the device starts the process of inhalation, it controls the time of inhalation and automatically decreases the pressure for exhalation within a set time.

G3 B30VT

The maximum working pressure of the G3 B30VT is 30 cmH_2O.

The G3 B30VT delivers the following therapies:

CPAP – Delivers Continuous Positive Airway Pressure; CPAP maintains a constant level of pressure throughout the breathing cycle. If your physician has prescribed ramp for you, you can turn **the Knob** to reduce the pressure and then gradually increase the pressure to the therapeutic pressure setting so that you can fall asleep more comfortably.

S – A bi-level mode which responds to both your inhalation and exhalation by increasing pressure when you start to inhale and decreasing pressure when you start to exhale. There is no automatic delivery of breathing gas if you do not inhale. IPAP (Inspiratory Positive Airway Pressure) and EPAP (Expiratory Positive Airway Pressure) are preset by a physician.

T – A bi-level mode in which the device automatically starts inhalation and exhalation, and automatically controls the time of inhalation and that of exhalation according to the preset parameter.

S/T – A bi-level mode which responds to both your inhalation and exhalation by increasing pressure when you start to inhale and decreasing pressure when you start to exhale. If you do not start inhaling within a set time, the device will automatically start the process of inhalation. When the device starts the process of inhalation, it controls the time of inhalation and automatically decreases the pressure for exhalation within a set time.

When detect obstructive apnea events, hypopnea events, snoring events rise the pressure according to the table.

If no respiratory event is detected within the specified time, reduce the pressure according to the table.

Current pressure (cmH_2O)	4	5	6	7	8	9	10	11	≥ 12
Pressure Rise (cmH_2O)	2.5	1.9	1.8	1.7	0.6	0.6	0.4	0.4	0.2

Current pressure (cmH_2O)	4	5	6	7	8	9	10	11	12
Pressure drop (cmH_2O)	0.1	0.3	0.3	0.4	0.5	0.5	0.6	0.7	0.7

Current pressure(cmH_2O)	13	14	15	16	17	18	19	20	-
Pressure drop (cmH_2O)	0.8	0.9	0.9	1	1.1	1.1	1.2	1.3	

7. Glossary

Apnea

A condition marked by the cessation of spontaneous breathing.

Auto Off

When this feature is enabled, the device automatically discontinues therapy whenever the mask is removed.

Auto On

With this feature, the device automatically initiates therapy when you breathe into the mask. This feature is always enabled.

SmartC

In CPAP mode, if SmartC is set to on, the device can adjust Treat P based on the patient's respiratory event during a certain time.

CPAP

Continuous Positive Airway Pressure.

EPAP

Expiratory Positive Airway Pressure.

IPAP

Inspiratory Positive Airway Pressure.

iCode

A feature designed to give access to compliance and therapy management information. "iCode" consists of six separate codes displayed in the Patient Menu, each code being a sequence of numbers. "iCode QR+" display two-dimensional codes.

LPM

Liters Per Minute.

OSA

Obstructive Sleep Apnea.

Patient Menu

The display mode in which you can change patient-adjustable device settings, such as the starting pressure of the Ramp feature.

Ramp

A feature that increases patient comfort at the beginning of treatment. It begins

from a low pressure and then gradually increases it to the prescribed setting so that the patient can fall asleep more comfortably.

Rise Time

The time it takes for the device to change from EPAP to IPAP. You can adjust this time for your comfort.

Res Rate

Respiratory Rate. Number of breaths per minute.

Reslex

A therapy feature that is enabled by your physician to provide pressure relief during exhalation.

Standby State

The state of the device when power is applied but the airflow is turned off.

min

Means the time unit "minute".

h

Means the time unit "hour".

yy mm dd / mm dd yy / dd mm yy

Denotes date.

8. Package Contents

After unpacking the system, make sure you have everything shown here:

No.	Articles	Qty.	Notes
1	Device	1	
2	Air Filter	2	
3	Power Adapter	1	
4	Power Cord	1	
5	PM2.5 Filter	1	Optional
6	Cellular Module	1	Optional
7	Tubing	1	Optional
8	Heated Tubing	1	Optional
9	SD Card	1	Optional
10	Carrying Case	1	Optional
11	Accompanying Documents	1	
12	Power Cord Locker	1	

All parts and accessories are not made of natural rubber latex.

The expected service life of the device is five years from first date of use, if it is used, maintained, cleaned and disinfected in strict accordance with the User Manual.

The expected service life of the Tubing and the Heated Tubing is six months from first date of use. The shelf life of the Tubing and the Heated Tubing is 3 years.

The expected service life of the Water Chamber is 6 months from first date of use.

WARNINGS!

• This device should only be used with the mask and accessories manufactured or recommended by REACT HEALTH or with those recommended by your physician. The use of inappropriate masks and accessories may affect the performance of the device and impair the effectiveness of treatment.

The mask manufactured or recommended by REACT HEALTH:

	Product name	Model	510 (k) Number
Mask	Rio II Nasal Pillows Intertface	P2	K112271
	Viva Nasal Mask	NM4	K163464
	Numa Full Face Mask	BMC-FM2	
	F2 Single-Patient Vented Full Face Mask	BMC-FM2	
	Numa II Full Face Mask	F4	
	Siesta Full Face Mask	F5A	K131901
	Siesta Nasal Mask	N5B	
	iOTM Mini Nasal Mask	iOMN	

• The use of accessories other than those specified, except for cables sold by the manufacturer of the equipment or system as replacement parts for internal components, may result in increased emissions or reduced immunity of the equipment or system.

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

• Do not attach any equipment to the device unless recommended by REACT HEALTH or your physician.

• Please contact REACT HEALTH for an SD card if needed.

• If the expected service life is exceeded, REACT HEALTH cannot guarantee the normal function of the device, nor the safety and effectiveness of the device.

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, be sure to follow the instructions that come with the accessories.

9. System Features

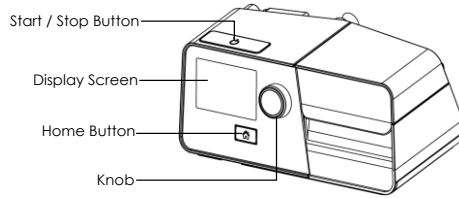

Fig. 9-1

Name	Function
Start / Stop Button	Start / Stop delivering air
Display Screen	Display operation menus, information, monitoring data, etc.
Home Button	Return to the previous menu or main interface
Knob	Adjust device settings

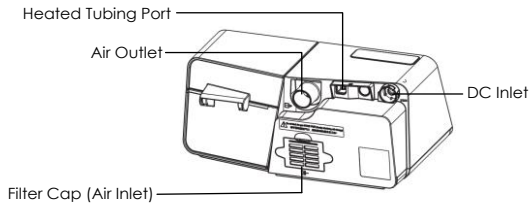

Fig. 9-2

Name	Function
Air Outlet	Deliver pressurized air; connects to the tubing
Heated Tubing Port	Connected to the plug of the heated tubing
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

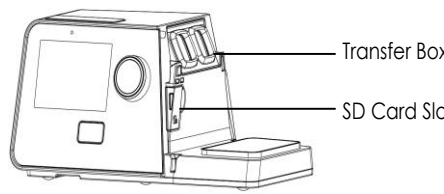

Fig. 9-3

Name	Function
Transfer Box	For the connection of the water chamber to the device
SD Card Slot	Insert the SD card into this slot

10. First Time Setup

10.1 Placing the Device

Place the device on a firm, flat surface.

WARNINGS!

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

• If the room temperature is above 95°F (35°C), the airflow generated by the device may exceed 109.4°F (43°C). The room temperature must be kept below 95°F (35°C) while the patient is using the device.

CAUTIONS!

• Always ensure that the device is placed in an area where the screen and indicators are clearly visible.

• If the device has been exposed to very hot or very cold temperatures, allow it to acclimate 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 items are not blocking the filter or vents of the device.

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

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

• Tobacco smoke may cause tar to build up in the device, which could lead to the malfunctioning of the device.

• Air must flow freely around the device to allow it to function properly.

• Empty the water chamber completely before moving the device.

