User Manual

G3 X APAP

G4600

REACTHEALTH

Table of Contents

1. Introduction

Thank you for your purchase of the G3 X APAP. This user manual provides important information about the use and care of your device. Please read it carefully. If you experience any difficulties or problems during use, please contact your healthcare provider or physician. If the package is damaged, contact your equipment provider.

2. Symbols

2.1 Control Buttons

 Home Button

 Start/Standby Button

 Knob

2.2 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

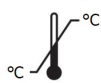
IP22 ≥12.5 mm diameter, dripping (15° tilted)

 There is high voltage, beware of electric shock

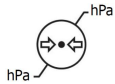
 European Conformity

RoHS RoHS compliant

 Hot surface

	Serial number
	Manufacturer
	Made in China. Date of manufacture
	Use-by date
	Maximum water level
	Batch code
	Non-Ionizing radiation
	SD card
	Waste electrical and electronic equipment
	Air inlet
	Air outlet
	Caution
	MR unsafe
	Complies with RTCA DO-160 section 21, category M.
	Medical device
	Prescription only
	Catalogue number
	Unique device identifier
	Model number
	Temperature limit

Humidity limit



Atmospheric pressure limit

2.3 Interface Symbols

The following icons will appear in the user interface.

	SD card inserted		Cellular Module Data Signal Strength
	Heated Humidifier, There are 6 levels that can be set: 0–5, 0 means Off		Heated Breathing Tube connection There are multiple levels that can be set: Off, 1–5, Auto, 0 means off
	Heated Humidifier preheating		Heated Breathing Tube not connected.
S	Smart function on		Page turning
	Alert		Silence Alert

3. Warning, Caution and Important Tip

⚠***WARNING!***
Indicates the possibility of injury to the user or operator.

CAUTION!
Indicates the possibility of damage to the device.

IMPORTANT TIP!
Indicates 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.

4. Intended Use

The G3 X APAP is a CPAP (Continuous Positive Airway Pressure) device designed for the treatment of Obstructive Sleep Apnea (OSA). The integrated humidifier is indicated for the humidification and warming of air from the flow generator device. These devices are intended for single-patient re-use in the home environment or for multi-patient re-use in the hospital/institutional environment. It is to be used on adult patients >66 lbs/30 kg for whom CPAP therapy has been prescribed.

⚠***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 REACT HEALTH accessories.
• Do not bring the device or accessories into a Magnetic Resonance (MR) environment as it may cause unacceptable risk to the patient or damage to the device or MR medical devices. The device and accessories have not been evaluated for safety in an MR environment.
• Do not use the device or accessories in an environment with electromagnetic equipment such as CT scanners, Diathermy, RFID and electromagnetic security systems (metal detectors) as it may cause unacceptable risk to the patient or damage to the device. Some electromagnetic sources may not be apparent, if you notice any unexplained changes in the performance of this device, if it is making unusual or harsh sounds, disconnect the power cord and discontinue use. Contact your healthcare provider.
• Do not introduce fragrances or aromatherapy odors into the interior of the device.
• If you discover foreign objects inside the device, tube, or mask, you should immediately stop using the device and contact the provider of your device.

CAUTIONS!
• U.S. federal law restricts this device to sale by or on the order of a physician.

• The intended operators are patients, physicians and medical staff. There is no restriction on the educational background of the patient, but the patient needs to be able to read and understand the user manual; the physician is required to be a medical professional with a license to practice medicine; and the medical staff is required to be a person with nursing experience or a healthcare-related profession, or be a respiratory therapist.
• The device is intended for use by operators trained or experienced in similar equipment.

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 healthcare provider or physician.

5. Contraindications

Studies have shown that the following pre-existing conditions may contraindicate the use of positive airway pressure therapy for some patients:

Absolute Contraindications: Pneumothorax, mediastinal emphysema; cerebrospinal fluid leak, traumatic brain injury, or pneumocephalus; shock caused by a variety of conditions before treatment; active epistaxis; upper gastrointestinal bleeding before treatment; coma or impaired consciousness making the use of mask during therapy impossible; giant vocal fold polyp, etc.

Relative Contraindications: Severe coronary heart disease complicated with left ventricular failure, acute otitis media, excessive respiratory secretions and weak cough, weak spontaneous breathing, nasal or oral tracheal intubation and tracheotomy, severe nasal congestion caused by a variety of conditions, lung bullae, and allergies to breathing masks, etc.

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

CAUTION!

• Contact your physician if symptoms of obstructive sleep apnea or respiratory Insufficiency reoccur. 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 obstructive sleep apnea symptoms.
• REACT HEALTH recommends use of REACT HEALTH supplied masks, and only masks compliant with ISO 17510:2015.

6. Specifications

Statement:

All requirements for the flow rate, volume and leakage

a) are expressed at STPD,

b) except for those associated with the VBS, which are expressed at BTPS.

Results are expressed as STPD (Standard Temperature and Pressure, Dry). Use the following table to convert the STPD flow setting to BTPS (Body Temperature and Pressure, Saturated) flow.

Accuracy may be reduced by the presence of leaks, supplemental oxygen, tidal volumes <100 mL or minute ventilation <3 L/min.

STPD to BTPS conversion

Altitude (m)	Ambient pressure (hPa)	STPD to BTPS conversion factor
0	1013.25	1.12
500	956.53	1.19
1000	902.41	1.27
1500	850.80	1.36
2000	801.60	1.45
2500	754.73	1.54
3000	710.11	1.65

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

Environmental Conditions

	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 hPa to 1060 hPa	760 hPa to 1060 hPa
Altitude	Sea level to 2300 m	Sea level to 2300 m

Note: The device can be operated or transported by airplane without the restriction of altitude.

Heated Humidifier

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

Maximum Operating Pressure: 40 cmH_2O

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

Maximum Delivered Gas Temperature: ≤43°C

Time between each refill of the Humidifier: 8 hours ± 0.5 hour (tested at 23 ± 2°C/73.4 ± 3.6°F)

Static Temperature Stability of Delivered Gas: 35°C to 42°C, in 35°C environmental

temperature

Heated Humidifier performance

Breathing Tube

Mask Pressure (hPa)	Nominal RH output % at 22°C (72°F) ambient temperature	Nominal system output mg/L AH[1], BTPS[2]
	Setting 5 (maximum setting)	Setting 5[3] (maximum setting)
4	100%	>12
10	100%	>12
20	100%	>12

[1] AH - Absolute Humidity in mg/L

[2] BTPS - Body Temperature Pressure Saturated

[3] Humidifier performance meets ISO 80601-2-74:2021 tested at 15°C to 35°C (59°F to 95°F) 15% relative humidity.

Mode of Operation

Continuous

Work Mode

CPAP, AutoCPAP

SD Card

The SD card is capable of storing patient treatment data and error information.

AC Power Consumption

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

Power to Heated Breathing Tube 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: 4 hPa to 20 hPa

Maximum limited pressure

40 hPa in single fault normal condition

Pressure accuracy

Static Pressure accuracy:

Maximum static pressure variation at 10 cmH_2O (10 hPa) according to ISO 80601-2-70:2020: ±0.5 hPa

Therapeutic-pressure adjustment accuracy: ±0.5 hPa

Under normal operating conditions, the therapeutic-pressure adjustment range is 4 hPa to 20 hPa in 0.5 hPa steps. Under single fault conditions, the therapeutic-pressure adjustment range is ≤30 hPa.

Maximum dynamic pressure variation according to ISO 80601-2-70:2020:

CPAP Mode: ±(0.5 hPa + 5% of the set pressure)

Display values accuracy

Mask pressure: 0–Pmax, the accuracy under steady-state conditions shall not be worse than ±(2% of the full scale reading + 4% of the actual reading).

Measurement system uncertainties

In accordance with ISO 80601-2-70:2020, the measurement uncertainty of the manufacturer's test equipment is:
For measures of pressure: ±0.15 hPa
For measures of temperature: ±1°C
For measures of flow: ±3%
In accordance with ISO 80601-2-74:2021, the measurement uncertainty of the manufacturer's test equipment is:
For measures of humidification output: ±1 mg/L BTPS

Ramp

The ramp time ranges from 0 to 60 minutes.

The A-weighted sound pressure level and sound power level

When operating at a pressure of 10 hPa, the device's sound pressure level and sound power level shall not exceed the values listed in the table below.

