RespShop

Luna TravelPAP™

Auto CPAP System

User Manual

BMC

REACTHEALTH

Table of Contents

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)		Date of Manufacture
	Class II (Double Insulated)		Prescription only
	AC Power		Federal Communications Commission Approved
	DC Power		Bluetooth® logo
	≥ 12.5 mm Diameter, Dripping (15° tilted)		Nonionizing radiation
	Serial Number		Logo of BMC Medical Co., Ltd.
	Model Number		Medical Device
	Made in China		Unique device identifier
	Temperature limit		Humidity limitation
	Atmospheric pressure limitation		

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.

IMPORTANTTIP!
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.

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.

WARNING!

- 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 home care 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.

CAUTION!

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

IMPORTANTTIP!

- Read and understand the entire user manual before operating this system. If you have any questions concerning the use of this system, contact your home care provider or physicians.
- The pictures in the user manual are only for reference, if they are different from th 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 ventric- ular 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 TIP!

- An irregular sleep schedule, alcohol consumption, obesity, sleeping pills, or sedatives may aggravate your symptoms.
- Please use a mask which meets ISO 17510: 2015 and ISO 18562 series standard.

CAUTION!

- Contact your physician if symptoms of sleep apnea recur. 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: 760~1060 hPa	760-1060 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 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 to 20 cmH20 (in 0.5 cmH20 increments),
≤ 30 cmH20 under single fault conditions.
Pressure Display Accuracy ±(0.5 cmH20+4%)
Static Pressure Stability ±0.5 cmH20 **Ramp** The ramp time ranges from 0 to 60 minutes in 5 minute increments.

The A-weighted sound pressure level and sound power level
When the device is working at the pressure of 10 cmH20, its sound pressure level and sound power level shall not be greater than the values in the following table:

Sound Pressure Level	Uncertainty	Sound Power Level	Uncertainty
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					
Test Pressures (cmH20)	4	8	12	16	20
Measured Pressure at the Patient Connection Port (cmH20)	3	7	11	15	19
Average Flow at the Patient Connection Port (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	Inner Diameter
Tubing	22 mm	6 ft. (1.83 m)	15 mm
Tubing	22 mm	6 ft. (1.83 m)	19 mm

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

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 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 apnea and snoring 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.

Reslex
A therapy feature that is enabled by you or your home care 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, 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 (cmH20)
Luna Travel PAP™	Main device	Mask	Carrying Case	DC Adapter	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	Option
8	Carrying Case	1	al
9	DC Adapter	1	Option
			al
			Option
			al

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 followed in strict accordance with the User Manual. The shelf life of the device is ten (10) years. For the expected service life of the tube and mask, refer to their respective user manuals.

WARNING!

- 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 inappropriate 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 TIP!

- If any of the listed package contents are missing, contact your home care provider.
- Contact your home care provider for additional information on the available accessories of this device. When using optional accessories, always follow the instructions enclosed with the accessories.

10. System Features

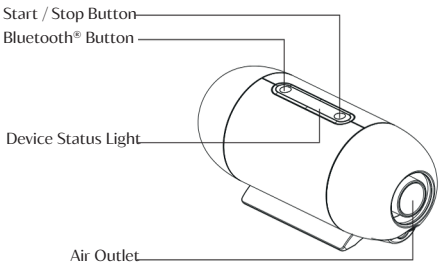

Fig 10-1

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

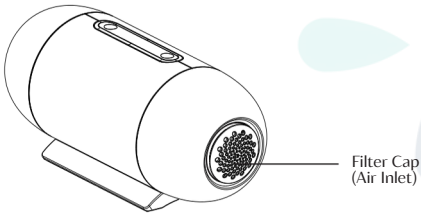

Fig 10-2

Name	Function
Filter Cap (Air Inlet)	Place the cap on the air filter, which is used to filter dust and pollen in the air entering the device.

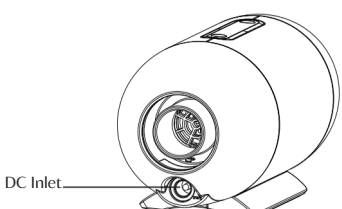

Fig 10-3

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 pad installed at the bottom of the device is designed to stabilize the device.