10.2 Installing the Air Filter and Filter Cap / PM2.5 Filter

(1) Attach the air filter to the filter cap, as shown in Fig. 10-1.

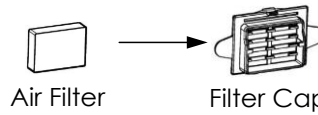

Fig. 10-1

(2) Install the filter cap containing the air filter to the device, as shown in Fig. 10-2.

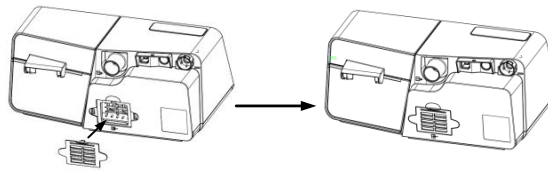

Fig. 10-2

(3) Change the air filter and filter cap to the PM2.5 filter, as shown in Fig. 10-3.

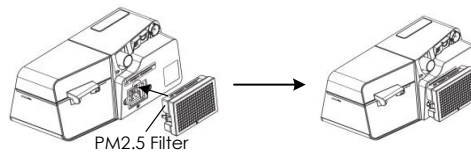

Fig. 10-3

WARNINGS!

• Do not block the air inlet, thereby interfering with the treatment.

• Humidification can increase the resistance of breathing system filters and the operator must monitor the breathing system filter frequently for increased resistance and blockage to ensure the delivery of the therapeutic pressure.

• Please change the Air Filter regularly and don't block it; Fire, open ignition source and smoking prohibited. (Refer to 16.1.6 Replacing the Air Filter / PM2.5 Filter)

CAUTIONS!

• The air filter or the PM2.5 filter must be in place when the device is operating.

• When installing the air filter and filter cap or PM2.5 filter, the device must be unplugged.

10.3 Connecting Power Supply

(1) Insert the plug of the power adapter into the DC inlet on the back of the device.

(2) Connect the power cord to the power adapter.

(3) Plug the other end of the power cord into the power outlet.

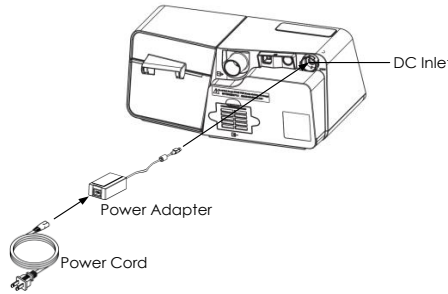

Fig. 10-4

Note: The length of the power cord and power adapter is 1.5 m and 1.8 m respectively without the function of preventing electromagnetic interference.

WARNINGS!

• The device is powered on for use when the power cord and power adapter are connected. Use **the Knob** to turn the blower On / Off.

• Using the device at an AC voltage outside the specified range (see Section 5 "AC Power Consumption") may damage the device or cause device failure.

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

• Check the power cord frequently for signs of damage. Replace 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 AC power, disconnect the power cord from the power outlet.

10.4 Connecting to Power Cord Locker

(1) Connect the device to power supply in accordance with *10.3 Connecting Power Supply*.

(2) Clip the narrow end of the power cord locker to the cord of the power adapter, as shown in Fig. 10-5.

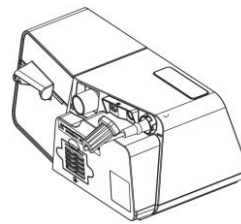

Fig. 10-5

(3) Insert the power cord locker into the buckle of DC inlet, as shown in Fig. 10-6.

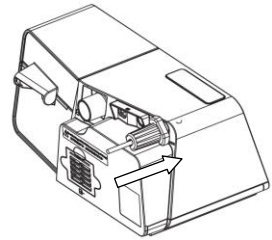

Fig. 10-6

(4) Press the power cord locker downward to fix power cord into the port, as shown in Fig. 10-7.

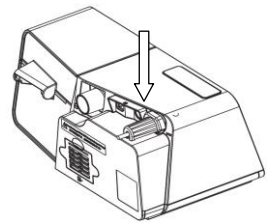

Fig. 10-7

The function of the locker is to prevent the power cord from falling off from the power port. After installation, you must make sure that the power adapter cable is stuck in the slot at the narrow end of the power cord locker.

10.5 Assembling the Tubing / Heated Tubing and Mask

(1) Connect one end of the tubing to the air outlet of the device, as shown in Fig. 10-8.

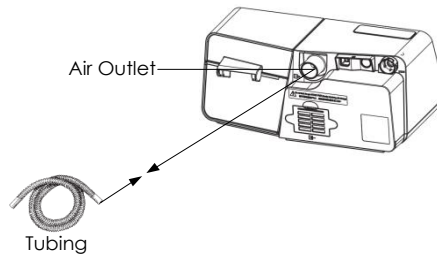

Fig. 10-8

(2) Connect the heated tubing joint to the air outlet of the device, and then insert the power plug into the heated tubing port on the back of the device, as shown in Fig. 10-9.

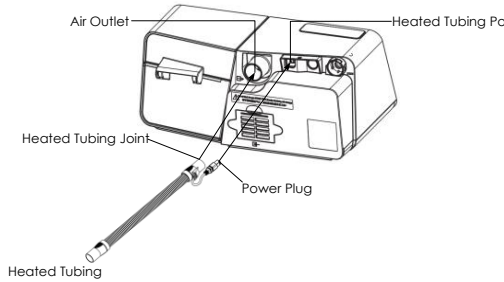

Fig. 10-9

CAUTION!

• As the ambient temperature decreases, the humidifier can be adjusted to a lower level to improve the performance of the device and avoid condensation in the tubing. If the ambient temperature is too low, in order to avoid condensation, it is recommended to use a heated tubing.

If the heated tubing is connected correctly, the line next to the icon will become a number in the Main Interface on the screen of the device, as shown in Fig. 10-10.

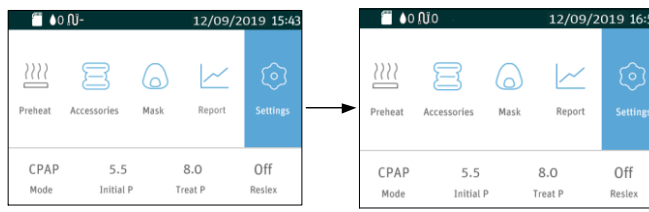

Fig. 10-10

Turn **the Knob** to turn the heated tubing on or off and to adjust the heat level according to the instructions in the Patient Menu of the device.

There are five heat levels available, and the number of heat levels will appear on the main screen of the device. The number 3 next to the icon indicates that the heat is adjusted to Level 3, as shown in Fig. 10-11.

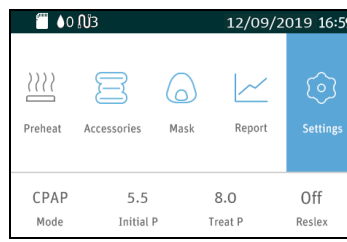

Fig. 10-11

(3) Connect the other end of the tubing to the mask according to the user manual

of the mask.

WARNINGS!

• If multiple persons are going to use the device (e.g., rental devices), a low-resistance, main flow bacteria filter should be installed in-line between the device and the tubing. Pressures must be verified by your home care provider when using spare or optional accessories.

• If you are using a mask with a separate exhalation port, connect the tubing to the exhalation port. Position the exhalation port so that the released air blows away from your face. Connect the mask's connector to the exhalation port.

• If you are using a full-face mask (a mask covering both your mouth and nose), the mask must be equipped with a safety (entrainment) valve.

• To minimize the risk of CO_2 rebreathing, the patient should observe the following instructions:

- Use the accompanying tubing and mask provided by REACT HEALTH.
- Do not wear the device before it is turned on and confirmed operational due to the risk of asphyxia.
- Use only masks with vent holes. Do not block or try to seal the vent holes in the exhalation port.

• If condensation appears in the tube, remove then drain the tube. Turn down the humidification.

10.6 Using Oxygen with the Device

Oxygen may be added at the mask connection. Please observe the instructions listed below when using oxygen with the device.

WARNINGS!

• Connect the oxygen tube to the oxygen inlet of the mask.

• The oxygen supply must comply with the local regulations for medical oxygen.

