Luna TravelPAP®

User Manual

Auto CPAP System

REACTHEALTH

RespShop

Luna TravelPAP® User Manual

Table of Contents

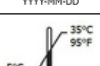
1. Symbols 1
1.1 Control Buttons 1
1.2 Device Symbols 1
2. Warning, Caution and Important Tips 2
3. Intended Use 2
4. Contraindications 3
5. Specifications 4
6. Available Therapies 6
7. Glossary 6
8. Model 7
9. Package Contents 8
10. System Features 9
11. First Time Setup 11
11.1 Download the LightTrip (US) App software 11
11.2 Placing the Device 11
11.3 Installing the Air Filter and Filter Cap 12
11.4 Connecting to Power 13
11.5 Assembling the Tubing and Mask 14
11.6 Establish connection via **Bluetooth®** wireless technology 15
11.7 Using the LightTrip (US) App 15
11.8 Starting Treatment 16
12. Routine Use 16
12.1 Connecting the Tubing 16
12.2 Adjusting the Tubing 16
12.3 Turning on the Airflow 16
12.4 Using the Ramp Function 17
12.5 Turning the Device Off 17
13. Prompts to Device and LightTrip (US) App Prompts 17
14. Software Upgrading 18
15. Cleaning and Maintenance 19
15.1 Cleaning the Mask and Headgear 20
15.2 Cleaning the Enclosure 20
15.3 Cleaning the Tube 20
15.4 Replacing the Air Filter 20
16. Traveling with the Device 21
16.1 Traveling 21
16.2 Traveling by airplane 21
17. Reordering 22
18. Disposal 22
19. Troubleshooting 22
19.1 Common Problems in Patients and Corresponding Solutions 23
19.2 Common Problems in the Device and Corresponding Solutions 25
20. EMC Requirements 26
21. Limited Warranty 32

1. Symbols

1.1 Control Buttons

Bluetooth® Button	Start/Stop Button
	

1.2 Device Symbols

	Follow Instructions for Use	LOT	Batch Code
	Compliant to RTCA DO-160G		Manufacturer
	Type BF Applied Part (mask) Class II (Double Insulated)	Rx Only	Prescription only
		FC	Federal Communications Commission Approved
	AC Power	Bluetooth®	Bluetooth® logo
	DC Power		Nonionizing radiation
IP22	≥12.5 mm Diameter, Dripping (15° tilted)	MD	Medical Device
SN	Serial Number	UDI	Unique device identifier
#	Model Number		Humidity limitation
	Made in China, date of manufacture		Atmospheric pressure limitation
	Operating temperature range		Storage temperature range

2. Warning, Caution and Important Tips

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 app ly.

3. Intended Use

Auto CPAP System is a CPAP (Continuous Positive Airway Pressure) device designed for the treatment of adult Obstructive Sleep Apnea (OSA) only, either in the hospital or at home.
Auto CPAP System is for prescription use only. It is a travel CPAP device intended for single-patient use.

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.
- 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, discontinue use and contact your healthcare provider.
- Do not use with oxygen.
- Any serious incidents that occur in relation to this device should be reported to the manufacturer and the competent authority in your country.

• Do not introduce fragrances or aromatherapy odors into the interior of the machine.
• 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.

CAUTION!

Federal law restricts this device to sale by or on the order of a physician.

IMPORTANT TIPS!

• Read and understand the entire user manual before operating this system. If you have any questions concerning the use of this system, contact your healthcare provider or physician.
• The pictures in the user manual are only for reference, if they are different from the material objects, the latter shall prevail.

4. 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 a 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 due 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

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.

CAUTION!
• Contact your physician if symptoms of obstructive sleep apnea reoccur. Contact your physician if you have any questions concerning your therapy.

5. Specifications

Device Size
Dimensions: 159 mm × 66 mm × 72 mm (6.25” × 2.59” × 2.83”)
Weight: <400 g (<14 oz)

Product Use, Transport and Storage

Operation	Transport and Storage
Temperature: 5°C to 35°C (41°F to 95°F)	-25°C to 70°C (-13°F to 158°F)
Humidity: ≤93% Non-condensing	≤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

Mode of Operation Continuous
Work Mode CPAP, AutoCPAP
AC Power Consumption 100 V to 240 V ~, 50 Hz/60 Hz, 1.0 A max
Main Device Input 19 V, 1.26 A
Type of Protection Against Electric Shock Class II Equipment
Degree of Protection Against Electric Shock Type BF Applied Part
Degree of Protection Against Ingress of Water IP22
Pressure Range 4 cmH2O to 20 cmH2O (in 0.5 cmH2O increments), ≤30 cmH2O under single fault conditions.
Pressure Display Accuracy ±(0.5 cmH2O + 4%)
Static Pressure Stability ±0.5 cmH2O
Ramp The ramp time ranges from 0 to 60 minutes in 5 minutes increments.