WARNING!

- If the device has been dropped or mishandled, if the enclosure is broken, or if water has entered the enclosure, disconnect the power cord and discontinue use. Contact your home care provider immediately.
- If the room temperature is higher than 95°F (35°C), the airflow produced by the device may exceed 109.4°F (43°C). The room temperature must be kept below 95°F (35°C) while the patient uses the device.

CAUTION:

- If the device has been exposed to either very hot or very cold 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 avoid 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.

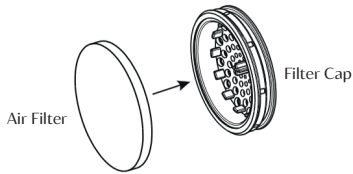

Fig 11-1

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

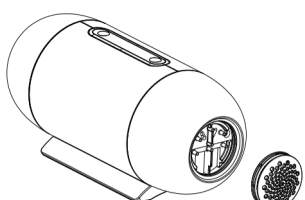

Fig. 11-2

CAUTION!

- 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; open fire and smoking are prohibited near the air filter.

11.4 ConnectingtoPower

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

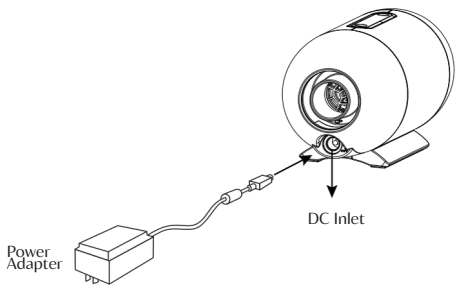

Fig 11-3

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

WARNING!

- The device is powered on for use when the power adapter is connected. The Button turns the blower On/Off.
- Use of the device at an AC voltage beyond the stated range (see Section 5 “AC Power Consumption”) may damage the device or cause device failure.
- 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. Replace a damaged power adapter immediately.

IMPORTANTTIP!

- 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.

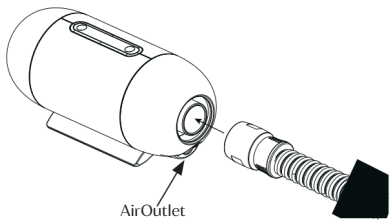

Fig. 11-4

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

WARNING!

- 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 operating.
  - Use a vented mask. Do not block or try to seal the vent holes in the exhalation port.
- 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 retransmitted.

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 ico in the LightTrip (US) App, the device will start delivering air.

WARNING!

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

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 Tim 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 and until there are 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** or 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's 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. If the automatic shutdown function of the device is off, when there
Leak!!	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 Light-Trip (US) App by Bluetooth® wireless technology, a prompt of "Low Input Voltage!!" will appear in LightTrip (US) App.
Please Change Filter!	When the remind cycle of air filter is set, the status light of device will flash if the preset remind cycle reaches but without replacing the air filter and reset remind cycle. 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 remind cycle of tubing is set, the status light of device will flash if the preset remind cycle reaches but without replacing the tubing and reset remind cycle. 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 remind cycle of Mask is set, the status light of device will flash if the preset remind cycle reaches but without replacing the mask and reset remind cycle. 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.

Prompt Message	Description
Please Change Moisture Exchanger!	When the remind cycle of moisture exchanger is set, the status light of device will flash if the preset remind cycle reaches but without replacing the moisture exchanger and reset remind cycle. If the main device is connected with LightTrip (US) App by Bluetooth® wireless technology, a prompt of "Please Change Moisture Exchanger!!" will appear in LightTrip (US) App.
Please clean and maintain!	When the remind cycle of cleaning and maintenance is set, the status light of device will flash if the preset remind cycle reaches but without cleaning or maintaining and reset remind cycle. 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

CAUTION!

- 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

WARNING!

- 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 humans.
- 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.

CAUTION!

- Overheating of the materials could lead to early fatigue of these materials.
- Do not use solutions containing chlorinated lime, chlorine, or aromatic to clean the device and its accessories. Liquid soap containing the humidifying agent 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.

