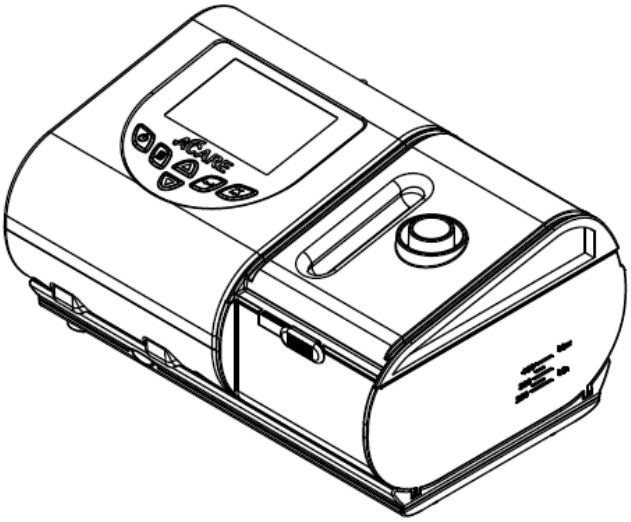
“Acare” APAP System
User Manual

Model No.: CPA-500



<u>Please read the instruction manual before use</u>

(With Doctor Operator Function)

Issued Date: 2019/01/30
Version: 3.1

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IMPORTANT SAFEGUARDS

SAVE THESE INSTRUCTIONS
READ ALL INSTRUCTIONS BEFORE USING

⚠ **WARNING -**

1. **THIS DEVICE IS NOT INTENDED FOR LIFE SUPPORT.** The unit cease operation due to power interruption but will cause no hazard to the patient. The Acare CPAP is designed for the treatment of Obstructive Sleep Apnea (OSA) only.
2. This device **SHOULD NOT** be used in the vicinity of a flammable anesthetic mixture in combination with oxygen or air and nitrous oxide.
3. The air flow for breathing generated by this device may be as much as 7ºC (12.6ºF) higher than the room temperature. This device **SHOULD NOT** be used if the room temperature is warmer than 40ºC to prevent the airflow temperature from exceeding 40ºC and causing irritation to your airway.
4. If this device overheats, it will stop operating and show “Error Message” on the display. After cooling down to proper temperature, the device can restart again.
5. This machine should be used only with masks (and connectors) recommend or prescribed by a physician. A mask should not be used unless the CPAP machine is turned on and operating properly. The vent holes associated with the mask should never be blocked for proper exhaling purpose.
6. At low APAP pressure, some exhaled gas may remain in the mask and be re-breathed.
7. The device is intended for use by professional or the patient should follow doctor’s instruction to use the device.

⚠ **NOTE** -

U.S. Federal law restricts this deice to sale by or on the order of a licensed physician.

⚠ **DANGER** – To reduce the risk of electrocution:

1. Always unplug this product immediately after using.
2. Do not use while bathing.
3. Do not place or store product where it can fall or be pulled into a tub or sink.
4. Do not place in or drop into water or other liquid.
5. Do not reach for a product that has fallen into water. Unplug immediately.

⚠ **WARNING** – To reduce the risk of burns, electrocution, fire or injury.

1. This product should never be left unattended when plugged in.
2. Close supervision is necessary when this product is used by, on, or near children or invalids.
3. Use this product only for its intended use as described in this manual, do not use attachments not recommended by the manufacturer.
4. Never operate this product if it has a damaged cord or plug, if it is not working properly, if it has been dropped or damaged, or dropped into water. Return the product to the provider for examination and repair.
5. Keep the cord away from heated surfaces.
6. Never block the air openings of this product or place it on a soft surface, such as a bed or couch, where their openings may be blocked. Keep the air opening free of lint, hair, and other similar particles.
7. Never drop or inset any object into any opening or hose.
8. Recommended operating atmospheric condition is above sea level up to 2400 m, if goes higher than 2400 m, re-calibration is then required.
9. Against servicing and maintenance while the ME EQUIPMENT is in use.
10. The AC power plug is served to disconnect the device, do not position the device to make it difficult to disconnect the adaptor plug.
11. No modification of this equipment is allowed.