• Turn on the device before turning on the oxygen. Turn off the oxygen supply before turning off the device. Explanation of Warning: When the device is turned off, but the oxygen flow remains, oxygen can accumulate inside the device's enclosure and pose a fire hazard. Turning off the oxygen supply before turning off the device will prevent oxygen accumulation in the device and reduce the risk of fire. This warning applies to CPAP devices.

• Oxygen supports combustion. Keep the device and the oxygen container away from heat, open flames, any oily substances, or other sources of ignition. DO NOT smoke in the area near G3 BPAP System or the oxygen container.

• Sources of oxygen should be more than 1 m away from the device.

• When using oxygen with this system, a Pressure Valve must be placed in-line with the patient circuit between the device and the oxygen source. The pressure valve

helps prevent the backflow of oxygen from the patient circuit into the device when the unit is off. Failure to use the pressure valve could result in a fire hazard.

• When the pressure valve is installed, the Auto On function on the device will not work. To turn on the device either breath into your mask or select the On/Off button.

• Supplemental oxygen must not be used while smoking or in the presence of an open flame.

• When using the device with an oxygen supply, check the following:

Starting therapy - ensure the device is on and blowing air before the oxygen supply is turned on.

Stopping therapy - ensure the oxygen supply is turned off first, then the device.

This will ensure oxygen does not accumulate within the device and create a risk of fire.

• Do not connect the device to an unregulated or high-pressure oxygen source. The pressure of oxygen source should not exceed the working pressure of the device.

10.7 Inserting the SD Card (Only for the device that equipped with SD card)

Insert the SD card into the SD Card Slot, as shown in Fig. 10-12.

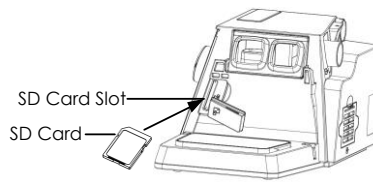

Fig. 10-12

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

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

CAUTIONS!

• If no SD card is inserted, neither of the symbols will appear on the main screen of the device.

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

10.8 Starting Treatment

Connect the device to a power outlet, press **the Start / Stop Button** and the device will start delivering air.

WARNINGS!

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

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

11. Routine Use

11.1 Connecting the Tubing

Connect the power cord, power adapter and tubing properly in accordance with the instructions in the First Time Setup (Chapter 10). Connect the mask and headgear according to the user manual of the mask.

CAUTION!

• Before each use, examine the tubing for any damage or foreign object. If necessary, clean the tubing to remove the foreign object. Replace any damaged tubing. Make sure that the mask does not leak.

11.2 Adjusting the Tubing

Lie down on your bed, and adjust the tubing so it is free to move if you turn over during sleep. Adjust the mask and headgear until you have a comfortable fit and until there is no airflow leakage around the mask.

11.3 Turning on the Airflow

Press **the Start / Stop Button**  to turn on the airflow. The screen will display treatment pressure and other information.

11.4 Heating the Water

Pay attention to the number next to the icon when using the humidifier. The number indicate the On / Off state of the humidifier. It is off when the number next to the icon is 0.

CAUTION!

• Observe the water level in the water chamber before using the humidifier. Make sure there is sufficient water in the water chamber, and avoid heating the device with an empty water chamber.

11.5 Using the Ramp Feature

Every time the feature is enabled, the pressure will drop to the initial pressure, and then gradually rise to the prescribed treatment pressure according to the preset

ramp time, so as to make it easy for the patient to fall asleep. The screen displays a real-time countdown of the remaining ramp time in minutes.

CAUTIONS!

• You can use the ramp feature as often as you wish during sleep.

• The ramp feature is not prescribed for all patients.

11.6 Accessing the iCode

After the device is powered on, move the cursor to the icon by turning **the Knob**, as shown in the Fig. 11-1. Access the iCode information by pressing **the Knob**, the screen displays the iCode Interface, as shown in the Fig. 11-2.

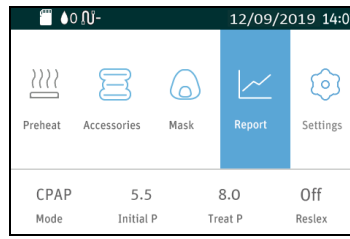

Fig. 11-1

Fig. 11-2

11.7 Turning the Device Off

Take off the mask and headgear, press **the Start / Stop Button**, and the device will stop delivering air. Disconnect the power cord from the power outlet to turn off the device.

CAUTION!

• Do not position the device where it is difficult to disconnect the power cord from the power outlet to power off the device.

12. Heated Humidifier

All device models will be provided with the humidifier. The humidifier can reduce nasal dryness and irritation by adding moisture (and heat if applicable) to the

airflow.

12.1 Filling the Water Chamber

12.1.1 Removing the Water Chamber

Press down the water chamber, and then remove it, as shown in Fig. 12-1.

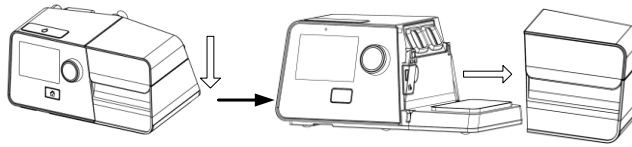

Fig. 12-1

WARNING!

• Turn the device off and allow the heating plate and water to cool for approximately 15 minutes before remove the Water Chamber.

12.1.2 Filling the Water Chamber

(1) Remove the water chamber, open the cap, as shown in Fig. 12-2, and fill the water chamber with approximately 360 mL of water, as shown in Fig. 12-3. Make sure that the water does not exceed the maximum water level line.

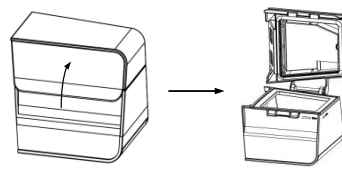

Fig. 12-2

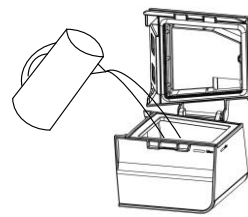

Fig. 12-3

(2) Open the cap, and fill the water chamber with approximately 360 mL of water, as shown in Fig. 12-4. Make sure that the water does not exceed the maximum water level line.

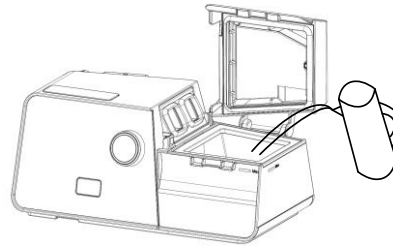

Fig. 12-4

WARNING!

• Change water before every use and do not exceed the maximum water level line.

CAUTIONS!

• Empty the water chamber when the heated humidifier is not in use.

• Distilled water is recommended.

IMPORTANT TIP!

• It is not necessary to remove the water chamber from the device. The operators can open the cap of the water chamber with it being attached to the device to fill it with water.

12.1.3 Putting the Water Chamber back

Close the cap when the water chamber is filled with water, as shown in Fig. 12-5, and put it back to the device, as shown in Fig. 12-6.

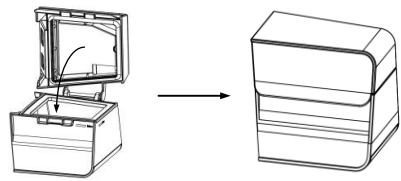

Fig. 12-5

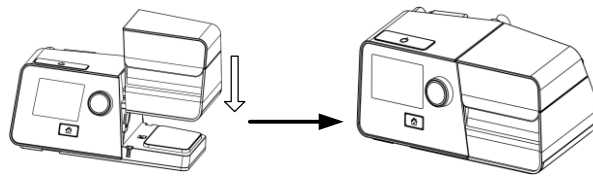

Fig. 12-6

WARNING!

• For safety, the device must be placed on a flat surface below the height of the

patient's head when he / she is lying on a bed, so that the condensation flows back to the water chamber rather than remaining in the tubing which can cause droplet spraying.

CAUTIONS!

- Avoid moving or tilting the device when the water chamber has water in it.
- Take precautions to protect furniture from water damage.

12.2 Emptying the Water Chamber

(1) Remove the water chamber according to instructions in 12.1.1.