Sound Pressure Level	Uncertainty	Sound Power Level	Uncertainty
28 dB(A)	2 dB(A)	36 dB(A)	2 dB(A)

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

Maximum Flow

For Breathing Tube (19 mm) and Heated Breathing Tube (19 mm):

	Maximum Flow				
	Pmin	Pmin + 1/4 (Pmax-Pmin)	Pmin + 1/2 (Pmax-Pmin)	Pmin + 3/4 (Pmax-Pmin)	Pmax
Test Pressures (hPa)	4	8	12	16	20
Measured Pressure at the Patient Connection Port (hPa)	3	7	11	15	19
Average Flow at the Patient Connection Port (L/min)	85	135	140	140	140
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.					

Note: The above data is measured according to ISO 80601-2-70 201.12.1.103.

Refer to the relevant measurement uncertainty from the Measurement system uncertainties.

Air Tube

Air tube	Length	Inner diameter
Breathing Tube	1.83 m (6 ft.)	19 mm
Heated Breathing Tube	1.83 m (6 ft.)	19 mm

Leakage of the tube

At 60±3 hPa pressure, the leakage rate is less than 10 mL/min.

The Form and the Dimensions of the Patient Connection Port

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

Maximum supplemental oxygen flow

4 L/min

Reusable Air Filter

Type	Material	Average arrestance
Reusable Air Filter	Polyurethane	>20% for 10 micron dust

Disposable Ultra-fine Filter (Optional)

Type	Material	Average arrestance
Disposable Ultra-fine Filter	Polypropylene	>95% for 5 micron dust

Cellular Module

Thales

Transportation Requirements	Shock, severe vibration, and moisture should be avoided in transportation
Frequency Bands	LTE Band 1, 2, 3, 4, 5, 8, 12, 13, 18, 19, 20, 25, 26, 27, 28, 66, 85
Communication Mode	LTE Cat M1/ NB1/2
Effective Radiated Power LTE	LTE Cat M1/ NB1: ≤+20 dBm ± 2 dB, Class 5
FCC ID	QIPEXS62-W

[1] The LTE bands supported by Cellular Module are defined above, while the following Table 1 describes the Receiver Input Sensitivity.

Table 1 Receiver Input Sensitivity

Parameter	**Conditions**	**Min.**	**Typical**	**Unit**
BW: 5 MHz, UL: Modulation: QPSK; NRB=6; DL: Modulation: QPSK; NRB=4	LTE 2100 Band 1	-103	-107	dBm
	LTE 1800 Band 2	-101	-106	dBm
	LTE 1900 Band 3	-100	-103	dBm
	LTE AWS-1 Band 4	-103	-107	dBm
	LTE 850 Band 5	-101.5	-103.5	dBm
	LTE 900 Band 8	-100.5	-105.5	dBm
	LTE 700 Band 12	-100	-108	dBm
	LTE 700 Band 13	-100	-106	dBm

	LTE 800 Band 18	-103	-105	dBm
	LTE 800 Band 19	-103	-107.5	dBm
	LTE 800 Band 20	-100.5	-107.5	dBm
	LTE 1900 Band 25	-101	-106.5	dBm
	LTE 800 Band 26	-101	-105	dBm
	LTE 800 Band 27	-101.5	-108	dBm
	LTE 700 Band 28	-101.5	-107.5	dBm
	LTE AWS-3 Band 66	-99	-107	dBm
	LTE 700 Band 85	-99.2	-107.5	dBm

FCC Requirements

The product complies with parts 15, 22, 24, 27, & 90 of the FCC Rules and ICES-003 Class B. Operation is subject to the following two conditions:

(1) The product may not cause harmful interference.

(2) The product must accept any interference received, including interference that may cause undesired operation.

Summary of Test Results

The EUT has been tested according to the following specifications:

Test Item	Test Requirement	Test Method	Result
Conducted Emission	FCC 47 CFR Part 15.107 ICES-003 Issue 6 Section 6.1	ANSI C63.4-2014	PASS
Radiated Emission	FCC 47 CFR Part 15.109 ICES-003 Issue 6 Section 6.2		PASS
Radiofrequency Radiation Exposure Evaluation	FCC 47 CFR Part 1 Subpart I RSS-102 Issue 5	--	PASS
Equivalent Isotropic Radiated Power (EIRP)	FCC 47 CFR Part 22 FCC 47 CFR Part 24 FCC 47 CFR Part 27 FCC 47 CFR Part 90 RSS-130 Issue 2 RSS-132 Issue 3 RSS-133 Issue 6 RSS-139 Issue 3 RSS-Gen Issue 5	ANSI C63.26-2015 & KDB 971168 D01v03r01 ANSI/TIA-603-E-2016	PASS
Conducted Output Power			PASS
Peak-to-average ratio			PASS
99%&26 dB Bandwidth			PASS
Band Edge at antenna terminals			PASS
Spurious emissions at antenna terminals			PASS
Field strength of spurious radiation			PASS
Frequency stability			PASS

Ublox

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 in above, while the following Table 2 describes the Transmitting and Receiving frequencies.

Table 2 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 Band 28 (700 MHz)	Uplink	703	748	MHz	Module transmit
	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	Uplink	1710	1785	MHz	Module transmit
	Downlink	1805	1880	MHz	Module receive

Parameter		Min.	Max.	Unit	Remarks
(1800 MHz)					
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) from the Cellular Module.

CAUTION!

• In accordance with network security requirements, the CPU on this equipment only supports our product software standards and is not compatible with other external software.

Power of heating plate

38 W

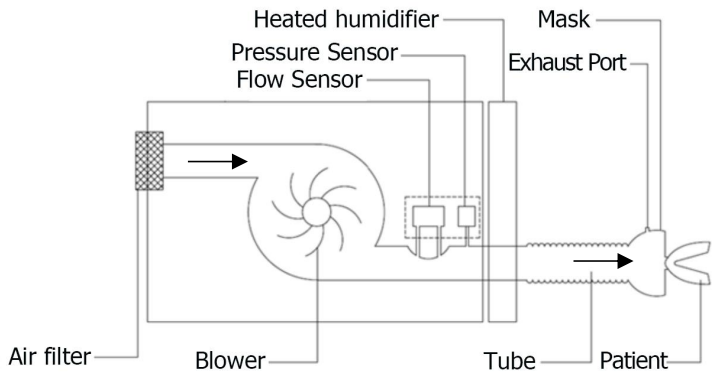
Essential performance

The main device doesn't have Essential Performance.

Intended part of the body or type of tissue applied to or interacted with:

Upper airway (nose, mouth, pharynx) via a mask; no tissue penetration.

Ventilator Pneumatic System Schematic Diagram



Blower	The pneumatic drive component, which delivers therapeutic pressure to the patient during operation.
Pressure Sensor	Pressure sensing unit capable of real-time pressure value feedback.
Flow Sensor	Flow sensing unit providing real-time volumetric flow data.

7. Available Therapies

The device delivers the following therapies:

CPAP – Delivers Continuous Positive Airway Pressure; CPAP maintains a constant level of pressure throughout the breathing cycle.

AutoCPAP – Automatically adjusts pressure in response to patient breathing events.

8. Glossary

Apnea
A condition marked by the cessation of spontaneous breathing.

AutoCPAP
. Automatically adjusts pressure in response to patient breathing events.

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 defaulted on but can be turned off.

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

SmartA
In AutoCPAP mode, if SmartA is set to on, the device can adjust Initial P and Min APAP according to the patient's respiratory event during a certain time.

Initial P
Initial pressure.

Min APAP
Minimum Automatic Positive Airway Pressure.

CPAP
Continuous Positive Airway Pressure.

iCode
A feature that is intended to give access to compliance and therapy management information. The "iCode" consists of six separate codes displayed in the Patient Menu, each code is a sequence of numbers. The "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 time for the Ramp feature.

Ramp

A feature that may increase patient comfort when therapy is started. It begins from a low pressure and then gradually increases to the prescribed setting pressure so that the patient can fall asleep more comfortably.

Reslex

A feature that reduces pressure during exhalation, if enabled by the clinician.

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.

CAUTION!

• Indexes such as Apnea, AHI, Hypopnea are only monitoring data provided by Sleep Apnea Therapy Device, not diagnostic parameters.