1. Introduction

This manual should be used for initial set up of the system and saved for reference purpose.

1.1 General Information

Obstructive Sleep Apnea (OSA) is a condition that an intermittent and repetitive obstruction of the upper respiratory tract causing a complete (apnea) or partial (hypopnea) blockage of the patient's airway during sleep. The syndrome varies depending on the degree of relaxation of the tongue and soft palate muscles.

The most common treatment for OSA is Automatic Positive Airway Pressure (APAP.) APAP devices can deliver a constant air pressure into your upper airway via a CPAP mask. This constant air pressure can keep your airway open during sleep, therefore preventing the OSA.

APAP is a micro-processor controlled continuous positive airway pressure device. APAP detection of various parameters and then use different algorithms to control the pressure increase or decrease. It features the illuminated, menu-driven LCD display, a universal power supply, and ramp time adjustment. The ramp time adjustment and ultra-quiet operation ensure you to fall asleep comfortably while air pressure slowly builds up to the prescribed treatment level. The unit's compliance meter records the system's operating time for physician's reference.

1.2 Intended Use

This device is intended to provide automatic positive airway pressure (APAP) for the treatment of adult Obstructive Sleep Apnea (OSA.)

2. Product Description

Components include:

(1) APAP device

(2) Water Tank

(3) Heater

(4) Detachable power cord

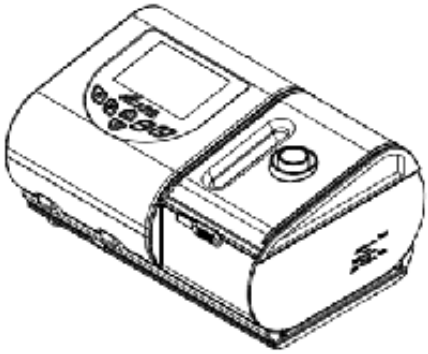
(5) User manual

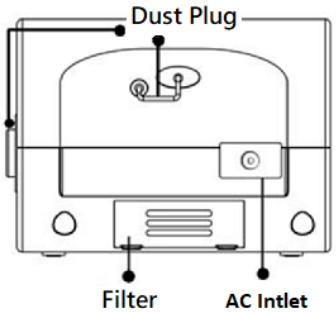
(6) CPAP Tubing, 1.8m

(7) Carrying bag

(8) Dust plug

(9) Filter



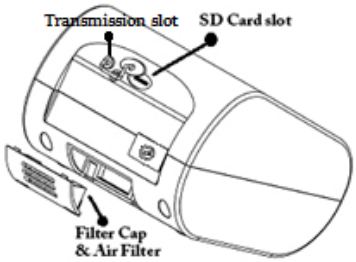


3. Installation

3.1 Unpacking

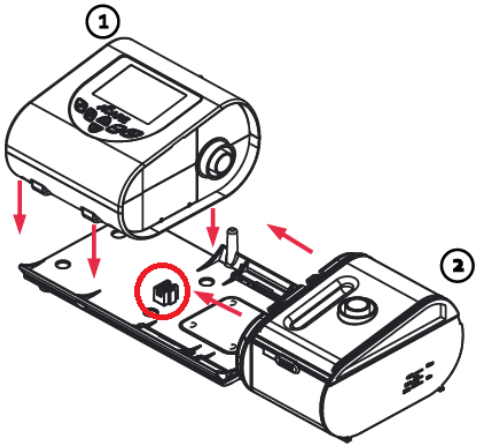
To secure its contents inside, the APAP device and accessories are bundled in a paper packaged box. Unpack this box by removing the APAP device and its accessory and checking for any damage, which may have occurred during shipping. If there are damages, please contact Acare or your Wholesale Source immediately.