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
30 dB(A)	2 dB(A)	38 dB(A)	2 dB(A)

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

Maximum Flow					
TestPressures(cmH2O)	4	8	12	16	20
Measured Pressure at thePatientConnection Port (cmH2O)	3	7	11	15	19
Average Flow at the PatientConnectionPort (L/min)	85	125	110	110	95

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.

The following are measured according to ISO 80601-2-70 201.12.1.103

Air Tubing			
Air Tubing	Connector Port	Length 1.83	Inner Diameter
Tubing	22mm 22mm	m (6 ft.) 1.83	15mm 19mm
Tubing		m (6 ft.)	

The Form and the Dimensions of the Patient Connection Port
The 22 mm conical air outlet complies with ISO 5356-1.

Air Filter
Filtration efficiency: >20% for 10 micron
Material: Non-woven fabric and Polyester

Bluetooth® Qualification Information
Product name: Luna TravelPAP®
DID: D062405
QDID: 154506

Bluetooth® Module Featuring	
Technology	Bluetooth
Connection types	GATT
Frequency	2400 MHz to 2483 MHz
Max RF power output	+4 dBm
Operating range	10 m (Class 2)

6. 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
Delivers CPAP therapy and automatically adjusts the pressure based on the patient's needs.

7. Glossary

Apnea
A condition marked by the cessation of spontaneous breathing.

AutoCPAP
Adjust CPAP pressure automatically to improve patient comfort based on monitoring of respiratory 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 always enabled.

CPAP
Continuous Positive Airway Pressure.

LPM
Liters Per Minute.

MD
Indicates the item is a Medical Device.

OSA
Obstructive Sleep Apnea.

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

Ramp
A feature that may increase patient comfort when therapy is started. It can reduce pressure and then gradually increase the pressure to the prescription setting so the patient can fall asleep more comfortably.

Res lex
A therapy feature that is enabled by you or your healthcare provider to provide pressure relief during exhalation.

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

min
Means the time unit "minute".

h
Means the time unit "hour".

yy mm dd/mm dd yy/dd mm yy
Means the date.

CAUTION!
• Indexes such as Apnea, AHI, Hypopnea shown on the screen are only monitoring data provided by the device, not diagnostic parameters.

8. Model

Model	Product Description					
	Product Contents	Optional Accessory 1	Optional Accessory 2	Optional Accessory 3	Work Mode	Maximum Work Pressure (cmH2O)
Luna TravelPAP®	Main device	Mask	Carrying	DC	CPAP, AutoCPAP	20

*Download the free LightTrip (US) App on the Android or IOS platform

9. Package Contents

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

No.	Articles	Qty,	Notes
1	Main Device	1	
2	Tubing	1	
3	Storage Bag	1	
4	Air Filter	3	
5	Power Adapter	1	
6	Accompanying Documents	1	
7	Mask	1	Optional
8	Carrying Case	1	Optional
9	DC Adapter	1	Optional

All parts and accessories are not made with natural rubber latex. The expected service life of the device is five (5) years from first date of use, if the use, maintenance and cleaning are in strict accordance with the User Manual. The shelf life of the device is ten (10) years. Refer to the user manuals of the tubing and mask for their respective service lives.

WARNINGS!

• This 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.
• 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 listed package contents 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.

10. System Features

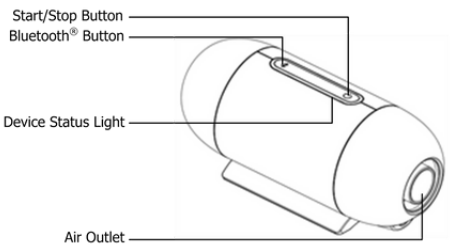


Fig. 10-1

Name	Function
Start/Stop Button	Press this button to Start/Stop delivering air. The indicator light is white.
Bluetooth®Button	Press this button to connect to Bluetooth® wireless technology, double click this button to stop using Bluetooth® wireless technology. The indicator light is blue.
Air Outlet	Delivers pressurized air; connected to the tube.
Device Status Light	This light is white in normal state and orange in case of prompt message.