9. Model

Model	Product Description		Mode	Maximum Working Pressure (cmH_2O)
	Product Content	Optional Accessory		
G4600	Device (3.5-inch LCD)	Breathing Tube (optional), Cellular Module (optional), Heated Breathing Tube (optional)	CPAP, AutoCPAP	20

10. Package Contents

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

No.	Articles	Qty.	Notes
1	Main Device	1	
2	Power Adapter	1	
3	Power Cord	1	
4	Tubing Elbow Adapter	1	Optional
5	Breathing Tube	1	Optional
6	Heated Breathing Tube	1	Optional
7	Reusable Air Filter	1	
8	Disposable Ultra-Fine Filter	3	Optional
9	SD Card	1	Optional
10	Cellular Module	1	Optional
11	Carrying Case	1	
12	Accompanying Documents	1	

All parts and accessories are natural rubber latex free.

The expected service life of the device is 5 years from first date of use, if the use, maintenance, cleaning and disinfection are in strict accordance with the User Manual.

The expected service life of the breathing tube and the heated breathing tube is 6 months from first date of use. The shelf life of the breathing tube and the heated breathing tube is 3 years.

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

The expected service life of the Cellular Module is 5 years from first date of use.

⚠***WARNINGS!***

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

• Do not stack the long tube or power cord near the patient's neck; during sleep they could become wrapped around the head or neck and cause strangulation. Strangulation can rapidly lead to airway obstruction, hypoxia, loss of consciousness, cardiac arrest, and death.

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

• Exceeding the Expected Service life, our company 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 healthcare provider.

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

11. System Features

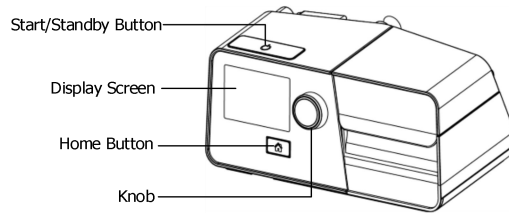


Fig. 11-1

Name	Function
Start/Standby Button	Start/Stop delivering air. The light is white. It turns off together with the display screen.
Display Screen	Display menus for operation, messages, monitoring data, etc.
Home Button	Return to the previous menu or main interface. The light is white. It turns off automatically after 30 s of inactivity.
Knob	Adjust device settings. The light is white. It turns off automatically after 30 s of inactivity.

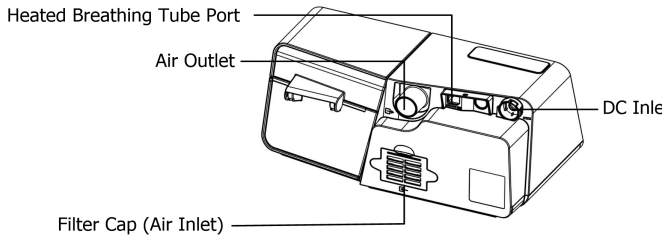


Fig. 11-2

Name	Function
Air Outlet	Deliver pressurized air; connect to the breathing tube.
Heated Breathing Tube Port	Connected to the plug of the heated breathing tube.
DC Inlet	An inlet for the DC power supply.
Filter Cap (Air Inlet)	Use the filter cap to secure the air filters used to filter dust and pollen in the air entering the device.

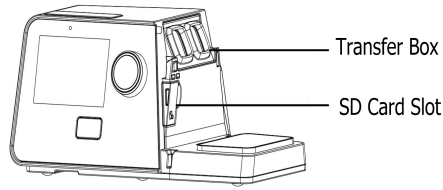


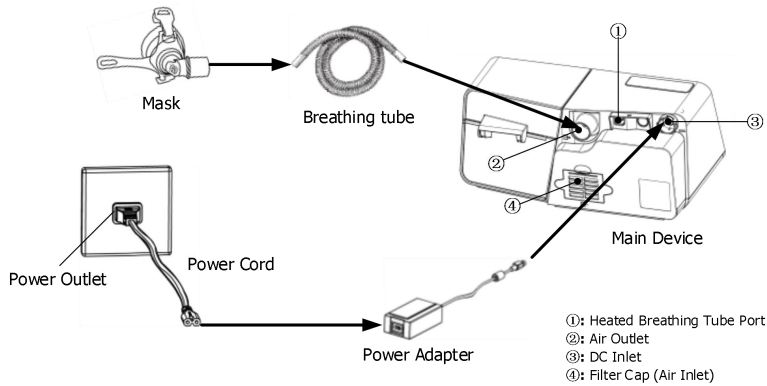
Fig. 11-3

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

CAUTION!

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

12. First Time Setup



12.1 Placing the Device

Place the device on a firm, flat surface.

The operator should stand directly in front of the device within 30 cm of the device and have an unobstructed view of the display and alert indicators.

⚠***WARNINGS!***

• The device must not be covered or positioned in such a way that the operation or performance of the device is adversely affected.

• If the device has been dropped or mishandled, if the enclosure is broken, or if water has

entered the enclosure, disconnect the power cord and discontinue use. Contact your healthcare provider immediately.

• If the room temperature is warmer than 35°C (95°F), the airflow produced by the device may exceed 43°C (109.4°F). The room temperature must be kept below 35°C (95°F) while the patient uses 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 either very hot or very cold temperatures, allow it to adjust to room temperature (approximately 2 hours) before beginning setup.

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

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

• Make sure that bedding, curtains, or other 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 prevent the risk of explosion, this device must not be used in the presence of flammable gases (e.g. anesthetics).

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

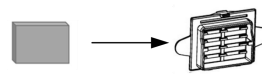
• Air must flow freely around the device for it to work properly.

• Empty the water chamber completely before moving the device.

• If condensation is present in the tube, remove and drain the tube. Lower the humidifier setting level.

12.2 Installing the Reusable Air Filter/Optional Disposable Ultra-Fine Filter and Filter Cap

(1) Attach the reusable air filter to the filter cap, as shown in Fig. 12-1.



Reusable Air Filter Filter Cap

Fig. 12-1

(2) If the disposable ultra-fine filter is applied, place the reusable air filter first, the reusable air filter should be closest to the filter cap and the disposable ultra-fine filter should be closest to the device, as shown in Fig. 12-2.

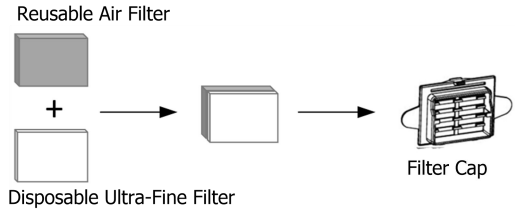


Fig. 12-2

(3) Install the filter cap containing the reusable air filter/disposable ultra-fine filter to the device, as shown in Fig. 12-3.

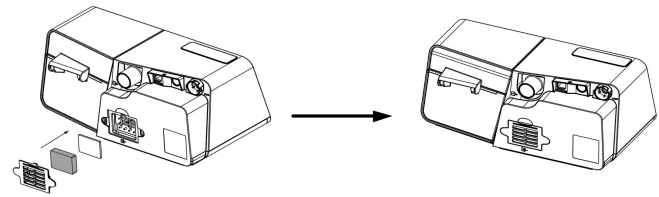


Fig. 12-3

⚠***WARNINGS!***

• Do not block the air inlet.

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

• Please replace and clean the air filter periodically, if it is contaminated. (Refer to 18.1.3 Cleaning and Replacing the Reusable Air Filter/Optional Disposable Ultra-Fine Filter)

• Fire, open flame and smoking are prohibited.

• Air filters provided by the manufacturer are recommended for use, otherwise foreign objects or odors may enter the device.

CAUTION!

• Device must be unplugged when installing the reusable air filter and filter cap.

12.3 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.

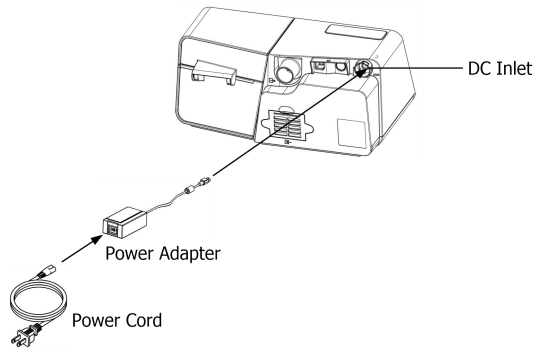


Fig. 12-4

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 is connected. Press the **Start/Standby Button** ⏻ to turn the blower On/Off.

• Use of the device at an AC voltage beyond the stated range (see Section 6 "AC Power Consumption") may damage the device or cause device failure.

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

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.