3.2 Setting Up

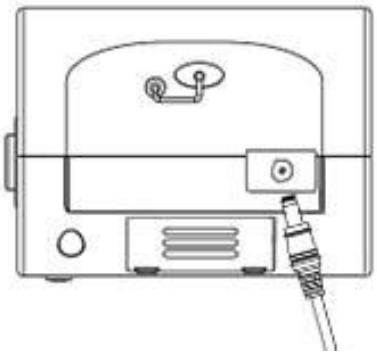


(1) Insert the micro SD card into SD card slot.
(2) Insert the filter into filter slot.

※<u>Transmission slot: there is no function</u>



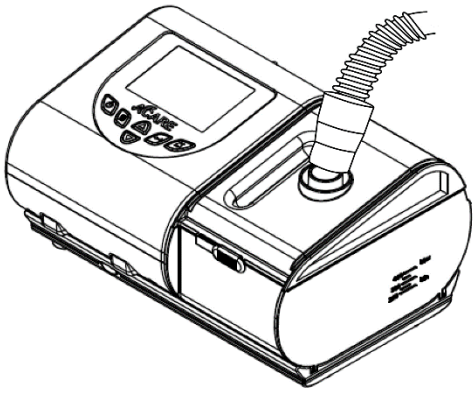
(3) Humidifier connect socket at APAP device bottom alignment to connect on the heater. Then put the APAP device on the heater.
(4) Assembly the humidifier along the slide of the heater. Also the humidifier air inlet should insert to the device air inlet.



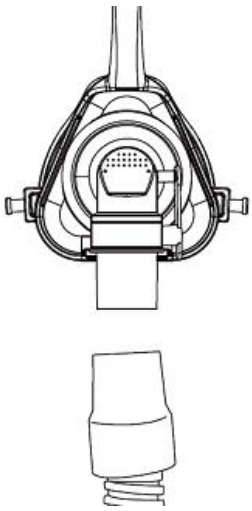
(5) Connect the power cord to CPAP device and plug into main electrical outlet.
Once the power cord is plugged into the electrical outlet, the device is in ready to operate position.

- 【STANDYBY】sign appears in LCD display.

⚠ **NOTE: The plug is also served to disconnect the device.**



(6) Connect one end of the air tubing firmly onto the air outlet of the APAP.

	(7) Connect the other end of the air tubing to the mask system. Be sure to assemble the mask and headgear according to the manufacturer's instruction manual.

3.3 WARNIGN & CAUTION

⚠ **WARNING:** This APAP machine should be used only with CPAP masks (or connectors) recommended by the patient's physician or respiratory therapist. A mask should not be worn unless the APAP machine is turned on and operating properly. The vent hole associated with the mask should never be blocked for proper exhalation. If the vent hole is blocked, the APAP machine will stop and show message "**Error**", after cooling down, please re-connect the power cord to reset the machine.

⚠ **WARNING:** When the APAP is not in operation, oxygen may accumulate within the APAP device enclosure, and it may create the risk of fire.

⚠ **WARNING:** This device **SHOULD NOT** be used if the room temperature is higher than 40ºC to prevent the temperature of air delivered to CPAP mask over 40ºC.

⚠ **WARNING:** This device **SHOULD NOT** be used in the vicinity of flammable anesthetic mixture in combination with oxygen or air and nitrous oxide.

⚠ **WARNING:** Recommended operating atmospheric condition is above sea level up to 2400m, if goes higher than 2400 m, recalibration is then required.

CAUTION: At low pressure, some exhaled gas may remain in the mask and be re-breathed.

CAUTION: Make sure the environment around the machine is dry and clean. Dust and foreign particles may affect the treatment. Keep the air inlet of the machine clear and the filter clean to prevent overheating and damage of the device. Do not place the machine near a source of hot or cold air. Extreme cold or hot environment may damage the user's respiratory airway.

CAUTION: If there is a possibility of electromagnetic interference with mobile phones, please increase the distance between devices.