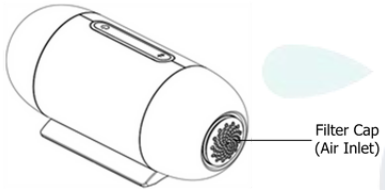


Fig. 10-2

Name	Function
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.

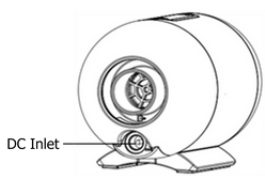


Fig. 10-3

Name	Function
DC Inlet	An inlet for the DC power supply.

11. First Time Setup

11.1 Download the LightTrip (US) App software

Search and download the LightTrip (US) App on the App Store. Supported on both Android and IOS platforms.

11.2 Placing the Device

Place the device on a firm, flat surface. The anti-skid pads installed at the bottom of the device are designed to stabilize the device.

WARNINGS!

• If the device has been dropped or mishandled, if the enclosure is broken, or if water has entered the enclosure, disconnect the power cord and discontinue use. Contact your healthcare provider immediately.
• If the room temperature is higher 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!

• If the device has been exposed to either very high or very low temperatures, allow it to adjust to room temperature (20°C, 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 children and pets away from the device to 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.

11.3 Installing the Air Filter and Filter Cap

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

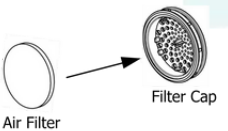


Fig. 11-1

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

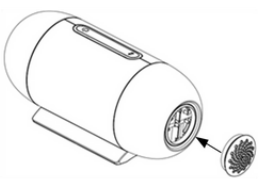


Fig. 11-2

CAUTIONS!

- The air filter must be in place when the device is operating.
- Do not block the gas INTAKE PORT, which would interfere with the treatment.
- Please change the Air Filter regularly and don't block it.
- Fire, open ignition source and smoking prohibited.
- Air filters provided by the manufacturer are recommended for use, otherwise foreign objects or odors may enter the device.

11.4 Connecting to Power

1. Insert the plug of the power adapter into the DC Inlet of the device.

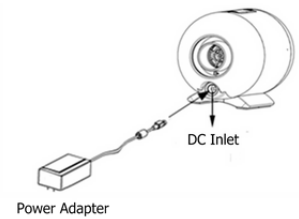


Fig. 11-3

2. Plug the other end of the power adapter into the power outlet.

WARNINGS!

• The device is powered on for use when the power adapter is connected. The Button ⏻ onstheblowerOn/Off.
• Use of the device at an AC voltage beyond the stated range (see Section 5 "AC Power Consumption") may damage the device or cause device failure.
• Do not place the device where it is difficult to disconnect the power supply.
• Do not stack long cables or tubing at the head of the bed, which may entangle the head or neck of the patient during sleeping.

CAUTION!

• Inspect the power adapter cord often for any signs of damage. If the cord is damaged, replace the power adapter immediately.

IMPORTANT TIP!

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

11.5 Assembling the Tubing and Mask

1. Connect one end of the tube to the air outlet of the main device, as shown in Fig. 11-4.

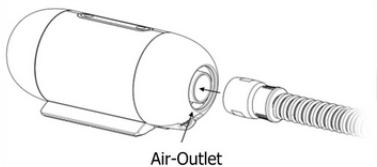


Fig. 11-4

2. Connect the other end of the tube to the mask according to the user manual for the mask. Wear the mask.

WARNINGS!

• If you are using a mask with a built-in exhalation port, connect the mask's connector to the tube.
• If you are using a mask with a separate exhalation port, connect the tube 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 CO2 rebreathing, the patient should observe the following instructions:
- Use the accompanying tube and mask provided by REACT HEALTH.
- Do not wear the mask for more than a few minutes while the device is not o pe rati ng.
- Use a vented mask. Do not block or try to seal the vent holes in the exhalation po rt.
• Failure to use a mask or accessory that minimizes rebreathing of carbon dioxide or permits spontaneous breathing can cause asphyxiation.
• The proper placement and positioning of the MASK on the face is critical to the consistent operation of this device.
• Do not use with oxygen.