(2) Empty the water chamber: Open the cap, as shown below, and pour remaining water out of the water chamber.

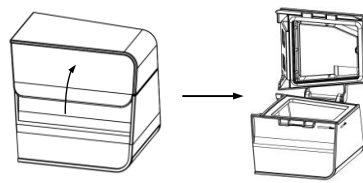

Fig. 12-7

(3) Put the water chamber back according to instructions in 12.1.3.

CAUTION!

- Empty and air-dry the water chamber when the device is not in use.

12.3 Setting the Humidity Level

After the device is powered on, turn **the Knob** to turn the heated humidifier on or off and to adjust the humidity level according to instructions in the Patient Menu of the device.

There are five humidity levels available, and the number of humidity level will appear on the main screen of the device. The number 2 next to the icon indicates that the humidity is adjusted to Level 2, as shown in Fig. 12-8. The water temperature in the water chamber is maintained at a constant set level.

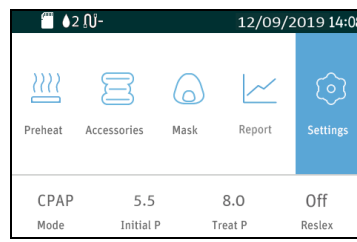

Fig. 12-8

WARNING!

• Do not touch the heating plate of the device when it is in operation, otherwise you may get burned. Stop heating when the heated humidifier is not in use.

CAUTIONS!

• Generally speaking, the humidity level inside the mask is low when the water temperature is low.

• The greater the difference between the temperature inside the air tubing and the room temperature, the more likely condensation will occur in the tubing.

• If there is only a small amount of condensed water droplets in the tubing in the morning after treatment, the humidity level is appropriate; if there is a large amount of condensed water droplets inside the tubing and / or the mask, the humidity level is too high and should be set lower. Nasal dryness means that the humidity level is too low and should be set higher.

13. Using the Cellular Module

The BPAP System with a Cellular Module can wirelessly communicate with the iCodeConnect cloud platform. iCodeConnect cloud platform is intended to enhance the standard follow-up care for patients diagnosed with obstructive sleep apnea by displaying usage and therapeutic information that has been transmitted from the patient's therapy device to the physician.

(1) Insert the Cellular Module into the device, and turn on the device. The device screen displays the Main Interface shown in Fig. 13-1.

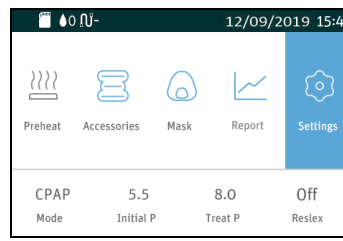

Fig. 13-1

(2) The Cellular Module starts searching for signals in a few seconds. Once a signal is found, the module will automatically connect to it, and a signal icon will appear in the status bar at the top of the device screen.

There are four different signal icons, as listed in Table 2:

Table 2 Description of Signal Icons

Icon	Description
	Strong signal
	Moderate signal
	Weak signal
	No signal found

Note:

(1) When the signal is weak, data transmission may become slow and even stop.

(2) The Cellular Module will keep searching for signals until one is found.

(3) The data transmission of the device through the Cellular Module to the cloud platform is automatic without human intervention.

If the signal is strong, the signal icon will appear on the Main Screen, as shown in Fig. 13-2 (the signal icons of different strength appear in a similar way).

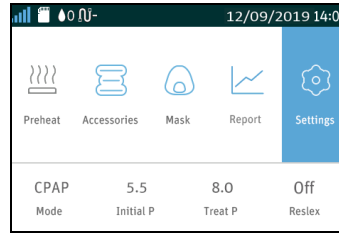

Fig. 13-2

No signal will appear on the screen, if the Cellular Module is connected to the device improperly or if the Module is not working properly.

WARNING!

• To ensure successful data transmission through the Cellular Module, computers, televisions, radios or similar devices should not be placed near the Cellular Module.

14. Navigating the Patient Menu

14.1 Steps to Navigating the Patient Menu

14.1.1 Accessing the Main Interface

Connect the power cord and power adapter properly, and the screen displays the Main Interface shown in Fig. 14-1. Press **the Start / Stop Button** , and the device will start to deliver air, as shown in Fig. 14-2 (Applicable to G3 B25VT, G3 B30VT models).

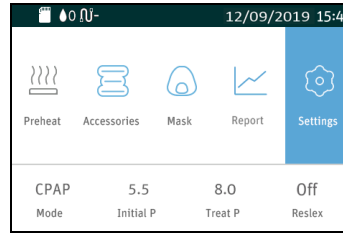

Fig. 14-1

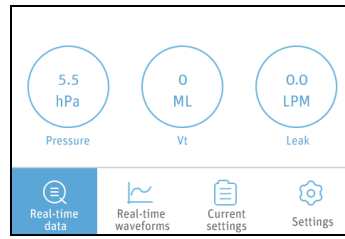

Fig. 14-2

Note: The above interface is only applicable to the devices that do not have the modes of SmartC, SmartA or SmartB activated. If SmartC, SmartA or SmartB is enabled, the symbol S will appear in the status bar at the top of the screen, as shown in Fig. 14-3.

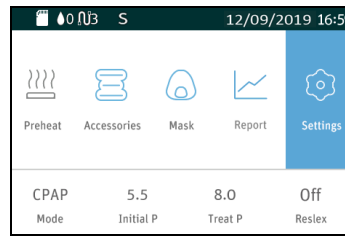

Fig. 14-3

The first icon on the upper part of the screen is the Preheat Function, the second icon indicates Accessories, the third icon is the Mask Setup, the fourth icon is the Report Interface, the fifth icon is the Initial Setup. As you turn **the Knob**, the cursor will switch among the five icons.

Note: As the humidifier is turned off, the Preheat Function Icon will turn grey, as shown in Fig. 14-3.

14.1.2 Bringing up the Initial Setup Interface

After the screen displays the Main Interface shown in Fig. 14-1, turn **the Knob**. When the cursor is on the icon, press **the Knob**, and the screen displays the Initial Setup Interface of the Patient Menu, as shown in Fig. 14-4.

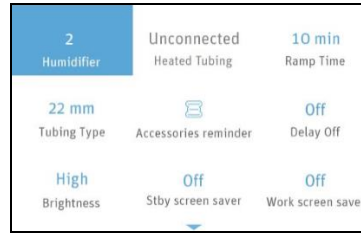

Fig. 14-4

Note: The **Heated Tubing** option can only be adjusted when the device is connected to a Heated Tubing, as shown in Fig. 14-5.

Fig. 14-5

14.1.3 Selecting Options

As you turn **the Knob** clockwise, the cursor moves downwards from one option to another. When the cursor is on a certain option, press **the Knob**, and the color of the option will change, meaning that the option is now adjustable, as shown in Fig. 14-6 by the Humidifier option.

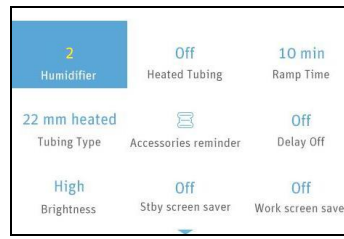

Fig. 14-6

14.1.4 Adjusting Options

Adjust the option by turning **the Knob**. As shown in Fig. 14-6, the **Humidifier** option is selected. As you turn **the Knob** clockwise, the number increases, indicating a higher humidity level. As you turn **the Knob** counterclockwise, the number decreases, indicating a lower humidity level, as shown in Fig. 14-7.

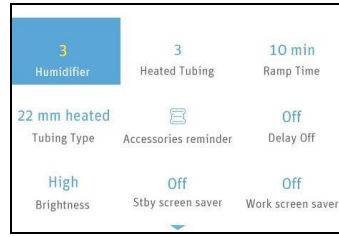

Fig. 14-7

14.1.5 Confirming Adjustments

Press **the Knob** to confirm your adjustment of a particular option. The option is then displayed in white, as shown in Fig. 14-8.