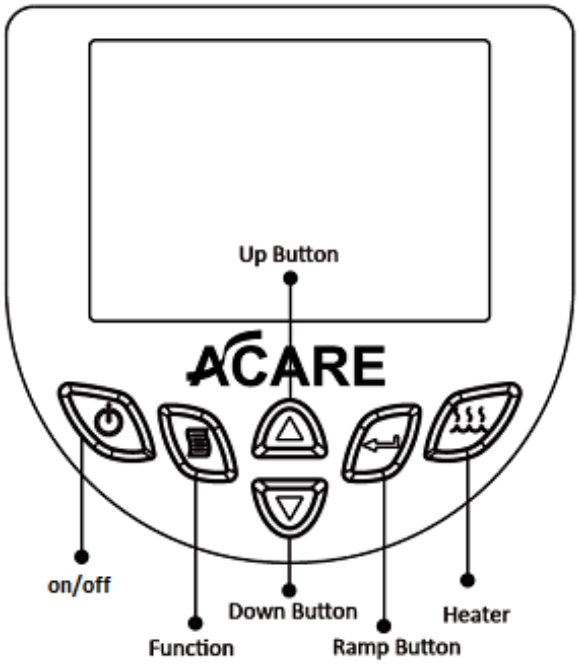
4. Operation

⚠ **NOTE:** Always read the operating instruction before use.

⚠ **WARNING:** Be carefully heater's heat.

⚠ **NOTE:** The maximum treatment time: Use the device during normal sleep time, do not continue to use the device after wake up.

4.1 Control Panel Description

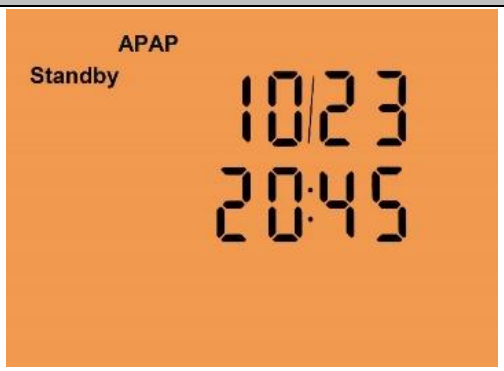
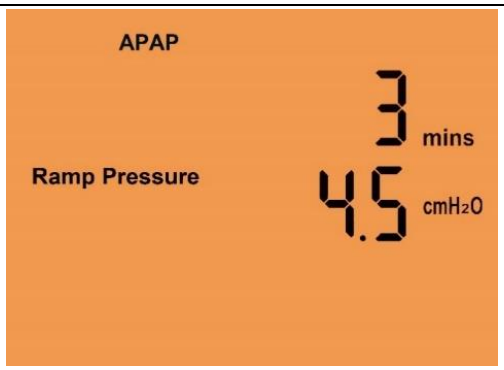
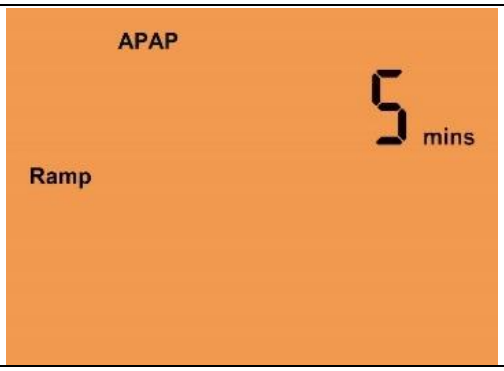