11.6 Establish connection via Bluetooth® wireless technology

1. Connect the device to a power supply. Press the Bluetooth® button on the main device. The Bluetooth® indicator light will flash. 2. Open the LightTrip (US) App, click the Bluetooth® icon, and start to search for the device. 3. Select the Luna TravelPAP® device in the device list by the name of device serial number on nameplate information for connection. 4. If the device is connected with LightTrip (US) App via Bluetooth® wireless technology successfully, the Bluetooth® indicator light on the main device will be always on. **QoS:** Wireless Quality of Service (QoS) refers to the necessary level of service and performance needed for the wireless functions of the device. It involves parameters such as reliability of data transmission, effective transfer rate, error rate, and mechanisms to define priority levels for time critical signals. **Bluetooth® QoS:** Bluetooth® wireless technology uses frequency hopping,
channel coding, and error correction to address interference, and is designed to operate with other devices that occupy the same spectrum. In addition to the measures defined in the Bluetooth® standard, the Luna TravelPAP® radio incorporates other methods to minimize likelihood of QoS problems. These include: - Data sent between the CPAP and any external devices use an additional checksum verification to ensure that data is correctly received without errors. - The device is portable and will not always be near the mobile device when it is ready to transfer data. The mobile device will attempt to reconnect until it has successfully connected and completed the data transfer.
- No real-time data needs to be transmitted. If the data transmission is unsuccessful, the data will not be lost. After the connection via Bluetooth® wireless technology is successful again, it will be re-transmitted.

11.7 Using the LightTrip (US) App

Once connected to the LightTrip (US) App - go to the More menu and select App Instructions for details on how to operate and set up your Luna TravelPAP® using the LightTrip (US) App.

11.8 Starting Treatment

Press the **Start/Stop Button** or click on the icon in the LightTrip (US) App, 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.
- 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.

12. Routine Use

12.1 Connecting the Tubing

Connect the power adapter and tubing properly according to the instructions in the First Time Setup (Chapter 11). Connect the mask and headgear according to the user First Time Setup (Chapter 11).

CAUTION!

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

12.2 Adjusting the Tubing

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

12.3 Turning on the Airflow

Press the **Start/Stop Button** or click on the icon in the LightTrip (US) App to turn on the airflow. The LightTrip (US) App will display treatment pressure and other information.

12.4 Using the Ramp Function

When the Ramp function is turned on, the pressure will gradually rise to the prescribed treatment pressure according to the preset ramp time from the initial pressure to help the patient fall asleep. The LightTrip (US) App displays a real time countdown of the remaining ramp time in minutes.

CAUTION!

• The ramp feature is not prescribed for all users.

12.5 Turning the Device Off

Take off the mask and headgear, press the **Start/Stop Button** click on the icon in the LightTrip (US) App, and the device will stop delivering air.

Disconnect the power adapter from the power outlet to power off the device.

13. Prompts to Device and LightTrip (US) App Prompts

Prompt Message	Description
Power Failure!!!	If the device is accidentally disconnected from power when it is delivering air and the main device is connected with LightTrip (US) App by Bluetooth® wireless technology, a prompt will appear in LightTrip (US) App. Note: The prompt will not appear if power failure occurs when the device is in standby state.
Device Fault!!!	If no airflow comes out of the machine when the device is started, the status light of device will flash. If the main device is connected with LightTrip (US) App by Bluetooth® wireless technology, a prompt of "Device Fault!!!" will appear in LightTrip (US) App.
Leak!!	If the automatic shutdown function of the device is off, when there is a large amount of air leakage in the device, the device status light will flash. If the main device is connected with LightTrip (US) App by Bluetooth® wireless technology, a prompt of "Leak!!" will appear in LightTrip (US) App.
Low Input Voltage!!	If the voltage supplied by the power adapter is too low, the status light of device will flash. If the main device is connected with LightTrip (US) App by Bluetooth® wireless technology, a prompt of "Low Input Voltage!!" will appear in LightTrip (US) App.