12.4 Assembling the Breathing Tube/Heated Breathing Tube and Mask

(1) Connect one end of the breathing tube to the air outlet of the device, as shown in Fig. 12-5.

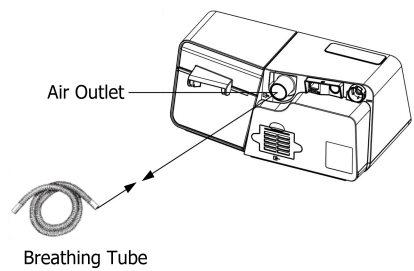


Fig. 12-5

(2) Or if the heated breathing tube is applied, connect the heated breathing tube joint to the

air outlet of the device, and then insert the power plug of the heated breathing tube into the heated breathing tube port on the back of the device, as shown in Fig. 12-6.

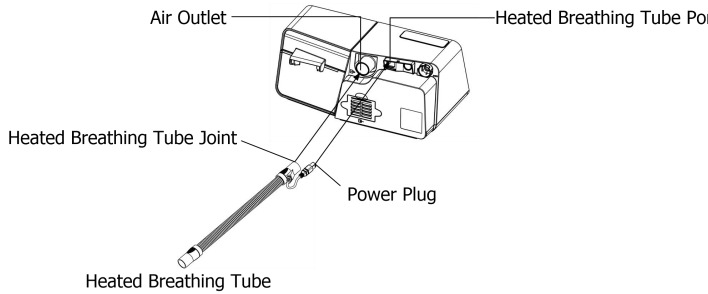


Fig. 12-6

CAUTION!

• You may experience condensation or moisture build-up in the breathing tube due to cold ambient room temperature and high humidifier output. Reducing your humidifier setting, using a heated breathing tube, or increasing your heated breathing tube setting can help reduce the condensation build-up.

If the heated breathing tube is connected correctly, the icon will become a number in the Main Interface on the screen of the device, as shown in Fig. 12-7.

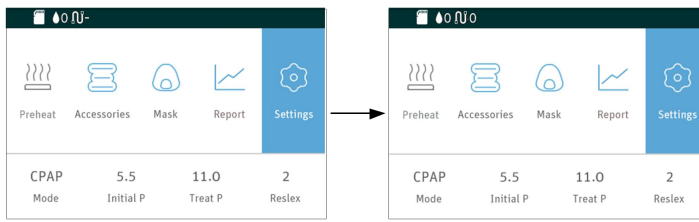


Fig. 12-7

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

There are five heat levels available, and the number of heat level will appear in the Main Interface on the screen of the device. The number 3 next to the icon indicating the heat is adjusted to Level 3, as shown in Fig. 12-8

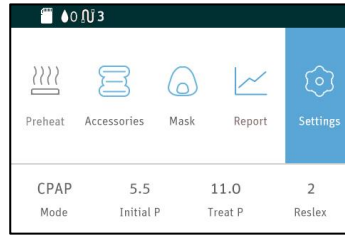


Fig. 12-8

(3) To apply the tubing elbow adapter, connect the tubing elbow adapter between the device air outlet and the tubing (heated breathing tube or breathing tube) as shown in Fig. 12-9. The 90-degree elbow helps to direct the tubing.

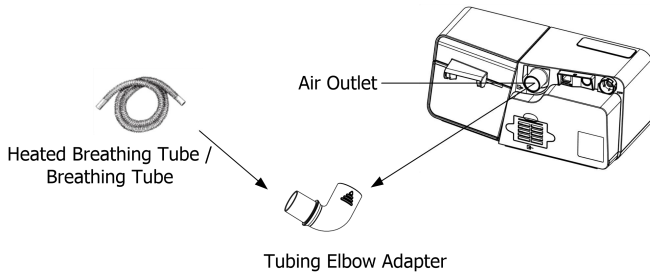


Fig. 12-9

(4) Connect the other end of the breathing tube / heated breathing tube to the mask according to the user manual for the mask.

⚠***WARNINGS!***

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

• If you are using a mask with a built-in exhalation port, connect the mask's connector to the tubing.

• 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 vented air is blowing 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.

• In order to minimize the risk of CO_2 rebreathing, the patient should observe the following instructions:

- Use only tubing and mask provided by REACT HEALTH.
- Do not wear the mask for more than a few minutes while the device is not operating.
- 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; then reduce the humidification.

• To prevent disconnection of the tubing or tubing system during use, especially during ambulatory use, only tubes in compliance with ISO 5367 or ISO 80601-2-74 should be used.

• Proper selection, placement and positioning of the mask are essential for effective therapy and stable operation of the device.

• Failure to use a mask or accessory that minimizes rebreathing of carbon dioxide or permits spontaneous breathing can cause asphyxiation.

12.5 Using Oxygen with the Device

The device is compatible with up to 15 L/min of supplemental oxygen.

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 before turning off the device. Explanation of Warning: When the device is turned off, but the oxygen flow still exists, oxygen may accumulate within the device's enclosure and pose a fire hazard. Turning off the oxygen before turning off the device will prevent oxygen accumulation in the device and reduce the risk of fire. This warning applies to CPAP and APAP 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 X APAP or the oxygen container.

• Sources of oxygen should be located more than 1 m 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 device's Auto On function will be disabled. Press the Start/Standby Button to initiate ventilation.

• 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 does not exceed the work pressure of the device.

12.6 Inserting the SD Card

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

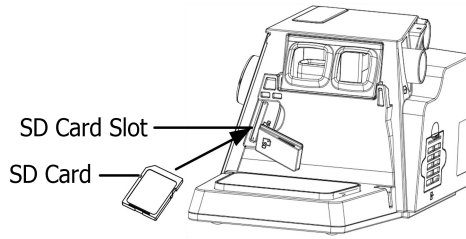


Fig. 12-10

If the SD card is properly inserted into the device, the correct insertion indicator will appear on the screen of the device.

CAUTIONS!

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

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

12.7 Starting Treatment

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

⚠***WARNINGS!***

• Be sure that your healthcare provider follows your physician's instructions on adjusting the settings! These settings should not be altered by the patient without consulting a physician.

• 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.

Note: To order any accessories not included with this device, contact your healthcare provider.

13. Routine Use

Periodic visual safety inspection (to be performed by the OPERATOR)

Examine the main power cord, plug and adapter for cracks, kinks or loose connections.

Inspect the enclosure for visible damage, deformation or contamination that could affect safety.

Check the breathing circuit (tube, mask, connectors) for wear, cracks, permanent kinks, discoloration or blockage; replace any damaged component immediately.

Verify that the air-inlet and air filter are clean, correctly seated and within the replacement interval stated in this manual.

Ensure the water chamber is free of cracks, calcification or leaking; confirm the seal is intact.

Confirm that all indicators and push-buttons function as described in Section 12.

Make sure labels, warnings and the serial number remain legible.

Frequency: quick check before each use; detailed inspection at least once a week. Record the results in a usage log.

If any abnormality is found, stop use and contact your home-care provider.

13.1 Connecting the Tube

Connect the power cord, power adapter, and tube properly according to the instructions in the First Time Setup (Chapter 12). Wear the mask and headgear according to the user manual for the mask.

13.2 Adjusting the Tube

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

WARNING!

• The breathing tube shall not be covered by a bed sheet or affected by any heat source (such as an electric blanket), otherwise, the breathing tube may become deformed and cause danger.

13.3 Turning on the Airflow

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

The therapy settings should be re-evaluated at regular intervals by a qualified clinician to confirm that effective treatment is being maintained.

WARNING!

• The temperature of the breathing tube may exceed 41°C during therapy.

13.4 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 of 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.

13.5 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, to allow the pressure to increase gradually over a set time. 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 users.

13.6 Viewing the Report

On the standby interface, move the cursor to the icon and enter the Report interface.

On this page, you can view the following information.

Usage Summary	Usage summaries for several time periods
iCode QR+	Information can be obtained by scanning the QR code with the App.

13.7 Turning the Device Off

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

14. Heated Humidifier

The humidifier is available from your healthcare provider. The humidifier may reduce nasal dryness and irritation by adding moisture (and heat if applicable) to the airflow.

14.1 Filling the Water Chamber

14.1.1 Removing the Water Chamber

Press down the water chamber on the part closest to the device and then remove it, as shown in Fig. 14-1.