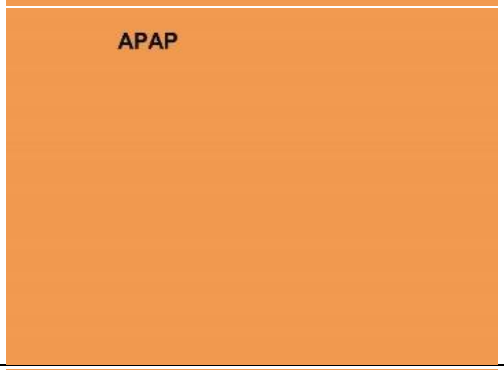
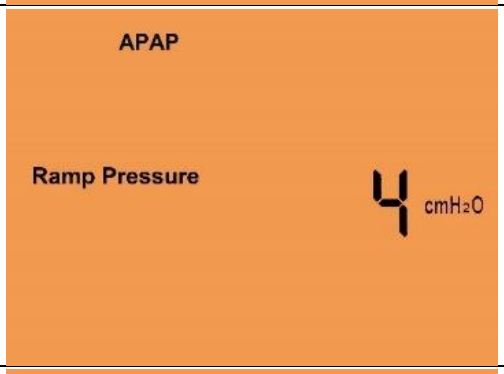
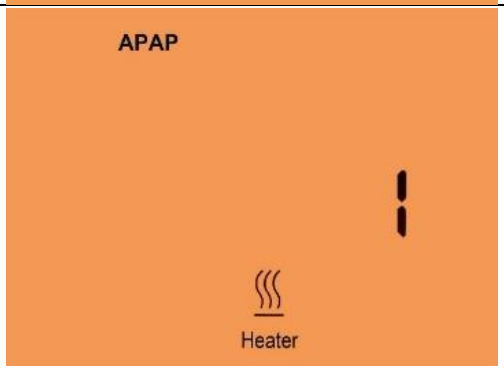
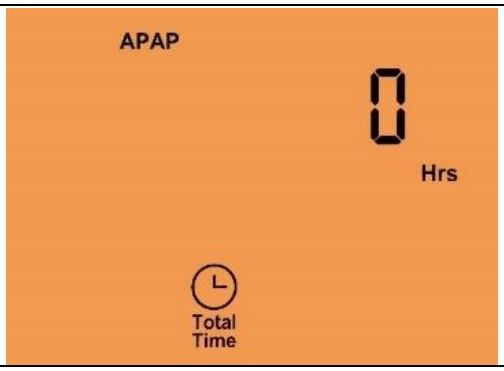
Name	Explain
On/off	Use this button to open the device and start/stop the airflow
Function	Configuration function selection
Up Button	Use this button to go to the page turning and increase setting parameter
Down Button	Use this button to go to the page turning and decrease setting parameter
Enter Button	Use this button to perform an action.
Heater	This button is for open or close the heater function

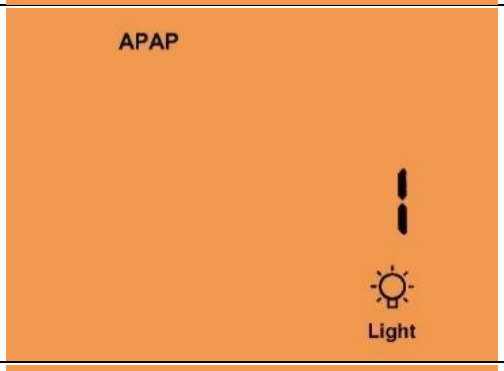
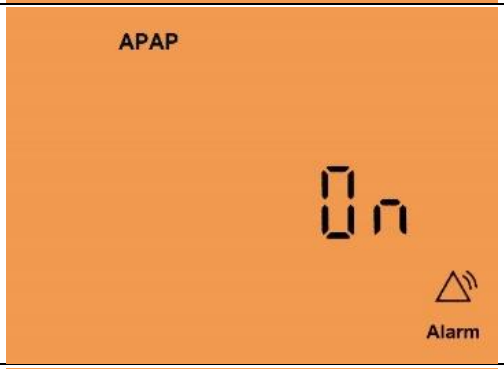
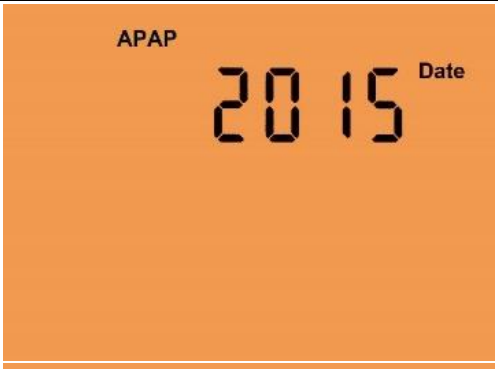
- When the power cord is plugged, the display shows 【**Standby**】
- When press the 【⏻】, the display shows Ramp time and pressure and starting pressure delivery under default setting
- When press again the "Start/Stop mark", the display come back to 【**Standby**】 mode
- Hold down 【⏻】 for 3 seconds to close the device
- Press 【⏻】 to open device