Prompt Message	Description
Please Change Filter!	When the Air Filter reminder is set, the status light of the device will flash if the set time expires without replacing the air filter and resetting the reminder. If the main device is connected with LightTrip (US) App by Bluetooth® wireless technology, a prompt of "Please Change Filter!" will appear in LightTrip (US) App.
Please Change Tube!	When the Tubing reminder is set, the status light of the device will flash if the set time expires without replacing the tubing and resetting the reminder. If the main device is connected with LightTrip (US) App by Bluetooth® wireless technology, a prompt of "Please Change Tube!" will appear in LightTrip (US) App.
Please Change Mask!	When the Mask reminder is set, the status light of the device will flash if the set time expires without replacing the mask and resetting the reminder. If the main device is connected with LightTrip (US) App by Bluetooth® wireless technology, a prompt of "Please Change Mask!" will appear in LightTrip (US) App.
Please clean and maintain!	When the Days Since Last Maintenance reminder is set, the status light of the device will flash if the set time expires without cleaning or maintaining the device and resetting the reminder. If the main device is connected with LightTrip (US) App by Bluetooth® wireless technology, a prompt of "Please clean and maintain!" will appear in LightTrip (US) App.

14. Software Upgrading

Refer to the section "Firmware Update" in your LightTrip (US) App manual.

CAUTIONS!

• Please maintain the connection by Bluetooth® wireless technology between the LightTrip (US) App and main device during firmware upgrading.
• In order to ensure the best performance, it is recommended to keep the latest version of the LightTrip (US) App and device firmware.

15. Cleaning and Maintenance

WARNINGS! • Regular cleaning of the device and its accessories is very important for the prevention of respiratory infections. • To avoid electric shock, always unplug the device before cleaning. • Use washing liquid that is nontoxic to humans and does not cause allergies in hu m an s. • Follow the manufacturer's instructions on cleaning the mask and tube and on determining the frequency of cleaning. • 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. Unauthorized service could cause injury invalidate warranty or results in costly damage. • Avoid the use of any CPAP cleaner or disinfection device that relies on ozone (i.e. activated oxygen). Device warranty may terminate if the damage is caused by the use of an ozone cleaner. • In order to prevent contamination of the device, use only manufacturer-approved filters on this device conforming to ISO 23328-1:2003 and ISO 23328-2:2002 standards. • Do not clean or disinfect the device other than is recommended in this manual, as it may damage the device.

CAUTIONS!

• Overheating of the materials could lead to early wear of these materials.
• Do not use solutions containing chlorinated lime, chlorine, or aromatic to clean the device and its accessories. Liquid soap containing humidifying agents or antimicrobials should not be used either. These solutions may harden cleaned materials or reduce their life.
• Do not clean with water above 80°C (176°F) or dry the device and its accessories in an environment with the temperature higher than 80°C (176°F). High temperatures could reduce product life.
• Do not immerse the device in any fluids.

15.1 Cleaning the Mask and Headgear

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

15.2 Cleaning the Enclosure

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

CAUTION!

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

15.3 Cleaning the Tube

For details, refer to the cleaning instructions in the user manual of the L1 tube.

15.4 Replacing the Air Filter

1. Filter must be replaced at least every 6 months. It cannot be washed.
2. Open the air filter cap to remove the air filter, as shown in Fig. 15-3.

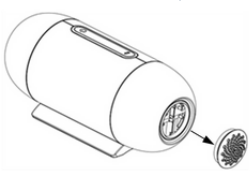


Fig. 15-3

3. Remove and discard the old air filter.
4. Put the new air filter in the filter area, and then place the filter cap back properly.

CAUTIONS!

• To avoid material damage, do not place the spare air filter in direct sunlight, in a humid environment or at temperatures below the freezing point. The air filter should be re-placed at least **every 6 months** (Local air quality may shorten the replacement cycle time). Replace the air filter if it is damaged or cracked.
• Operating the device with a dirty air filter may stop it from working properly and may cause damage to the device.

16. Traveling with the Device

16.1 Traveling

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 to 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. If necessary, bring a power socket adaptor, which can be bought in electronics stores. 3. Remember to bring a spare air filter and the emergency documents (filled and assigned by your physician) about this device. If you plan to travel by air, remember to bring the emergency documents about respiratory therapy, in case that the border and customs officers in your destination country inspect the device. With the emergency documents, you can prove to them that it is a medical device. 4. Airport Security including TSA: For convenience at security stations, there is a note on the bot- tom 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.

CAUTION!

• If the device is used when the atmospheric pressure is out of the range listed below, the accuracy of the leakage alert will be affected.

Operation	Transport and Storage
Atmospheric Pressure: 760 hPa to 1060 hPa	760 hPa to 1060 hPa

16.2 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 Luna TravelPAP® 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.

WARNINGS!

• When connected to power, double click the Bluetooth® button to stop using the Bluetooth® wireless technology (enter airplane mode).
• Do not use the LightTrip (US) App when on the plane.