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

CAUTION!

15.3 Cleaning the Tubing

1. Remove the tubing from the device and mask before cleaning.
2. Hold the cuff of the tubing and gently pull it away from the device as shown in Fig. 15-1.

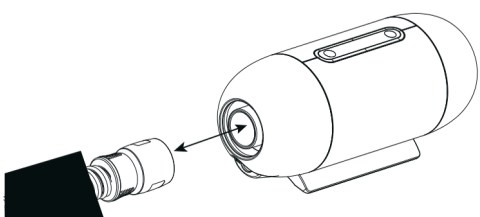

Fig 15-1

3. Hold both the cuff of the air tubing and the swivel of the mask, then gently pull apart as shown in Fig. 15 2.

Fig 15-2

4. Clean the components with a soft bristled brush for one minute while soaking in detergent solution (see the table below). Pay particular attention to all crevices and cavities.

Detergent	Water temperature	Tubing
AlconoxTM (diluted at 1%)	Warm water (approx 113 to 140°F or 45 to 60°C)	√

5. Run the detergent solution through the tubing repeatedly until no contamination is visible.
6. Thoroughly rinse each component according to the detergent manufacturer's instructions.
7. Thoroughly rinse the tubing in drinking quality water (five liters per assembly) by immersing it completely for a minimum of one minute in duration.
8. Repeat the rinse procedure two additional times using fresh water for a total of three rinses.
9. Air dry out of direct sunlight and/or heat.
10. Perform a visual inspection of the components. If any visible deterioration is apparent (holes, tears or cracks etc.), the components should be discarded and replaced. Slight discoloration may occur and is acceptable.

WARNING!

- Please wash by hand.
- The tubing should be cleaned daily.
- If the tubing is damaged (such as broken hole, tear, exposed heated wire, etc.) or functioning poorly, replace immediately.
- Failure to clean in accordance with the Manual may result in reduced performance of the tubing or reduced product life.
- After cleaning and prior to reuse, the tubing should be inspected for holes, creases and tears.

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.

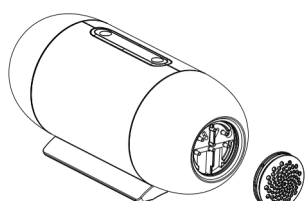

Fig 15-3

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.

CAUTION!

- 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**. The replacement cycle maybe shortened based on local air quality. Please replace if filter 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 - 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.
4. Airport Security including TSA: 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.

CAUTION!

- Using the device at an incorrect elevation setting could result in airflow pressures higher than the prescribed setting. Always verify the elevation setting when traveling traveling or relocating.
- 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 to 1060 hPa	760 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.

WARNING!

- When connected to power, double click the Bluetooth® button to stop using the Bluetooth® wireless technology, and enter airplane mode.
- Do not use the LightTrip (US) App.
- Use the Start/Stop Button on your device to start therapy.
- To reconnect the connection by Bluetooth® wireless technology (exit airplane mode), press the Bluetooth® button on the device.

17. Reordering

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

WARNING!

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

19.1 Common Problems in Patients and Corresponding Solutions

Problem	Possible Cause	Solution(s)
Dry, cold, runny, and blocked nose; having a cold	The nose reacts to the airflow and cold. Due to fast airflow, the air becomes cold, leading to nasal mucosa irritation and subsequent dryness and swelling	Contact your physician, and continue treatment unless the physician suggests the opposite
Dry mouth and throat	Probably because the patient sleeps with his or her mouth open, and the pressurized air goes out via the mouth, leading to nasal and throat dryness	Use a chin strap to prevent the mouth from opening during sleep, or use a full-face mask. Contact your physician for details
Eye irritation	The mask size or model may not be correct, or the mask is not positioned correctly, thereby leading to air leakage	Narrow the distance between the forehead support of the mask and the forehead. Note that adjusting the mask too tight may leave markings on the patient's face
	Mask cushion (the soft part of the mask) hardens	Replace the mask or mask cushion Loosen the headgear
Facial redness	The mask is too tight	Try a different distance. The angle and size of the forehead and support differ according to the type of masks
	The distance between the forehead support of the mask and the forehead is not correct	Contract your home care provider for a correct-size mask
	Wrong mask size	Contact your physician and home care provider
	The patient is allergic to the materials of the mask	Use a mask which is not made with natural rubber latex Place a lining between the skin and mask