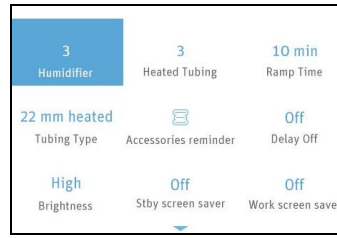

Fig. 14-8

14.1.6 Turning Pages

When the cursor is on **Work screen saver**, the last option shown in Fig. 14-8, the remaining options will appear on a new page if you continue to turn **the Knob** clockwise, as shown in Fig. 14-9.

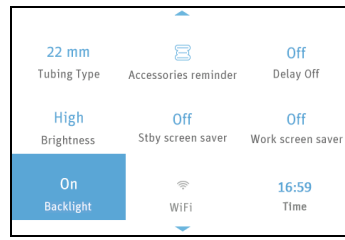

Fig. 14-9

Note: are page turning symbols.

14.1.7 Exiting the Patient Menu

The operators can press **the Home button** to return to the Main Interface shown in Fig. 14-1.

14.2 Options in the Patient Menu and Corresponding Descriptions

Option	Range	Description
Humidifier	Off, Auto, 1 ~ 5	There are five humidity levels available. As the number increases, the humidity rises accordingly. "Off" means the humidifier is turned off.
Preheat	On / Off	Set humidifier to preheat by adjusting this option. This feature is automatically turned off after 30 minutes.
Reslex	Off, 1 ~ 3	This feature enables the device to automatically reduce the treatment pressure when the patient exhales, so as to make patient more comfortable. The higher the number, the more pressure the device reduces. "Off" means this feature is disabled.
Heated Tubing	Off, 1 ~ 5	There are five heat levels available. As the number increases, the heat rises accordingly. "Off" means the heat is turned off. **Note: Heated Tubing** is displayed in the patient menu only when a heated tubing is connected.
Ramp Time	Auto, 0 ~ Max Ramp	In order to increase comfort and help the patient fall asleep easily, the pressure can be increased gradually, when the Ramp feature is enabled. The ramp time during which the initial pressure rises to the preset treatment pressure can be adjusted. As you turn **the Knob** to the nearest point, the number increases or decreases by five minutes. The screen displays a real-time countdown of the remaining ramp time in minutes.
Delay Off	On / Off	When the humidifier is on, this feature allows the airflow to continue for about 15 minutes at a low pressure (about 2 cmH_2O) after you press **the Start / Stop** Button to discontinue the treatment. In this process, the vapor left in the water chamber will be blown away to avoid any damage to the device. When this feature is set to "Off", which means it is disabled, the device will stop delivering air instantly after you press **the Start / Stop** Button.
Date Format	yy mm dd / mm dd yy / dd mm yy	Turn **the Knob** to choose among three date formats.
Time	00:00 — 23:59	Set time by adjusting this option.

Time Format	12-hour / 24-hour	Turn **the Knob** to choose between two time formats.
Brightness	High / Low	Set the brightness of the screen by adjusting this option.
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 be turned off automatically after 30 seconds of inactivity. If it is set to "On", the backlight will be always on.
Mask Type	Full Face / Nasal / Nasal Pillows / Other	There are three mask types available: Full Face (full-face mask), Nasal (nasal mask) and Nasal Pillows (nasal pillow mask). When selecting masks other than the above three types of REACT HEALTH masks, the patient can set the mask type as Other.
Mask Fitting Test	Start	Test whether the mask is worn correctly,the screen will display the "great" icon if it is qualified, otherwise the screen will display "need to adjust".
iCode	iCode, iCode QR+	iCode provides access to the patient's compliance data during a recent time period. The iCode mode displays data in number sequence, and the iCode QR+ mode displays data in two-dimensional codes.
Accessories	——	Reset the use time of the filter, tubing and mask.
Accessories Reminder	30 days / 60 days / 180 days / 365 days / off	This function is used to set filter reminder, tube reminder and mask reminder. After opening, can set the use time of filter, tube and mask.
Language	English	The default setting is "**English**".
About	——	Displays related information of the device (Model, SN, Version, ID). This is read-only and cannot be edited.

15. Alarm

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

After the device is running, disconnect its power supply by unplugging the power cord, an audible alarm will sound like "beep beep beep, beep-beep, beep beep beep, beep-beep", which means that the alarming system of the device works normally.

15.1 Alarming Grades and Description

The alarm grades and description of this equipment are shown 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

15.2 Visual Alarm

The visual alarm grades are indicated by the background of the alarming information on the top of the screen and the color of the LED light under the Knob which is shown 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

15.3 Auditory Alarm

The alarming sounds at different levels will occur and are shown 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 relevant standards, the volume of the audible alarm signal meets the requirements. 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

15.4 Alarm Silence

When the device sounds an alarm, press the home button and it will become silent for 100 to 120 seconds. Then the alarm will sound again immediately at the end of the silence. If the home button is re-pressed during the silence period, the alarm sound will resume.

15.5 Alarm Messages and Description

Alarm Message	Alarm Priority	Alarm Type	Description
Power Failure!!!	High Priority	Technology Alarm	An audible alarm will sound in 6s if the device is accidentally disconnected from power supply when it is delivering air. Alarming duration time is no less than 30 s. **Note:** (1) The alarm will not sound if power failure occurs when the device is in standby state. (2) No alarm message will appear on the screen during a power failure.
Device Fault!!!	High Priority	Technology Alarm	An audible alarm will sound if no airflow comes out of the machine; the screen will display "**Device Fault!!!**".
Tube Disconnected!!! (only applies to G3 B25VT, G3 B30VT)	High Priority	Function Alarm	When the airflow is on, an audible alarm will sound if the tube accidentally detached, the screen will display "**Tube disconnected!!!**".
High Pressure!!!	High Priority	Function Alarm	When the airflow is on, an audible alarm will sound if the airway pressure exceeds the alarm limit; the screen will display "**High Pressure!!!**". **Note:** The thresholds for different models: Off, 5 ~ 26 cmH_2O applies to G3 B25VT, in 0.5 cmH_2O increments, the default setting is "**25 cmH_2O**". Off, 5 ~ 31 cmH_2O applies to G3 B30VT, in 0.5 cmH_2O increments, the default setting is "**30 cmH_2O**".
Low Pressure!!	Middle Priority	Function Alarm	When the airflow is on, an audible alarm will sound if the airway pressure is below the alarm limit; the

			screen will display "**Low Pressure!!**". **Note:** The limens for different models: Off,3 ~ 24 cmH_2O applies to G3 B25VT, in 0.5 cmH_2O increments, the default setting is "**4 cmH_2O**". Off, 3 ~ 29 cmH_2O applies to G3 B30VT, in 0.5 cmH_2O increments, the default setting is "**4 cmH_2O**".
Low RR!!! (only applies to G3 B25VT, G3 B30VT)	High Priority	Function Alarm	When the airflow is on, an audible alarm will sound if the respiratory rate is below the alarm limit; the screen will display "**Low RR!!!**". Setting range: Off, 4 ~ 40 BPM, in 1 BPM increments, the default setting is "**6 BPM**". **Note:** This function is available under the work mode of S/T or T.
Leak!!	Middle Priority	Function Alarm	When the airflow is on, an audible alarm will sound if the air leak rate exceeds 150 L/min; the screen will display "**Leak!!**". The alarming duration time is no less than 30 s.
Mask Blocked!! (only applies to G3 B25VT, G3 B30VT)	Middle Priority	Function Alarm	When the airflow is on, an audible alarm will sound if the vents of the mask are blocked; the screen will display "**Mask Blocked!!**".
Low MV!! (only applies to G3 B25VT, G3 B30VT)	Middle Priority	Function Alarm	When the airflow is on, an audible alarm will sound if the minute volume is below the alarm limit; the screen will display "**Low MV!!**". Setting range: Off, 1 ~ 30 L/min, in 1 L/min increments, the default setting is "**1 L/min**".
Low Input Voltage!!	Middle Priority	Technology Alarm	If the voltage supplied by power adaptor is lower than 22 V, an audible alarm will sound and the screen will display "**Low Input Voltage!!**".
High RR!! (only applies to G3 B25VT, G3 B30VT)	Middle Priority	Function Alarm	When the airflow is on, an audible alarm will sound if the respiratory rate exceeds the alarm limit; the screen will display "**High RR!!**". Setting range: Off, the setting value of Low RR ~ 80 BPM, in 1 BPM