•UsetheStart/StopButton onyourdevicetostartorstoptherapy.
• To reconnect the connection by Bluetooth® wireless technology (exit airplane mode), press the Bluetooth® button on the device.

17. 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 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 healthcare provider for technical support and documents.

18. Disposal

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

19. Troubleshooting

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

19.1 Common Problems in Patients and Corresponding Solutions

Problem	PossibleCause	Solution(s)
Dry,cold,runny,and blockednose;	The nose reacts to the airflow and cold. Due to fast airflow, theair becomescold cold, leading to mucosa irritation andphysiansuggeststheopposite subsequent dryness and swell ing	Contact your physician, and continue treatment unless the
Drymouthandthroat	Probably because the patient sleeps with his or hermouthopen,andthemouth during pressurized air goes out via the mouth, leading to	Use a chin strap to prevent the from opening sleep, or use a full-face mask. Contact your physician for
Eyeirritation	Themasksizeormodelmay not be correct, or the is not positioned correctly, thereby leading to leakage	Narrow the distance between the forehead support of the mask and the forehead. Note airthatadjustingthemasktootight may leave markingson the patient's face
	Mask cushion (the soft part ofthemask)hardens	Replace the mask or mask cushion
Facialredness	Themaskistootight	Loosentheheadgear
	The distance between the forehead support of the angle mask and the forehead is notcorrect	Try a different distance. The and size of the forehead support differ according to the typeofmasks
	Wrongmasksize	Contactyourhealthcareprovider foracorrect-sizemask
	The patient may be allergic to the materials of the mask	Use a mask which is not made with natural rubber latex. Contact your physician and healthcare provider. Place a lining between the skin and mask

Problem	PossibleCause	Solution(s)
Nasal,sinus,orearpain Sinus or middle earContact inflammation		your physician immediately
Discomfortduetoinability toadapttothetreatment patient's conditions, and cannot treat sleep apnea if the treatment pressure is set too low	The patient will feel uncomfortable when the treatmentpressureishigher than the treatment pressure is determinedaccordingtothe	It takes a maximum of four 12 cm H2O to adapt to pressurized air. Relaxandbreathethroughthe nose.Iftheproblemstillexists, contact your physician
Obstructivesleepapnea occurswhenthemouth, throat, or blockage in the respiratory tract	Probably because the patient sleeps with his or her mouth open, leading to pressurizedairgoesoutviasleep	Use a chin strap to prevent the mouth from opening during oruseafull-facemask. Contact your physician for details
Air delivered from the device isabnormallyhot	Reconnect the tube properly The tube is not connected properly The air inlet of the device maybepartiallyblocked,leading to insufficientwhereairflowsfreely,andmake surethedeviceisatleast20 centimeters (7.88 inches) away from the wall, curtain, or other things	Replacing the Air Filter), and cleantheairinlet Placethedeviceinanarea allowsthedevice

19.2 Common Problems in the Device and Corresponding Solutions

Problem	PossibleCauses	Solution(s)
The device does not work whenitisturnedon	The Auto On/Off feature is enabled, and the device will start automatically	Take a few deep breaths with the mask on and the device will start automatically
	Power is not connected properly	Ensure that the power adapter, and the device are connected properly
	There is no voltage	Check whether a power outage occurs by turning on a light or other means. If you are sure the fuse in the device is broken, contact your healthcare provider for repair
	Cannot find any cause	Contact your healthcare provider
The device is working, but the pressure inside the mask differs from the set treatment pressure	The tube is not connected properly	Reconnect the tube properly
	There may be holes in the mask or pressure sensing tube	Contact your healthcare provider
	It is a faulty device	Contact your healthcare provider
	The effects of degraded sensors and electrodes, or loosened electrodes	Contact your healthcare provider
The device produces very low pressures	The air inlet of the device may be blocked	Replace the air filter (see 15.4 Replacing the Air Filter), and clean the air inlet. Make sure the air inlet is unblocked
	The treatment pressure has been changed accidentally	Contact your physician
	When the Ramp feature is enabled, it takes some time for the initial pressure to feature rise to the treatment pressure. This is normal	If necessary, disable the Ramp feature, or set the ramp time shorter
The device is in standby, and will not start	The operating system of the device needs to be readjusted or restarted	Unplug the power cord of the device, and re-plug it 20 seconds later

20. EMC Requirements

According to Clause 201.4.3.101 of ISO 80601-2-70:2020, sleep apnea breathing therapy equipment is considered to not have essential performance.
Notwithstanding this fact, when the standard refers to essential performance as acceptance criteria, the static pressure shall be evaluated.
The cables must be provided by REACT HEALTH. The information of each cable is as follows:
1. Power adapter: 1800 mm ± 45 mm, unshielded.
2. Tubing: 1800 mm ± 10%, unshielded.