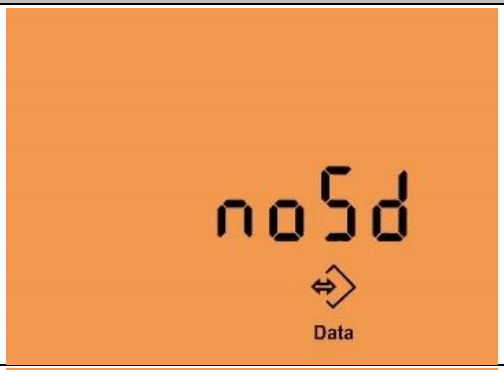
- Under【**Standby**】mode, press【**Function**】will enter the【**Configuration**】model, in this model can process different function selection
- Use 【**Up▲**】 and the【**Down▼**】to adjust the function selection
- Press 【**Enter Button**】for confirmation of adjustment
- Press 【**Heater**】 to turn on or turn off the heater function
- After confirmation, Press【⏻】to return standby mode

4.2 Function Description

Display	Monitor	Description
Standby Mode		Insert the plug make this equipment is power on and be in standby state.
Operating Mode		Ramp time and pressure on the operating mode display.
Ramp Time		The Ramp time setting for reaching the preset pressure Range: 0~45 minutes Increment: 5 minutes <u>Default setting: 0 minute</u>

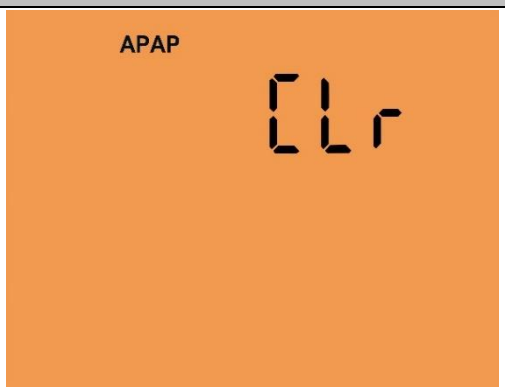
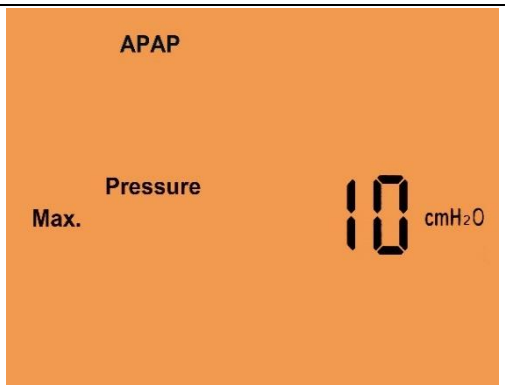
Display	Monitor	Description
APAP/CPAP	 	APAP/CPAP adjustment Convert APAP and CPAP mode <u>Default setting: APAP</u>
Ramp P		The initial pressure start Range: 3-19 cmH2O Increment: 1cmH2O <u>Default setting: 3~10 cmH_2O</u>
Heater		The humidifier function setting Range: 1-6 (35°C~60°C) Increment:1 <u>Default setting: 1</u> ⚠ **DON'T OPEN THE HEATER FUNCTION WITHOUT HUMIDIFIER ASSEMBLY ON THE HEATER.**
Total Time		To record the device operates **※CAN NOT ADJUST THIS DATA**