			increments, the default setting is "**40 BPM**". **Note:** This function is available under the work mode of S/T or T.
Humidifier Failure!!	Middle Priority	Function Alarm	When humidifier is applied, an audible alarm will sound when the humidifier fails to work in 10 minutes; the screen will display "**Humidifier Failure!!**".
Please Change Filter!	Low Priority	Technology Alarm	When the Filter Reminder feature is enabled, an audible alarm will sound if the preset replacement time is reached but the air filter is not replaced; the screen will display "**Please Change Filter!**".
Please Replace Tubing!	Low Priority	Technology Alarm	When the Tubing Reminder feature is enabled, an audible alarm will sound if the preset replacement time is reached but the tubing is not replaced; the screen will display "**Please Replace Tubing!**".
Please Replace Mask!	Low Priority	Technology Alarm	When the Mask Reminder feature is enabled, an audible alarm will sound if the preset replacement time is reached but the mask is not replaced; the screen will display "**Please Replace Mask!**".
SD Card Full!	Low Priority	Technology Alarm	The screen will display "**SD Card Full!**" if the SD card has reached its maximum capacity.
Reinsert SD Card!	Low Priority	Technology Alarm	The screen will display "**Reinsert SD Card!**" if the SD card fails to work.

Note: the delay time of alarming system of this device is no more than 1 second.

15.6 Reposition of Alarming

After the alarm faults are cleared, the residual alarm messages still remain (alarm messages are shown on the top of the screen without any visual and auditory alarm). Turn **the Knob** leftwards or rightwards to reduce the residual alarm messages.

15.7 Alarm Journal

The alarm journal is designed to record the latest 6 alarm messages. Retained inside the device, the alarm log will not be lost after a power interruption and the latest alarm message will replace the previous one, retaining 6 messages.

WARNINGS!

• Before using the device, the operator should check whether the current alarm preset value is applicable to each patient. Such preset value can only be changed by a physician and cannot not be modified by the patients at home.

• In the case of a power failure or power cut for no more than 30 seconds, the last set alarm value will be restored at the next operation.

CAUTION!

• The message in the alarm log will be maintained when the device is powered down, but the instantaneous time of power down will not be recorded.

15.8 Alarming Verification

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

Tube disconnected alarm test

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

(2) Press the home button and it will become silent for 100 to 120 seconds. If the alarm state is not eliminated, the alarm will sound again immediately at the end of the silence.

(3) Reinstall the tube.

(4) Turn the button leftwards or rightwards to reduce the residual alarm message.

Mask blocked alarm test

(1) When the device is operating normally, adjust the device to the appropriate patient settings. Block the vent hole of the mask for 35 seconds by hand or soft cloth, and then verify whether the mask blocked alarm occurs.

(2) Press the home button and it will become silent for 100 to 120 seconds. If the alarm state is not eliminated, the alarm will sound again immediately at the end of the silence.

(3) Turn the button leftwards or rightwards to reduce the residual alarm message.

Low minute ventilation alarm test

(1) Connect the device to the simulated lung.

(2) Observe the value of minute ventilation displayed on the screen.

(3) Make the alarm value of the minute ventilation larger than the displayed value, and then verify whether the alarm of low minute ventilation occurs.

(4) Press the home button and it will become silent for 100 to 120 seconds. If the alarm state is not eliminated, the alarm will sound again immediately at the end of the silence.

(5) Turn the button leftwards or rightwards to reduce the residual alarm message.

(6) Set the alarm setting of the low minute ventilation to "Off".

Power failure alarm test

(1) Verify whether an audible alarm will sound in 6 seconds when the device is disconnected from power supply when it is delivering air.

(2) Reconnect the power supply, and then verify whether the device restarts delivering air.

WARNING!

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

16. Cleaning and Disinfection

WARNINGS!

• Cleaning the device and its accessories as recommended in the following sections is essential to prevent respiratory infections.

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

• Use mild soap that is nontoxic to humans.

• Follow the manufacturer's instructions on cleaning the mask and tubing and on determining the frequency of cleaning.

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

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

• Avoid the use of any CPAP cleaner or disinfection device that relies on ozone (i.e. activated oxygen). Device warranty may terminate if the damage is caused by the use of an ozone cleaner.

• In order to prevent contamination of the device, use only manufacturer-approved filters on this device conforming to ISO 23328-1:2003 and ISO 23328-2:2002 standards.

• The device shall not be serviced or maintained while a patient is using it.

CAUTIONS!

• Overheating of the materials could lead to early fatigue of the 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 above 80°C (176°F). High temperatures could reduce product life.

• Do not immerse the device in any fluids.

16.1 Cleaning

Accessories that need to be cleaned	**Detergent**	**Water temperature**
Water chamber	Alconox (diluted at 1%)	Warm water (approx 113 to 140°F or 45 to 60°C)
Transfer box	Alconox (diluted at 1%)	Warm water (approx 113 to 140°F or 45 to 60°C)
Air filter	-	The tap water 5°C to 35°C (41˚F to 95˚F)

16.1.1 Cleaning the Water Chamber

(1) **Opening the Water Chamber:** Open the cap of the water chamber, as shown in Fig. 16-1.

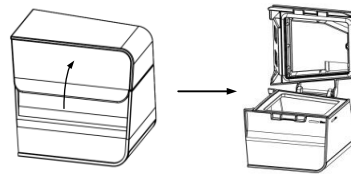

Fig. 16-1

(2) **Cleaning the Water Chamber:** Dilute Alconox to 1% with water 45°C to 60°C (113°F to 140°F). Soak the water chamber in the detergent for 5 minutes. Clean the water chamber with a soft bristled brush for one minute. Pay particular attention to all gaps and cavities. Then rinse the water chamber with running water for 5 minutes. Wipe it dry with a soft cloth or air dry it away from direct sunlight.
(3) **Putting the Water Chamber back:** according to instructions in 12.1.3.

WARNINGS!

• Emptying and cleaning the water chamber daily will help prevent mold and bacteria growth.
• Allow the water in the chamber to cool down to room temperature before removing it from the device.

CAUTIONS!

• Clean the water chamber only after the water in it cools. Make sure that no water enters the device.
• After cleaning, rinse the water chamber thoroughly in clean water to make sure that no soap residue is left; then wipe it dry with a lint-free cloth, so as to prevent calcareous accumulation.
• Check the water chamber for any leak or damage. Replace the water chamber if there is any damage.
• It is recommended to clean the water chamber and change the water daily.

16.1.2 Cleaning the Transfer Box

(1) **Removing the Transfer Box:** First remove the water chamber from the device, then remove the transfer box, as shown in Fig. 16-2.

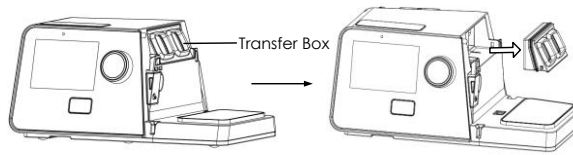

Fig. 16-2

(2) **Cleaning the Transfer Box:** Dilute Alconox to 1% with water 45°C to 60°C (113°F to 140°F). Soak the transfer box in the detergent for 5 minutes. Clean the transfer box with a soft bristled brush for one minute. Pay particular attention to all gaps and cavities. Then rinse the transfer box with running water for 5 minutes. Wipe it dry with a soft cloth or air dry it away from direct sunlight.

(3) **Putting the Transfer Box back:** as shown in Fig. 16-3.

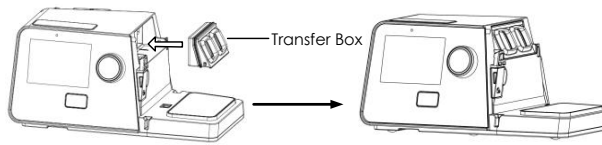

Fig. 16-3

CAUTION!

• It is recommended to clean the transfer box once a week.

16.1.3 Cleaning the Tubing

(1) Remove the tubing from the device and mask before cleaning.

(2) Hold the cuff of the air tubing and gently pull it away from the device as shown in Fig. 16-4. Or disconnect the power of the heated tubing, then hold the cuff of the heated tubing and pull it away from the device, as shown in Fig. 16-5.