Guidance and manufacturer's declaration - electromagnetic emissions	
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should ensure that it is used in such an environment.	
EmissionsTest	Compliance
RFemissionsCISPR11	Group1
RFemissionsCISPR11	ClassB
HarmonicemissionsIEC61000-3-2	ClassA
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies

Guidance and manufacturer's declaration - electromagnetic immunity		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
ImmunityTest	IEC60601TestLevel	ComplianceLevel
Electrostaticdischarge(ESD) IEC61000-4-2	±8kVcontact ±15kVair	±8kVcontact ±15kVair
Electricalfasttransient/burst IEC61000-4-4	±2kVfor powersupplylines	±2kVfor powersupplylines
SurgeIEC61000-4-5	±1kVline(s)toline(s)	±1kVline(s)toline(s)
Voltage dips, short interruptions and voltage variations on power supplyinputlines IEC61000-4-11	0%UT;0.5cycle At 0°, 45°, 90°, 135°, At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 180°, 225°, 270° and 315° 0%UT;1cycle 70%UT;25/30cycle; At0° 0%UT;250/300cycle	0%UT;0.5cycle 0%UT;1cycle 70%UT;25/30cycles At0° 0%UT;250/300cycle
Power frequency (50Hz/60Hz)magneticfield IEC 61000-4-8	30A/m	30A/m
NOTE: UTis the a.c. mains voltage prior to application of the test level.		

Guidance and manufacturer's declaration - electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

ImmunityTest	IEC60601TestLevel	ComplianceLevel
ConductedRF IEC61000-4-6 RadiatedRF	3V0.15MHzto80MHz 6VinISMbandsbetween6VinISMbandsbetween0.15 0.15MHzand80MHz	3V0.15MHzto80MHz MHzand80MHz
IEC61000-4-3	10V/m 80MHzto2.7GHz	10V/m 80MHzto2.7GHz

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

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)	150kHzto80MHz $d = 1.1\sqrt{p}$	80MHzto800MHz $d = 0.35\sqrt{p}$	800MHzto2.5GHz $d = 0.70\sqrt{p}$
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 din meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where Pis 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	IEC60601 TestLevel	Compliance Level
385	1.8	0.3	27	27
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				
5240	2	0.3	28	28
5500	0.2	0.3	9	9
5785				

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

WARNINGS!

• This device should not be used in the vicinity of other electronic equipment such as diathermy, electrocautery and radio frequency identification (RFID), security systems (such as electromagnetic anti-theft systems and metal detectors), cellphone, transceiver or radio control products. If you have to do so, the device should be observed to verify normal 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 Luna TravelPAP® device, including cables specified by the manufacturer. Otherwise, it may result in a reduction in the performance of the device.

• Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this device could result in increased electromagnetic emissions or decreased electromagnetic immunity of this device and result in improper operation.

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

• The device may be interfered 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 soldering, electrosurgery, defibrillation, X-ray (γ ray), infrared radiation, transient electromagnetic field, including nuclear magnetic resonance (MRI) and radio interference environment, the device 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) Device will restart automatically. These situations will not affect the normal use of the device, and will not cause permanent performance degradation or function loss of the device.

21. Limited Warranty

REACT HEALTH warrants that the device shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of two (2) years for main device and three (3) months for all accessories from the date of sale by **REACT HEALTH** to the 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:

REACT HEALTH
5475 Rings Road
Suite 550
Dublin, OH 43017
T: (863) 226-6285
For additional information, please visit our website at: www.reacthealth.com

MANUFACTURER:

BMC Medical Co., Ltd.
Room 10, 17F, Building 4,
Huiya Plaza, No.16 Lize Road,
Fengtai District, 100073 Beijing,
PEOPLE'S REPUBLIC OF CHINA
Tel: +86-10-51663880
URL: en.bmc-medical.com
E-mail: intl@bmc-medical.com

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

Luna TravelPAP® User Manual

V2.2
YF-MP-2-43
300302M391551
Issue date: October 28, 2024

300302M391551