Display	Monitor	Description
Compliance Meter		To record the air flow output time. **※CAN NOT ADJUST THIS DATA**
Light		The back light can be selected in 1/ 2 / OFF. <u>Default setting: 2</u>
Alarm		This function provides an buzzer alarm when air leak is detected. It can be selected in ON / OFF. <u>Default setting: ON</u>
Time/ Date/ Year	 	The time, date and year can be set up

Display	Monitor	Description
SD card function		Do not insert the SD card The device can't find the SD card to save the data ⚠ **DO NOT REMOVE THE SD CARD WHEN THE DEVICE SAVING THE DATA**
		The SD card inserts into device. If the SD card device can read it, will turn into Standby Mode. If the SD card is broken or the device can't read it, will show the Err 5 on the display. ⚠ **DO NOT REMOVE THE SD CARD WHEN THE DEVICE READING IT**
		The setting and using data saving in to SD card
Automatic Start Function		Put on face mask and breathe normally in standby mode, the machine will start automatically.
Auto Adjust Pressure Mode		Under the APAP function and setting range, the machine will automatically increase the pressure if apnea occurred. And decrease the pressure if user breath normally for certain while.

4.3 Doctor operator function

- Pressing the 【**UP button**】for 5 seconds and hold it then press 【**Function**】entered doctor operator function.
- Pressing 【**Function**】 to select doctor operator interface.
- Using【**Up button**】/【**Down button**】to selected or adjust function.
- Press down【**Enter button**】to confirm the revise became effective.
- Pressing 【⏻】 return to standby mode.

Display	Monitor	Description
Clean Function		Clean the treatment history except the user setting, Ramp Time, Ramp Pressure, and time setting. Yes: Clean the treatment history. No: keep the treatment history. **※Treatment History include the total time, compliance meter and data saved in the device.**
Treatment pressure		Treatment pressure setting. Range: 4~20 cmH2O Increment: 1cmH2O <u>Default setting: 10 cmH2O</u>

5. Cleaning & Maintenance

5.1 Device

The device should be checked and dusted regularly (at least every 30 days). Wipe with a damp cloth and a mild detergent and keep it free from dust. If other detergent is used, choose one that will have no chemical effects on the surface of the plastic case. All parts should be air-dried thoroughly before use.

⚠ **WARNING:** Don't try to open this device. Repairs and internal servicing should only be performed by an authorized service agent and qualified technician. Liquid or foreign objects should always be kept from entering the APAP outlet for this can cause the system to malfunction.

5.2 Dust plug

The waterproof and dust plug should be checked its still there, to keep the device running is unaffected. If you lose the dust plug, please contact your equipment provider service agent.

5.3 Tubing and Mask

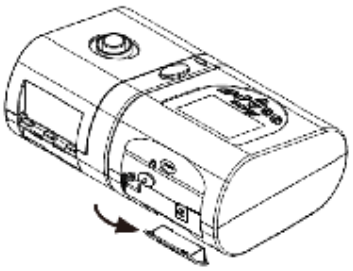
The 6' corrugated tubing should be cleaned regularly and replaced every 30 days.

- Disconnect the air tubing from the air outlet of the device.
- Disconnect the mask.
- Use a mild detergent (prepare the detergent according to manufacturer's recommendations). Wash both the inside and outside of the tubing.
- Rinse thoroughly and make sure the tubing is completely dry before reconnecting for the next use.
- Please refer to the separate cleaning and replacement instructions included with the mask.

⚠ **WARNING:** Do not use any cleaner containing fragrance or conditioners as they will leave a residue.

5.4 Air Filter

The air filter should be checked and replaced every 30 days, or more often if this device is operated in a dusty environment.



1. Remove the dirty filter.
2. Insert a new filter.

5.5 Expected Service Life

Product	Expected Date
APAP Device	5 years
Humidifier	5 years
Heater	5 years
Dust plug	5 years
Tubing and Mask	6 months
Air Filter	30 days

6. Troubleshooting

The table below lists troubleshooting solutions for the problems that may happen. If the problem persists, contact your equipment provider service agent.