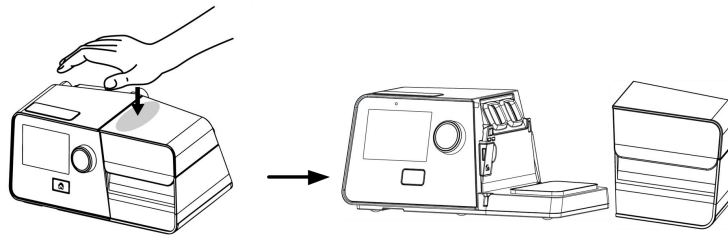


Fig. 14-1

⚠***WARNING!***

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

14.1.2 Filling Water

Remove the water chamber, open the cap, as shown in Fig. 14-2, and fill the water chamber with approximately 360 mL of distilled water (recommended), as shown in Fig. 14-3. Make sure that the water does not exceed the maximum water level line.

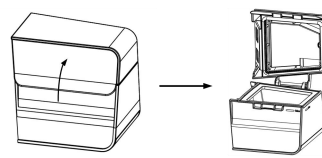


Fig. 14-2

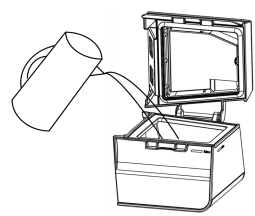


Fig. 14-3

⚠***WARNING!***

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

CAUTIONS!

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

• Use only distilled water.

14.1.3 Reinstalling the Water Chamber

Close the cap after it is filled with water, as shown in Fig. 14-4, and press it firmly into the device, as shown in Fig. 14-5.

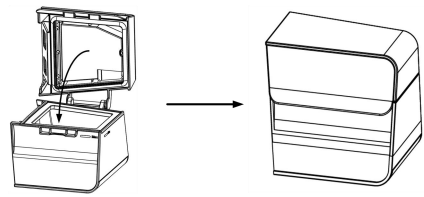


Fig. 14-4

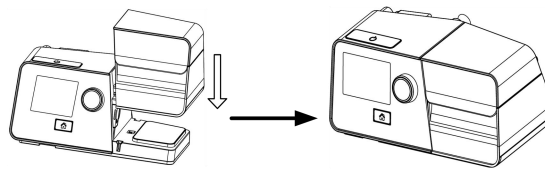


Fig. 14-5

⚠***WARNING!***

• For safety purposes, the device must be placed on a flat surface at a level lower than the patient's head on a bed, so that the condensation flows back to the water chamber rather than remain in the tubing causing rainout.

• Do not use the humidifier at an altitude above 2300 m or outside a temperature range of 5°C (41°F) to 35°C (95°F). Using the humidifier outside of this temperature range or above this altitude can affect the quality of the therapy or injure the patient.

CAUTIONS!

• Avoid moving or tilting the device when the water chamber has water in it.

• Take precautions to protect furniture from water damage.

14.2 Emptying the Water Chamber

(1) **Remove the water chamber** according to instructions in 14.1.1.

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

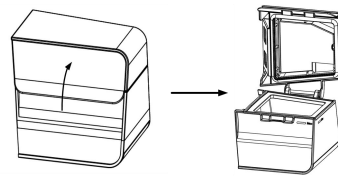


Fig. 14-6

CAUTION!

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

(3) **Return the Water Chamber** according to instructions in 14.1.3.

14.3 Setting the Humidity Level

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

There are multiple humidity levels available (such as Off, 1–5, Auto), and the number of humidity level will appear in the Main Interface on the screen of the device. The number 2 next to the icon indicating the humidity is adjusted to Level 2, as shown in Fig. 14-7. The temperature of the water in the water chamber maintains a constant set level.

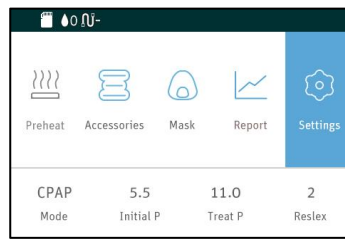


Fig. 14-7

⚠***WARNING!***

• Do not touch the heating plate of the device when it is working, otherwise you may get burned. Turn off the heat when the heated humidifier is not in use.

CAUTIONS!

• Humidity inside the mask depends on humidifier settings and ambient temperature.

• Condensation inside the tubing is more likely to occur as the difference between the air tubing temperature and room temperature increases.

• If there are only a few condensed water droplets inside the tubing in the morning after therapy, it means that the humidity level is appropriate; if there is a lot of condensed water droplets inside the tubing and/or mask, it means that the humidity level is too high and should be set lower. Nasal or oral dryness means that the humidity level is too low and should be set higher.

15. Using the Cellular Module

The G3 X APAP with a Cellular Module can wirelessly communicate with the React Health Connect cloud platform. The Cellular Module transmits device usage and performance data to the clinician through the React Health Connect cloud platform.

(1) Once device is powered on, the device screen displays the Main Screen shown in Fig. 15-1.

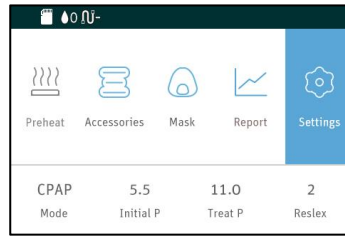


Fig. 15-1

(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 3:

Table 3 Description of Signal Icons

Icon	Description
	Strong signal
	Moderate signal
	Weak signal
	No signal found

Notes:

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

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

If the signal is strong, the signal icon appears in the Main Screen, as shown in Fig. 15-2 (the signal icons of different strength appear in a similar way).

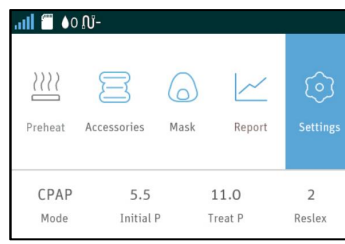


Fig. 15-2

The device screen will not show the signal 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.

16. Navigating the Patient Menu

16.1 Steps to Navigate the Patient Menu

16.1.1 Accessing the Main Interface

Connect the power cord and power adapter properly. The screen displays the Main Interface shown in Fig. 16-1.

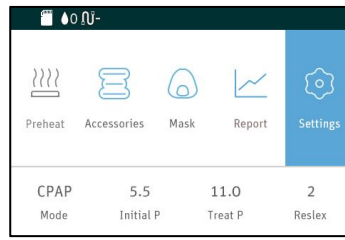


Fig. 16-1

The first icon on the upper part of the screen indicates the Preheat Function Icon, the second indicates the Accessories the third icon indicates Mask Setup, the fourth icon indicates the Report Interface and the fifth icon indicates the Initial Setup. As you turn the **Knob**, the cursor switches among the five icons, and the interface displayed on the screen changes accordingly.

Note: As the humidity levels is off, the Preheat Function Icon will become gray.

16.1.2 Bringing up the Initial Setup Interface

After the display screen displays the Main Interface shown in the Fig. 16-1, turn the **Knob**. When the cursor is on the icon, press the **Knob**, the screen displays the Initial Setup Interface of the Patient Menu, as shown in Fig. 16-2.

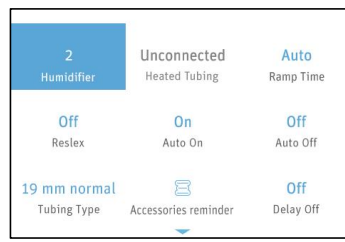


Fig. 16-2

Note: The **Heated Tubing** option can only be adjusted when the device is connected to the heated breathing tube, as shown in Fig. 16-3.

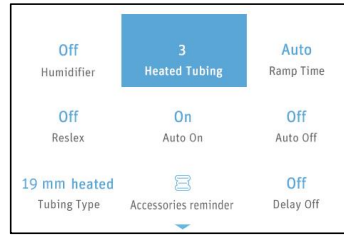


Fig. 16-3

16.1.3 Selecting Options

As you turn the **Knob** clockwise, the cursor moves left to right and 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 to yellow , meaning that the option can now be adjusted, as shown by the **Humidifier** option in Fig. 16-4.

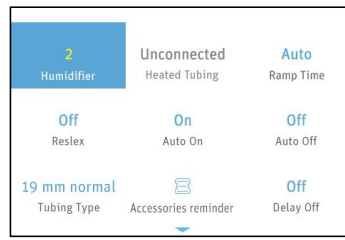


Fig. 16-4

16.1.4 Adjusting Options

Adjust the option by turning the **Knob**. As shown in Fig. 16-5, the **Humidifier** option is selected. As you turn the **Knob** clockwise, the numbering increases, indicating a higher humidity level. As you turn the **Knob** counterclockwise, the numbering decreases, indicating a lower humidity level.