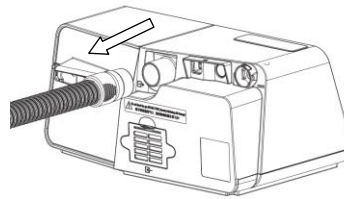

Fig. 16-4

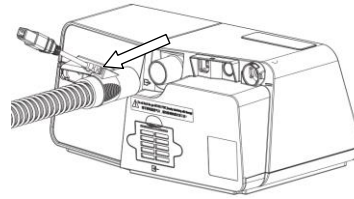

Fig. 16-5

(3) Hold both the cuff of the air tubing and the swivel of the mask, then gently pull them apart as shown in Fig. 16-6.

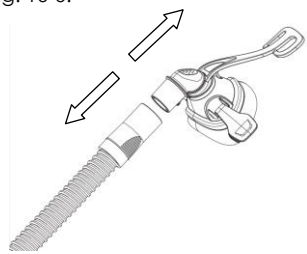

Fig. 16-6

(4) Soak the tubing in 2% soapy water at 35°C to 40°C for 10 minutes, then clean the inside and outside surfaces with a soft brush 5 times, and rinse it with sterile water for 5 minutes.

(5) Gently tap the tubing to remove excess moisture from the connector ports. Hang the tubing so that both ends of the opening face the floor, let the tubing naturally dry, out of direct sunlight.

(6) Inspection

Carry out a visual inspection of the components. If there are any obvious signs of deterioration (holes, tears or cracks, etc.), these parts should be discarded and replaced. A slight fade may occur, which is acceptable.

WARNINGS!

• Please clean the tubing by hand.

•The tubing should be cleaned daily.

• If the heated tubing is damaged (such as broken hole, tear, exposed heating wire) or does not function well, please do not repair and use it by yourself, but replace it immediately.

• Failure to clean in accordance with the User Manual may result in reduced performance of the heating tubing or shortened product life.

• After cleaning and before reuse, the tubing should be inspected for holes, creases and tears.

16.1.4 Cleaning the Mask and Headgear

For details, refer to the cleaning instructions in the user manual of the mask.

16.1.5 Cleaning the Enclosure

Wipe the enclosure 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.

16.1.6 Cleaning and Replacing the Air Filter / PM2.5 Filter

(1) Attach the air filter to the filter cap, as shown in Fig. 16-7.

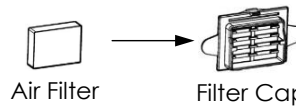

Fig. 16-7

(2) Install the filter cap containing the air filter to the device, as shown in Fig. 16-8.

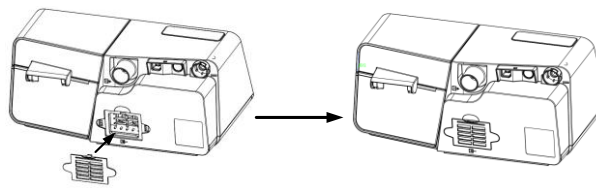

Fig. 16-8

(3) Disassemble the PM2.5 Filter from the device, as shown in Fig. 16-9.

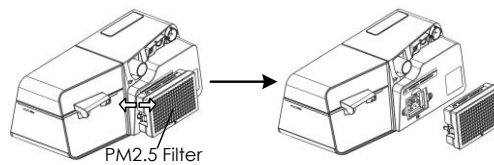

Fig. 16-9

(4) When the filter is dirty, the filter can be cleaned as follows:

Hold the air filter and align it with the tap water flow. Rinse the air filter with running water. When cleaning, gently press the air filter, but do not pull the air filter.

Allow the filter to air dry completely before reinstalling it.

CAUTION: Never install a wet filter into the device. You must ensure sufficient drying time for the cleaned filter.

CAUTIONS!

• To avoid material damage, do not place the spare air filter / PM2.5 Filter in direct sunlight, humid environments, or temperatures below the freezing point. The air filter / PM2.5 Filter should be replaced every 6 months (It may be replaced more frequently based on actual sanitary conditions).

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

16.2 Disinfection

Accessories that need to be disinfected	**Chemical Disinfection**	**UHT Disinfection**
Water chamber	Johnson's CIDEX OPA 0.55%	90 ± 2°C water
Transfer box	Johnson's CIDEX OPA 0.55%	90 ± 2°C water

Generally speaking, if you have strictly followed the above cleaning instructions, you do not have to disinfect the device and / or the water chamber. If the device is contaminated or used in clinical trials, you can purchase disinfectants from a medical equipment company to disinfect the device.

Disinfection of the Water Chamber and Transfer Box:

In the following procedures, only one disinfection process needs to be performed at one time.

Chemical Disinfection:

(1) Clean the water chamber or the transfer box by following the steps in the cleaning instructions.

(2) Put the Johnson's CIDEX OPA 0.55% into a plastic box, so that the water chamber or the transfer box can be completely submerged.

(3) Immerse the water chamber or the transfer box in CIDEX OPA 0.55% for 12 min.

(4) Rinse the water chamber or the transfer box 3 times with running water to remove any residual disinfectant.

(5) Wipe the water chamber or transfer box dry with a soft cloth or air dry out of direct sunlight.

UHT Disinfection (90 ± 2°C water)

(1) Clean the water chamber or the transfer box by following the steps in cleaning instructions.

(2) Open the cap of the water chamber, and then immerse the water chamber or the transfer box in the water tank. Heat the water to 90 ± 2°C and immerse the water chamber or the transfer box for 5min.

(3) Wipe the water chamber or the transfer box dry with a soft cloth or air dry them away from direct sunlight.

CAUTIONS!

• Disinfectants tend to damage the 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.

WARNINGS!

• After disinfection, rinse any disinfected component in clean water thoroughly, especially components in close contact with the patient such as the mask, headgear and tubing, so as to prevent disinfectant residuals from damaging the skin or respiratory tract or causing allergies.

• Sterilization of this device and its components other than that is recommended is not permitted.

• To prevent cross-infection of patients or contamination of the device, a BSF (Breathing System Filter) that meets the standards of ISO 23328-1:2003 and ISO 23328-2:2002 and has medical device registration certificates can be used.

(1) A new BSF is required for different patients before using this device.

(2) When using the BSF, please follow the instructions of the BSF for installation and operation, and pay attention to adjust the output pressure setting of the device according to resistance of the BSF to ensure that proper treatment pressure can be provided.

(3) Humidification will increase the resistance of the BSF. The operator must frequently monitor the BSF for increased resistance and blockage to ensure that proper treatment pressure can be provided.

• If you use ozone or other cleaning and disinfection methods that are not recommended by REACT HEALTH, REACT HEALTH will not be able to verify the safety or performance of the device.

17. Traveling

17.1 Traveling with the Device

(1) Use the carrying case to carry the device and accessories along with you. Do not put them in your checked baggage.

(2) This device operates on a power supply of 100 V ~ 240 V and 50 Hz / 60 Hz, and is suitable for use in any country in the world. No special adjustment is required, but you will need to find out the types of the power sockets at your destination. If necessary, bring a power socket adaptor, which can be purchased at electronics stores.

(3) Remember to bring a spare air filter and emergency documentation (filled and signed by your physician) about this device. If you plan to travel by air, remember

to bring the multilingual emergency documentation about the respiratory therapy, in case that the border and customs officers in your destination country inspect the device. With emergency documentation, you can prove to them that it is a medical device.
(4) Security Stations: For convenience at security stations, there is a note on the bottom of the device stating that it is medical equipment. It may be helpful to bring this manual with you to help security personnel understand the device.

CAUTIONS!
• Empty the water chamber before packing the device for your trip to prevent any remaining water from entering the device.
• If the device is used when the atmospheric pressure is outside the specified range (See Section 5), the accuracy of the leak alarm will be affected.

17.2 Traveling by airplane

For some airlines, medical devices do not count toward carry-on luggage limits.
Please check with your airline for their policy regarding medical equipment.
You can use your device on a plane as it meets the Federal Aviation Administration (FAA) requirements.