Problem	Possible Cause	Solutions
No display	1. The power cord is not connected to the power socket. 2. LCD failure or controlled PCB failure	1. Ensure the power cord is connected. 2. Contact your equipment provider for repair.
Display code incorrect	LCD failure or controlled PCB failure.	Contact your equipment provider for repair.
Illuminant under LCD is not on	LED failure	Contact your equipment provider for repair.
Buttons disable	Button failure	Contact your equipment provider for repair.
Air delivered is slow	1. During ramp time. 2. Filter is too dirty. 3. Flow generator failure.	1. Check the ramp time setting. 2. Change or clean the filter regulator. 3. Contact your equipment provider for repair.
Heater function cannot work	1.The device don not combine with humidifier well 2. Do not connect the humidifier 2. The connect or heater control failure	1. Set up the device again 2. Connect the humidifier on the heater 3. Contact your equipment provider for repair.

6.1 Error Code

The table below lists error code display on the monitor. If the problem persists, contact your equipment provider service agent.

Err1	Blower is not running.	Please Return to factory or distributor for repair.
Err 2	Pressure abnormal or pressure sensor failure.	Restart CPAP, if still Err 2, please return to factory or distributor for repair.
Err3	Internal system memory not enough.	Please return to factory or distributor for clear internal memory data.
Err4	Internal system memory will be full.	Please return to factory or distributor for clear internal memory data.
Err5	Memory card communication failure.	1. Check the Micro SD card is damaged. 2. If still Err 5, please return to factory or distributor for repair.
Err6	Memory card less than 64 KB.	Replace the Micro SD card.
Err7	Humidifier abnormal	1. Check the humidifier assembly correctly 2. Please Return to factory or distributor for repair.
Err8	The temperature of heating panel is too hot	Wait few minute to cool down or ignore the alarm

7. Technical Specifications

Item	Specifications
Operation Model	Auto CPAP
Adapter Information	Manufacturer: PROTEK POWER Model: PMP105
Pressure Range	4 ~ 20 cm H_2O (adjustable in 1 cmH_2O increments)
Pressure Accuracy	± 0.5 cmH_2O
Unit Dimensions (L x W x H)	248mm x 176mm x 128mm
Weight	1.5 g
Sound Pressure Level	< 30 dB (A)
Supply Voltage	AC 100-240V, 47/63Hz, 60W
Operation Range	Temperature: 5 ° C ~ + 40° C Humidity: 15% ~ 95% Non-condensing
Transport and Storage Range	Temperature: - 20 ° C ~ + 70° C Humidity: 10% ~ 90% Non-condensing
Atmospheric pressure	753-1060 hpa
Expiration Date	5 years
Standard Compliance	IEC 60601-1 IEC 60601-1-2 ISO 80601-2-70
IEC 60601-1 Classification	Class II Equipment Type BF Applied Part IP21-Drip-Proof, Vertical

NOTE: The manufacturer reserves the right to modify the specification without notice.

7.1 Symbol

Symbol	Explain	Symbol	Explain
	Type BF applied part The applied part is mask	IP21	Protect finger, Drip-Proof, Vertical 15°
	Attention, Consult accompanying documents	SN	Serial number of the product
	Class II (double insulated)		Do not dispose the device in the urban waste.
	manufacturer	EC REP	Authorized representative in the European Community.
	Manufacturing Date		On / Off / Stand-by
	Refer to user manual before application		

8. NOTE, CAUTION, AND WARNING STATEMENTS

⚠ **NOTE:** Indicates information that you should pay special attention to.

CAUTION: Indicates correct operating or maintenance procedures in order to prevent damages to or destruction of the equipment or other property.

WARNING: Calls attention to a potential danger that requires correct procedures or practices in order to prevent personal injury.

9. Electromagnetic Compatibility

EMC warning in user’s manual of Acre Auto CPAP

a) Install and put into service the equipment according to the EMC information provided in the manual.

b) **WARNING**: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

c) **WARNING**: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

d) **WARNING**: 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 equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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