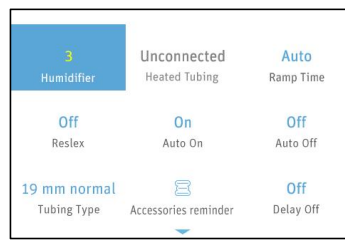


Fig. 16-5

16.1.5 Confirming Adjustments

Confirm your adjustment to an option by pressing the **Knob** . The option is then displayed in white, as shown in Fig. 16-6.

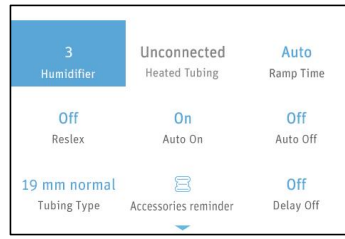


Fig. 16-6

16.1.6 Turning Pages

When the cursor is positioned on the last option on the page, the remaining options will appear on a new page if you continue to turn the Knob clockwise, as shown in Fig. 16-7.

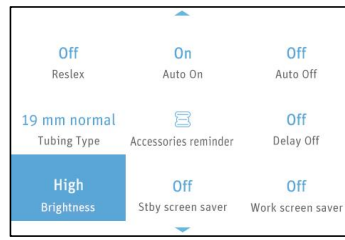


Fig. 16-7

Note: are page turning symbols.

16.1.7 Exiting the Patient Menu

The users can press the **Home Button** to return to the Main Interface shown in Fig. 16-1.

16.2 Options of the Patient Menu and Corresponding Descriptions

Option	Range	Description
Preheat	On/Off	Set humidifier to preheat by adjusting this option. This feature is automatically turned off after 30 minutes.
Accessories	——	Reset the use time of the filter, tubing and mask.
Mask	——	Choose a mask type or test that the mask is worn correctly.
Report	——	Choose to view the usage summary or iCode/iCode QR+.
Humidifier	Off/Auto/ 1 to 5	There are five humidity levels available. As the numbering increases, the humidity rises accordingly. "Off" means the humidifier is turned off.
Heated Tubing	Off/ 1 to 5	There are five heat levels available. As the numbering increases, the heat rises accordingly. "Off" means the heat is turned off. Note: **Heated Tubing** can only be accessed when heated tubing is connected.
Ramp Time	Auto/ 0 to Max Ramp	When the Ramp feature is enabled, the pressure **increases gradually from the initial pressure to the prescribed treatment pressure over a set period of time**. The ramp time can be adjusted.
Reslex	Off/1 to 3	This feature enables the device to automatically reduce the treatment pressure when the patient exhales, to make the user more comfortable. The higher the numbering is, the more pressure the device reduces. "Off" means this feature is disabled.
Auto On	On/Off	This feature enables the device to start automatically and deliver air at a preset pressure after the patient takes a few deep breaths with the mask on.
Auto Off	On/Off	This feature enables the device to automatically discontinue the therapy and shut off when the mask is removed.
Tubing Type	19 mm normal/ 19 mm heated	There are two available tubing types.
Accessories reminder	30 days/60 days/ 90 days/180 days/ 365 days/Off	This function is used for setting filter reminder, tube reminder and mask reminder.

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/Standby Button** to discontinue treatment. This will blow off the vapor left in the water chamber to avoid any damage to the device. When this feature is set to "Off", which means it is disabled, the airflow stops delivering air instantly after you press the **Start/Standby Button**.
Brightness	High/Low	Set screen brightness by adjusting this option.
Stbyscreen saver	On/Off	Set Stby(Standby) screen saver by adjusting this option.
Work screen saver	On/Off	Set Work screen saver 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 turn off automatically after 30 seconds of inactivity. If it is set to "On", the backlight will always be on.
Time	00:00 to 23:59	Set time by adjusting this option.
Date Format	yy mm dd/ mm dd yy/dd mm yy	Turn the **Knob** to choose among three date formats.
Time Format	12-hour/24-hour	Turn the **Knob** to choose between the two time formats.
Language	English	The default setting is "**English**".
Used Time	0 to 50000 h	Use Time displays how long has the device been used by the patient. The use time can be reset in the clinical menu.
About	——	Displays related information of the device (Model, SN, Version, ID). This is read-only and cannot be edited.

17. Alert

Alert Message	Description
Power Failure!!!	An audible alert will sound in 6 s if the device is accidentally disconnected from power when it is delivering air. **Notes:** (1) The alert will not sound if power failure occurs when the device is in standby state. (2) No alert message on the screen during a power failure.
Device Fault!!!	An audible alert will sound if no airflow comes out of the device; the screen will display "**Device Fault!!!**".
Leak!!	When the airflow is on, an audible alert will sound if the air leak rate is excessive; the screen will display "**Leak!!**".
Low Input Voltage!!	If the voltage supplied by power adaptor is lower than 22 V, an audible alert will sound, and the screen will display "**Low Input Voltage!!**".
Humidifier Failure!!	When humidifier is applied, an audible alert will sound when the humidifier fails to work in 20 minutes; the screen will display "**Humidifier Failure!!**".
Please Change Filter!	When the Filter reminder feature is enabled, an audible alert will sound if the preset replacement time reaches but without replacing the reusable air filter; the screen will display "**Please Change Filter!**".
Please Replace Tubing!	When the tubing reminder feature is enabled, an audible alert will sound if the preset replacement time reaches but without replacing the tubing; the screen will display "**Please Replace Tubing!**".
Please Replace Mask!	When the Mask reminder feature is enabled, an audible alert will sound if the preset replacement time reaches but without replacing the mask; the screen will display "**Please Replace Mask!**".
SD Card Full!	The screen will display "**SD Card Full!**" if the SD card has reached its maximum capacity.
Reinsert SD Card!	The screen will display "**Reinsert SD Card!**" if the SD card fails to work.

18. Cleaning and Disinfection

⚠***WARNINGS!***

• Cleaning and disinfection can be performed by the patient.

• Cleaning and disinfection of 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 and disinfection.

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

• Before cleaning and disinfection, 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.

• 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.

• After disinfection, rinse any disinfected component in clean water thoroughly, to prevent disinfectant residuals from damaging the skin or respiratory tract or causing allergies.

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

• Disinfection of this device and its components other than as recommended by the manufacturer 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 should be used.

(1) A new BSF (Breathing System Filter) 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 adjusting the output pressure setting of the device according to the 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 not recommended by REACT HEALTH, REACT HEALTH will not be able to verify the safety or performance of the device.

CAUTIONS!

• Overheating of the materials could lead to early wear 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.

• The disposable ultra-fine filter should not be cleaned or reused.

• Disinfectants tend to damage the materials and reduce the life of components. Use manufacturer recommended disinfectants (section 18.2 below) and follow the manufacturer's instructions and recommendations.

• After disinfection, check the disinfected component for any signs of damage. Replace any damaged component immediately.

18.1 Cleaning

Accessories that need to be cleaned	**Detergent**
Device Enclosure	Hydrogen peroxide cleaning and disinfection wipes
Water chamber and Transfer box	Home Cleaning: Mild dishwashing liquid or soapy water Clinical Cleaning: Mild alkaline, anionic detergent (diluted at 1%)
Reusable Air Filter	-
Mask and Headgear	Refer to Mask Manual for details
Tube	Refer to Tube Manual for details

18.1.1 Cleaning the Device Enclosure

Clean the device enclosure using **a hydrogen peroxide–based cleaning and disinfection wipe**. **Diversey Oxivir has been validated by the manufacturer for this purpose**.

1. Wipe the device enclosure **until it is visually clean**, following the wipe manufacturer's cleaning instructions. **Use a minimum of two wipes**.
2. Allow the device to air-dry in an area protected from direct sunlight.

Inspection After Cleaning Perform a visual inspection of the device enclosure. If any visible deterioration is apparent (cracking, crazing, etc.) discontinue use and contact your care provider.

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.

18.1.2 Cleaning the Water Chamber and Transfer Box

1. Disassembly

(1) Remove the Water Chamber according to the instructions in Section 14.1.1.

Remove the Transfer Box as shown in Fig. 18-1.

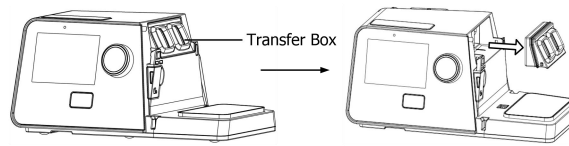


Fig. 18-1

(2) Open the cap of the Water Chamber as shown in Fig. 18-2 and discard any remaining water.