Aircraft Use
REACT HEALTH confirms that the device meets the Federal Aviation Administration (FAA) requirements (RTCA DO 160, section 20, category T and section 21, category M) for all phases of air travel.

18. Transferring the Device to Another Patient

If the device is transferred to another patient, components in close contact with the previous patient, including the mask, headgear, tubing and air filter, should be replaced to prevent cross-infection.

19. Reordering

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

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, please stop using the device and contact your home care provider.
• If the device fails to work properly, contact your home care provider immediately. Never attempt to open the enclosure of the device. Repairs and adjustments must

be performed by authorized service personnel only. Unauthorized service could cause injury, invalidate the warranty, or result in costly damage.

• If necessary, contact your local authorized distributor or REACT HEALTH, for technical support and documents.

20. Technical Support

Please contact REACT HEALTH 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. REACT HEALTH will provide the circuit diagram and / or other technical documents in whole or in part according to your needs.

21. Disposal

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

22. Troubleshooting

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

22.1 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, resulting in the irritation of nasal mucosa and subsequent dryness and swelling.	Increase the humidity setting of the device. Contact your physician, and continue treatment unless the physician suggests otherwise.
Dry mouth and throat	It may be because the patient sleeps with the mouth open, and the pressurized air flows out through the mouth, causing dryness of the nasal passage and throat.	Use a chin strap to prevent the mouth from opening during sleep, or use a full-face mask. Contact your physician for details.
Eye irritation	The mask may not be the correct size or type, or the mask may be incorrectly positioned, resulting in an air leak.	Narrow the distance between the forehead support of the mask and the forehead. Note that adjusting the mask too tight may leave marks on the patient's face. Add additional filling to the mask so it does not leak. Contact your home care provider for an appropriate mask. Add additional filling to the mask if necessary.
	Mask cushion (the soft part of the mask) hardens.	Replace the mask or mask cushion.
Facial reddening	The mask is too tight.	Loosen the headgear.
	The distance between the forehead support of the mask and the forehead is not correct.	Try a different distance. The angle and size of the forehead support differ according to the type of masks.
	Wrong mask size.	Contact your home care provider for a correct-size mask.

Problem	Possible Cause	Solution (s)
Facial reddening	The patient is allergic to the materials of the mask.	Contact your physician and or home care provider. Use a mask which is not made of natural rubber latex. Place a lining between the skin and mask.
Water in mask	When the humidifier is used, the humidified air tends to condense in the cold tubing and mask if the room temperature is low.	Turn the humidity setting down, or raise the room temperature. Place the tubing under the quilt, or use the tubing cover. Hang the tubing loosely, and make sure that the lowest part of the tubing should be lower than the patient's head.
Nasal, sinus or ear pain	Sinus or middle ear inflammation.	Contact your physician immediately.
Discomfort due to inability to adapt to the treatment pressure	The patient will feel uncomfortable when the treatment pressure is higher than 13 cmH_2O. However, the treatment pressure is determined by the patient's conditions, and the device will not be able to treat sleep apnea if the treatment pressure is set too low.	It takes a maximum of four weeks for the patient to adapt to pressurized air. Relax and breathe through the nose. If the problem still exists, contact your physician.
Obstructive sleep apnea symptoms recur	It may be because the patient sleeps with the mouth open, and the pressurized air flows out through the mouth, causing a blockage in the respiratory tract.	Use a chin strap to prevent the mouth from opening during sleep, or use a full-face mask. Contact your physician for details.
The device is too noisy	The tubing is not connected properly.	Reconnect the tubing properly.
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 16.1.6 Cleaning and Replacing the Air Filter / PM2.5 Filter), and clean the air inlet. Place the device in an area where air flows freely, and make sure that the device is at least 20 centimeters away from the wall, curtain or other things.

22.2 Common Problems in the Device and Corresponding Solutions

Problem	Possible Cause	Solution (s)
The device does not work when it is turned on	The Auto On / Off feature is enabled.	Take a few deep breaths with the mask on, and the device will start automatically.
	Power is not connected properly.	Ensure that the power cord, power adapter 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 home care provider for repair.
	Cannot find any cause.	Contact your home care provider.
The device is working, but the pressure inside the mask differs from the set treatment pressure	The tubing is not connected properly.	Reconnect the tubing properly.
	There may be holes in the mask or pressure sensing tubing.	Contact your home care provider.
	It is a faulty device.	Contact your home care provider.
The device produces very low pressures	The air inlet of the device may be blocked.	Replace the air filter (see 16.1.6 Cleaning and Replacing the Air Filter / PM2.5 Filter), and clean the air inlet. Make sure the air inlet is unblocked.
	The treatment pressure has been changed accidentally.	Contact your physician.
	When the Ramp feature is enabled, it takes some time for the initial pressure to rise to the treatment pressure. This is normal.	If necessary, disable the Ramp feature, or set the ramp time shorter.
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 cannot 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.

23. Information of QoS

QoS is a security mechanism of the network and a technology used to solve problems such as network delay and congestion.

The data transfer between the BPAP System with a Cellular Module and iCodeConnect is a daily transfer. The Cellular Module transmits the following four types of data: Treatment summary data within a defined period of time, compliance data, system settings and device information.

This process is not real-time communication.

The size of data transferred to the Cellular Module does not exceed 1 K per second in normal conditions, and does not exceed 1 M per night over an 8-hour period.

Acceptable latency

Since patient information is not viewed by the physician in real time, there may be delays of 24 hours or more at times.

Acceptable level of probability of information loss within the network

The data has little impact on treatment effectiveness. These are key data, and their integrity should be ensured, but they do not involve real-time control of therapeutic medical devices, and are not dependent on network quality.

Incorrect transmission of the information described in the above sections data will be abandoned based on a check mechanism, and correct data will be sent continuously until it is completely received.

The data transfer protocol between the module and the server includes the unpacking information and the ID value, which ensure the integrity of the data transfer.

Signal priorities of the network

The treatment devices themselves do not have high-priority medical device alerts, and their treatment of patients does not rely on wireless communications.

Based on the above analysis, the Cellular Module does not have high requirements for QoS.

24. 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 ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±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	±2 kV for power supply 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)	±1 kV Line(s) to line(s)	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
Power frequency (50 Hz / 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 AC 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).
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	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:

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 of other electronic equipment such as diathermy, electrocautery and radio frequency identification (RFID), security systems (such as electromagnetic anti-theft systems and metal detectors), cell phone, transceiver or radio control products. If you have to do so, the device should be observed to verify normal operation.

• Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they can operate normally.

• The use of accessories, transducers and cables which are not specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or reduced electromagnetic immunity of this equipment and result in abnormal operation.

• Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the BPAP System, including cables specified by the manufacturer. Failure to do so may result in the performance degradation of this equipment.

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

• The device may be subject to interference by the electromagnetic field of some known or unknown radio frequency transmitters in the environment during use. If interference occurs, please keep the device away from the electromagnetic environment, or find and turn off the source of the electromagnetic field interference before continuing to use.

• When the product is exposed to welding, electrosurgery, defibrillation, X-ray (γ ray), infrared radiation, transient electromagnetic field, including nuclear magnetic resonance (MRI) and radio interference environment, the product may be damaged.

• During the operation of the device, due to electrostatic interference, the following phenomena may occur: (1) Temporary loss of function or performance degradation, such as abnormal screen display. The device will return to normal after being restarted; (2) Automatic restart of the device. These phenomena will not affect the normal use of the device, nor will they cause permanent performance degradation or loss of function of the device.

25. Limited Warranty

REACT HEALTH 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 two (2) years for main device and three (3) months for all accessories from the date of sale by REACT HEALTH to the distributor. If the product fails to perform in accordance with the product specifications, REACT HEALTH will repair or replace, at its option, the defective material or part. REACT HEALTH will pay customary freight charges from REACT HEALTH to the distributor location only. This warranty does not cover damage caused by accident, misuse, abuse, alteration and other defects not related to material or workmanship.

REACT HEALTH 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 distributor or:

Manufactured for:

REACT HEALTH

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Sarasota, FL 34232
T: (863) 226-6285
For additional information, please visit our Patient Portal at:
www.reacthealth.com
icodeconnect.com – Web-based cloud for report generation and storage

Manufacturer:

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