Problem	Possible Cause	Solution(s)
Nasal, sinus, or ear pain	Sinus or middle ear inflammation	Contact your physician immediately
Discomfort due to inability to adapt to the treatment pressure	The patient will feel uncomfortable when the treatment pressure is higher than 13 cmH2O. However, the treatment pressure is determined according to the patient's conditions, and cannot treat sleep apnea if the treatment pressure is set too low	It takes a maximum of four weeks to adapt to pressurized air. Relax and breathe through the nose. If the problem still exists, contact your physician
Obstructive sleep apnea symptoms recur	Probably because the patient sleeps with his or her mouth open, and the pressurized air goes out via the mouth, leading to blockage in the respiratory tract	Use a chin strap to prevent the mouth from opening during sleep, or use a full-face mask. Contact your physician for details
The device is too noisy	The tube is not connected properly	Reconnect the tube properly
Air delivered from the device is abnormally hot	The air inlet of the device may be partially blocked, leading to insufficient airflow into the device	Replace the air filter (see 18.4 Replacing the Air Filter), and clean the air inlet
		Place the device in an area where air flows freely, and make sure the device is at least 20 centimeters (7.88"inches) away from the wall, curtain, or other things

19.2 Common Problems in the Device and Corresponding Solutions

Problem	Possible Causes	Solution(s)
The device does not work when it is turned on	The Auto On / Off feature is enabled	Take a few deep breaths with the mask on, and the device will start automatically
	Power is not connected properly	Ensure that the power 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 equipment supplier for repair
	Cannot find any cause	Contact your home care provider
The device is working, but the pressure inside the mask differs from the set treatment pressure	The tube is not connected properly	Reconnect the tube properly
	There may be holes in the mask or pressure sensing tube	Contact your home care provider
	It is a faulty device	
	The effects of degraded sensors and electrodes, or loosened electrodes	Contact your home care provider Contact your home care provider
	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 device produces very low pressures	The treatment pressure has been changed accidentally	Contact your physician
	When the Ramp feature is enabled, it takes some time for the initial pressure to rise to the treatment pressure. This is normal	If necessary, disable the Ramp feature, or set the ramp time shorter
	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 apnoea breathing therapy equipment is considered to not have essential performance.

Not withstanding 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.	
Emissions Test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Class A
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.		
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air
Electrical fast transient / burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines
Surge IEC 61000-4-5	±1 kV line (s) to line (s)	±1 kV line (s) to line (s)
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% UT; 0.5 cycle At 0˚, 45˚, 90˚, 135˚, 180˚, 225˚, 270˚ and 315˚ 0% UT; 1 cycle 70% UT; 25 / 30 cycle; At 0˚ 0% UT; 250 / 300 cycle	0% UT; 0.5 cycle At 0˚, 45˚, 90˚, 135˚, 180˚, 225˚, 270˚ and 315˚ 0% UT; 1 cycle 70% UT; 25 / 30 cycles At 0˚ 0% UT; 250 / 300 cycle
Power frequency (50 Hz / 60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m
NOTE: UT is the a.c. mains voltage prior to application of the test level.		

Guidance and manufacturer's declaration - electromagnetic immunity		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**
Conducted RF IEC 61000-4-6	3 V 0.15 MHz-80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz	3 V 0.15 MHz-80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz
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

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

Rated maximum output of transmitter W	150 kHz~80 MHz d=1.17 √p	80 MHz~800 MHz d = 0.35 √p	800 MHz~2.5 GHz d = 0.70 √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**
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	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.				

WARNING!

- This device should not be used in the vicinity of other electronic equipment such as diathermy, electrocautery and radio frequency identification (RFID), security sys- tems (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.

- 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 i

- 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:

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For additional information, please visit our website at: www.reacthealth.com.

icodeconnect.com is the web-based cloud solution for report generation and storage.

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