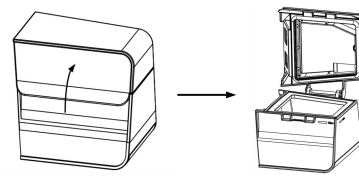


Fig. 18-2

2. Cleaning

Select the appropriate cleaning method based on the intended use conditions.

A. Home Cleaning

(1) Prepare a mild dishwashing liquid solution using 1 teaspoon of dishwashing liquid (the manufacturer has validated DAWN) per gallon of warm drinking-quality water. Do not exceed 60°C.

(2) Soak the Water Chamber and Transfer Box in the solution for 5 minutes, then gently agitate to clean.

(3) Thoroughly rinse the Water Chamber and Transfer Box under running water for 1 minute to eliminate all dishwashing liquid residue.

(4) Inspect the components for cleanliness. If necessary, repeat the cleaning steps until all surfaces are visibly clean.

(5) Wipe the components dry with a soft cloth or allow them to air-dry out of direct sunlight.

NOTE: The Water Chamber and Transfer Box may be washed in a dishwasher on the delicate cycle (top shelf only).

Dishwasher parameter setting requirements:

Water temperature: 45°C to 55°C

Washing time: Minimum 60 minutes

Washing mode: Delicate cycle

Drying: Air-dry out of direct sunlight

Detergent: Dishwasher detergent pods (the manufacturer has validated Cascade).

B. Clinical Cleaning

(1) Preparation

Preparation tools: Soft-bristled brush, drinking-quality water, mild liquid detergent

Detergent: Mild alkaline, anionic detergent (the manufacturer has validated Alconox)

Concentration: 1:100

Temperature: 45°C to 60°C (113°F to 140°F)

(2) Rinse the Water Chamber and Transfer Box with running water for at least 2 minutes.

(3) Immerse the Water Chamber and Transfer Box in the detergent solution for at least 5 minutes. While immersed, clean the Water Chamber and Transfer Box with a soft-bristled brush for at least 1 minute, paying particular attention to crevices and cavities.

(4) Then rinse with running water for 5 minutes. Wipe it dry with a soft cloth or air dry out of direct sunlight.

3. Reassembling

Reinstall the Transfer Box as shown in Fig. 18-3.

Reinstall the Water Chamber according to the instructions in Section 14.1.3.

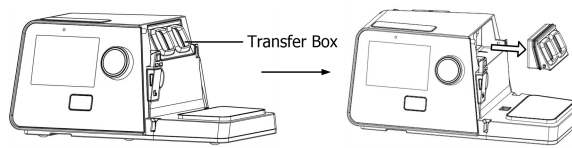


Fig. 18-3

⚠***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. To make sure that no water enters the device, please disconnect the water chamber from the device prior to cleaning.

• 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, 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 do daily cleaning of the water chamber.

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

18.1.3 Cleaning and Replacing the Reusable Air Filter/Optional Disposable Ultra-Fine Filter

Replace the reusable air filter every 6 months. Replace the disposable ultra-fine filter every 2 weeks. Replace the filters sooner if holes, damage, or blockage due to dirt or dust are observed.

(1) Open the filter cap and remove the reusable air filter. To install a new reusable air filter, place it into the filter cap as shown in Fig. 18-4..

Fig. 18-4

(2) If using the optional disposable ultra-fine filter, remove the filter cap and remove the disposable ultra-fine filter. To install a new disposable ultra-fine filter, place the reusable air filter into the filter cap first, then place the disposable ultra-fine filter on top. The disposable ultra-fine filter must be positioned closest to the device, as shown in Fig. 18-5.

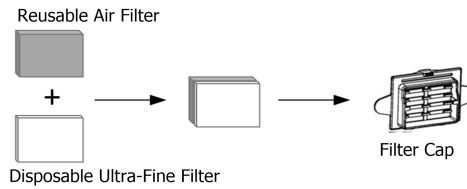


Fig. 18-5

(3) Install the filter cap containing the reusable air filter and, if applicable, the disposable ultra-fine filter onto the device as shown in Fig. 18-6.

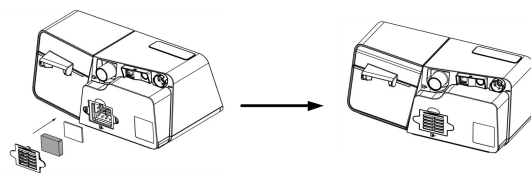


Fig. 18-6

(4) If the reusable air filter is dirty, clean it as follows:

Preparation tools: Tap water [5°C to 35°C (41°F to 95°F)].

Rinse the reusable air filter under running tap water at 5°C to 35°C (41°F to 95°F) for at least 2 minutes. While rinsing, gently press the air filter, but do not pull on it.

After cleaning, place the reusable air filter in a cool area to air-dry away from direct sunlight.

Allow the reusable air filter to dry completely before reinstalling

CAUTION: Do not install a wet filter into the device. Ensure the reusable air filter is completely dry before installation.

The reusable air filter may be cleaned up to four times per month when used in environments with high dust levels.

The disposable ultra-fine filter is not washable or reusable.

CAUTIONS!

• To avoid material damage, do not place the spare reusable air filter in direct sunlight, humid environments, or temperatures below the freezing point. The reusable air filter should be replaced every 6 months, and the disposable ultra-fine filter should be replaced at least every 2 weeks. Replace the filters more often if there are any holes or blockages by dirt or dust.

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

• Please replace the manufacturer-recommended filter periodically; Please clean the reusable air filter if it is contaminated.

18.1.4 Cleaning the Mask and Headgear

For cleaning instructions, refer to the user manual provided with the mask.

18.1.5 Cleaning the Tube

For cleaning instructions, refer to the user manual provided with the L1 and LH1 tubing.

18.2 Disinfection

Accessories that need to be disinfected	**Chemical Disinfection**	**High Temperature Disinfection**
Device Enclosure	hydrogen peroxide cleaning and disinfection wipes	-
Water chamber and Transfer box	OPA solution at 0.55% concentration	90°C to 92°C water
Mask and Headgear	Refer to Mask Manual for details	
Tube	Refer to Tube Manual for details	

18.2.1 Disinfecting the Device Enclosure

1. Repeat the cleaning procedure using a new wipe, following the wipe manufacturer's instructions for disinfection.
2. Allow the device to air-dry in an area protected from direct sunlight.

NOTE: Failure to clean the device enclosure as indicated may result in inadequate

disinfection.

NOTE: Drying is not required after cleaning if disinfection is performed immediately.

Inspection After Disinfecting

Perform a visual inspection of the device enclosure. If any visible deterioration is observed (cracking, crazing, etc.), discontinue use and contact your healthcare provider.

18.2.2 Disinfecting the Water Chamber and Transfer Box

Refer to section 18.1.2 for disassembly and reassembly procedures.

Preparation Before Disinfection

Preparation tools: Soft-bristled brush, drinking-quality water, applicable disinfectant.

Disinfection is not required for home use if the cleaning instructions have been followed. Disinfection may be required if the device or components are contaminated or used in clinical or investigational settings.

Perform only one disinfection method at a time.

A. Chemical Disinfection:

The Water Chamber and Transfer Box may be disinfected using an OPA solution at a concentration of 0.55%. The manufacturer has validated CIDEX OPA for this purpose.

1. Clean the Water Chamber and Transfer Box according to the cleaning instructions.
2. Prepare a plastic container with sufficient CIDEX OPA solution (0.55%) to completely submerge the components.
3. Immerse the Water Chamber and Transfer Box in the solution for 12 minutes.
4. Rinse the components three times using 8 L of purified water to remove residual disinfectant.
5. Wipe the components dry with a soft cloth or allow them to air-dry out of direct sunlight.

B. High Temperature Disinfection (90°C to 92°C water)

1. Clean the Water Chamber and Transfer Box according to the cleaning instructions.
2. Open the cap of the Water Chamber. Immerse the Water Chamber and Transfer Box in water heated to 90°C to 92°C and maintain immersion for at least 5 minutes.
3. Wipe the components dry with a soft cloth or allow them to air-dry away from direct sunlight.

18.2.3 Disinfecting the Mask and Headgear

For cleaning instructions, refer to the user manual provided with the mask.

18.2.4 Disinfecting the Tube

For cleaning instructions, refer to the user manual provided with the L1 and LH1 tubing

19. Traveling

19.1 Traveling with the Device

(1) Use the REACT HEALTH carrying case to carry the device and accessories along with you. Do not put them in your checked baggage.
(2) This device operates on power supplies 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 necessary, but you will need to find out the types of the power sockets in your destination. Bring, if necessary, a power socket adaptor which can be purchased in electronics stores.
(3) Bring spare filters and necessary documentation if traveling. (filled and signed by your physician).
(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 along with you to help security personnel understand the device.

CAUTIONS!

• Empty the water chamber before packing the device for your trip; in order to prevent any remaining water from entering the device.
• If the device is used when the atmospheric pressure is out of the stated range (See Section 6), the accuracy of the leakage alert will be affected.

19.2 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.

20. Reordering

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

⚠***WARNINGS!***

• If you notice any unexplained changes in the performance of the device, if it is making unusual or harsh sounds, if it has been dropped or mishandled, if the enclosure is broken, or if water has entered the enclosure, discontinue use. Contact your healthcare provider.
• If the device malfunctions, contact your healthcare provider immediately. Never attempt to open the enclosure of the device. Repairs and adjustments must be performed by REACT

HEALTH - authorized service personnel only. Unauthorized service could cause injury, invalidate the warranty, or result in costly damage.

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

21. Technical Support

Please contact your equipment provider 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.

22. Disposal

Electrical product components contain chemical substance which may pollute environment, when the device reaches the end of its service life, dispose of the device and packaging in accordance with local laws and regulations.

23. Troubleshooting

WARNINGS!

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

• Any modification to the device (hardware, software, or accessories) not authorized by the manufacturer will void the warranty and may cause patient injury, death, or legal liability. Retrofitted devices are considered unlicensed medical equipment and must undergo new regulatory approval before clinical use.

CAUTION!

• The effects of degraded sensors and electrodes, or loosened electrodes, that may degrade performance or cause other problems.

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

23.1 Common Problems in Patients and Corresponding Solutions

Problem	Possible Cause	Solution(s)
Dry, cold, runny, and blocked nose	The nasal passages may be sensitive to airflow that is cool or dry.	• Increase the humidifier setting on the device. • Contact your healthcare provider if symptoms persist.
Dry mouth or throat	Air may escape through the mouth during therapy.	• Use a chin strap or a full-face mask, if appropriate. • Contact your healthcare provider for further guidance
Eye irritation	The mask size or model may be incorrect, or the mask may not be positioned correctly, resulting in air leakage.	• Adjust the mask fit and position according to the mask instructions for use. • Do not overtighten the mask, as this may cause pressure marks. • Contact your healthcare provider for assistance with mask selection or fitting.
	Mask cushion (the soft part of the mask) hardens.	• Replace the mask or mask cushion.
Facial redness	The mask is too tight.	Loosen the headgear.
	The mask cushion is worn or damaged. The mask is overtightened.	• Replace the mask or mask cushion if worn or damaged. • Loosen the headgear straps as needed.
	The mask size is incorrect.	• Contact your healthcare provider for a correct-size mask.
	Sensitivity to mask materials.	• If sensitivity to mask materials is suspected, contact your healthcare provider. • Use a mask that is not made with natural rubber latex. Place a lining between the skin and mask.

Problem	Possible Cause	Solution(s)
Water in mask	When the humidifier is in use, condensation may form in the tubing or mask if the room temperature is low.	• Lower the humidifier setting or increase the room temperature. • Place the tubing under bedding or use a tubing cover. • Hang the tubing loosely, and 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 healthcare provider.
Discomfort due to inability to adapt to the treatment pressure	The prescribed treatment pressure may be higher than 13 cmH_2O. Treatment pressure is determined according to the patient's prescription. If the pressure is set too low, therapy may be ineffective.	• Some users may require time to adapt to therapy pressure. • If discomfort persists, contact your healthcare provider or equipment provider for assistance.
Obstructive sleep apnea symptoms reappear.	Symptoms may reoccur due to factors such as weight change, medication use, or mask fit.	• Contact your healthcare provider.
The device is too noisy.	The tubing may not connected properly.	• Ensure the tubing is securely connected.
Air delivered from the device is abnormally hot.	The air inlet of the device may be partially blocked, restricting airflow.	• Replace the reusable air filter and, if applicable, the disposable ultra-fine filter (refer to Section 18.1.3). • Clean the disposable ultra-fine filter, if applicable, and clean the reusable air filter. • Place the device in an area with unrestricted airflow. Ensure the device is at least 20 cm away from walls, curtains, or other objects.

23.2 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 normal breaths with the mask on to activate the device if Auto On/Off is enabled.
	The power cord or power adapter is not connected properly	• Ensure the power cord, power adapter, and device connections are secure.
	There is no power supply.	• Check whether a power outage has occurred. If other devices are functioning and the issue persists, contact your healthcare provider or equipment provider.
The device is working, but the pressure inside the mask differs from the set treatment pressure.	The tubing is not connected properly.	Ensure the tubing is securely connected.
	There may be holes in the mask or pressure sensing tubing.	Inspect the mask and tubing for damage. Contact your healthcare provider or equipment provider for assistance.
	The device may be faulty.	• Contact your healthcare provider or equipment provider for assistance.
The device produces very low pressures.	The air inlet of the device may be blocked.	• Replace the reusable air filter and, if applicable, the disposable ultra-fine filter (refer to Section 18.1.3). • Clean the reusable air filter and, if applicable, the disposable ultra-fine filter. Ensure the air inlet is not obstructed.
	The treatment pressure has been changed accidentally.	Verify the prescribed treatment pressure settings. Contact your physician.
	The Ramp feature is enabled.	If necessary, disable the Ramp feature or reduce the ramp time.
After the device is turned on, the screen displays intermittent or no information	The device operating system may require restarting.	Unplug the power cord of the device and reconnect it after 20 seconds later.
The device is in standby, and will not start.	The device operating system may require restarting.	Unplug the power cord of the device and reconnect it after 20 seconds later.

24. 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 transmission between the G3 X APAP with a Cellular Module and React Health Connect is a daily transmission. The Cellular Module transmits the following four types of data: Therapy summary data in a defined period, compliance data, system settings, and device information.

This process is not real time communication.

The size of the data transmitted to Cellular Module per second is no more than 1 KB in normal condition, and no more than 1 MB within 8 hours per night.

Acceptable latency

As the user information is not viewed by the physician in real time, sometimes it can be delayed for 24 or more hours.

Acceptable level of probability for loss of information within the network

The data has little effects 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 do not rely on network quality.

Based on the checking mechanism, if the data mentioned above is transmitted incorrectly, then it will be discarded and the correct data will be sent continuously.

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

Signal priorities of the network

The therapy device itself does not have high-priority medical device alerts, and its treatment of patients does not rely on wireless communications.

Based on the above analysis, the Cellular Module has low requirements for QoS.

25. 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 to 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz	3 V 0.15 MHz to 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.17\sqrt{p}$ $d = 0.35\sqrt{p}$ 80 MHz to 800 MHz $d = 0.70\sqrt{p}$ 800 MHz to 2.5 GHz Where p is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	
Note 1: At 80 MHz and 800 MHz, the higher frequency range applied. Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device. [b] Over the frequency range 150 kHz to 80 MHz, the field strengths should be less than 10 V/m.			

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

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

Rated maximum output of transmitter (W)	150 kHz to 80 MHz $d = 1.17\sqrt{p}$	80 MHz to 800 MHz $d = 0.35\sqrt{p}$	800 MHz to 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!***

• The 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 must do so, the device should be observed to verify normal operation.

• Use of the device 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 are operating normally.

• Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper 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 G3 X APAP, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

• The device may be interfered with by other equipment, even if that other 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 stay away from the interfered electromagnetic environment, or find and turn off the electromagnetic field interference source before continuing to use it.

• When the device 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 operation of the device, due to electrostatic interference, the following phenomena may occur: (1) Temporary loss of function or degradation of performance, such as abnormal screen display. The device will recover to normal after being restarted; (2) Automatic restart of the device. These phenomena will not affect the normal use of the device and will not cause permanent performance degradation or function loss of the device.

26. 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 five (5) years for main device and three (3) months for all accessories from the date of sale by REACT HEALTH to the dealer. 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 dealer 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 dealers or:

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For patent information, see en.bmc-medical.com/legal-statement.html

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