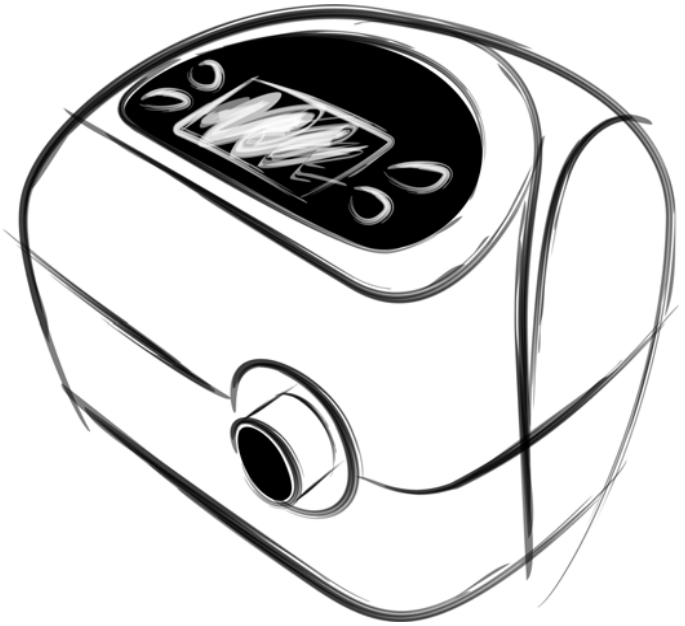
804 APAP

Instruction Manual



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676001-6310 V1.3

Model No.: 9S-005740

Please read the instruction manual before use.

Limited Warranty

evo warrants the 804 APAP to be free from defective workmanship and materials for a period of 2 years from the date of purchase. This warranty is limited to the dealer. Any defective part or assembly will be repaired or replaced, at the sole discretion and determination of evo if the unit has not been misused or tampered with during the warranty period. Normal maintenance items, as outlined in this manual, and disposable components are not covered by this warranty. Shipping charges, if any, shall be paid by the purchaser.

NOTE: There is no other express warranty. Implied warranties, including those of merchantability and fitness for a particular purpose, are limited to the duration of the express limited warranty and to the extent permitted by law and all implied warranties are excluded. This warranty does not cover providing a loaner APAP, compensating for costs incurred for APAP rental, or labor costs incurred in repairing or replacing defective part(s).

Contents

IMPORTANT SAFEGUARDS
SAVE THESE INSTRUCTIONS
READ ALL INSTRUCTIONS BEFORE USING

WARNING –

1. THIS DEVICE IS NOT INTENDED FOR LIFE SUPPORT. It may stop operating due to power interruption but no hazards to patient.
2. If oxygen is used with the device, the oxygen flow must be turned off when the device is not in use. **Explanation of the Warning:** When the device is not in operation and the oxygen flow is left on, oxygen delivered into the tubing may accumulate within the device's enclosure and create a risk of fire.
3. Oxygen supports combustion. Oxygen **should not** be used while smoking or in the presence of an open flame.
4. Always ensure the device is generating airflow before the oxygen supply is turned on. Always turn off the oxygen supply before stopping the airflow from the device.
5. This device **should not** be used in the vicinity of a flammable anesthetic mixture in combination with oxygen or air and nitrous oxide.
   ⚠ NOTE: L'équipment ne peut étre utilisé s'il y a risqué de mélange d'un anesthésique inflammable avec l'air ou l'oxygène ou oxide nitreux.
6. The airflow for breathing generated by this device may be as much as 7°C (44.6°F) higher than the room temperature. This device **should not** be used if the room temperature is warmer than 35°C (95°F) to prevent the airflow temperature from exceeding 40°C (104°F) and causing irritation to your airway.
7. If this device overheats, it will stop operating and show message "Error 002" on the display. After cooling down to proper temperature, the device can restart again.
8. This machine should be used only with masks (and connectors) recommended by the manufacturer, or by your physician or respiratory therapist. 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. If the vent hole is blocked, the CPAP machine will stop and show message "**Error 002**". Unplug the power cord and allow unit to cool down. After unit has cooled, please re-connect the power cord to reset the machine.
9. At low CPAP pressure, some exhaled gas may remain in the mask and be re-breathed.

CAUTION –

1. Make sure the environment around the machine is dry and clean. Dust and foreign particles may affect the treatment. Keep the air inlet on the back of the machine clear 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 user's respiratory airway.
2. If there is a possibility of electro-magnetic interference with mobile phones, please increase the distance between devices or turn off the mobile phone.
3. Do not connect the device to the personal computer for data downloading during the treatment. This may cause the CPAP system failure.
4. U.S. Federal law restricts this device to sale by or on the order of a licensed physician.

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

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

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Guidance and Manufacturer's Declaration- Electromagnetic Immunity:

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Immunity Test	IEC60601 test level	Compliance	Electromagnetic Environment-Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of this device, including cables, than there commended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF IEC 61000-4-6	3Vrms150 kHz to 80 MHz outside ISM bands[a]	3Vrms	$d = 1.2\sqrt{P}$ 150kHz to 80MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3V/m	$d = 1.2\sqrt{P}$ 150kHz to 80MHz $d = 2.3\sqrt{P}$ 80 MHz to 2.5G MHz
			Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey [c], should be less than the compliance level in each frequency range[d]. Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz;13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

b The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

c 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 reorienting or relocating the device.

d Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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 to persons:

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 a service center 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 insert any object into any opening or hose.
8. Follow the national requirement to dispose unit.

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 intermitted and repetitive obstruction of the upper respiratory tract causes a complete (apnea) or partial (hypopnea) block of breathing airflow during sleep. The syndrome varies depending on the degree of relaxation of the tongue and soft palate muscle.

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

This device is a micro-processor controlled continuous positive airway pressure device. It features the illuminated, menu-driven LCD display, universal power supply, and ramp time adjustment. The ramp time adjustment and ultra quiet operation ensure you to fall asleep comfortably while air pressures slowly build up to treatment level. The user compliance meter records the total system's operating time for physician's reference.

The system has been tested and successfully approved to the following standards:

CE 0197	EN 60601-1 EN 60601-1-2 EN 61000-3-2 Class A EN 61000-3-3

⚠ For US and CANADA only

E228589

53DG

Medical Equipment- CPAP with respect to electrical shock, fire and mechanical hazards only in accordance with UL60601-1 and CAN/CSA C22.2 No. 601.1

Le produit à été testé avec des équipements médicaux et respecte les normes UL 60601-1 & CAN/CSA C22.2
No.601.1. prévenant les choc électrique, le feu et les risques de blessures physiques.

Appendix A: EMC Information

Guidance and Manufacturer's Declaration- Electromagnetic Emissions:

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment-Guidance
Harmonic emissions IEC61000-3-2	Class A	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network.
Voltage fluctuations / Flicker emissions IEC61000-3-3	Complies	

Guidance and Manufacturer's Declaration- Electromagnetic Immunity:

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Immunity Test	IEC60601 test level	Compliance	Electromagnetic Environment-Guidance
Electrostatic Discharge(ESD) IEC61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/ burst IEC61000-4-4	±2kV for power supply line ±1kV for input/out line	±2kV for power supply line ±1kV for input/out line	Mains power quality should be that of atypical commercial or hospital environment
Surge IEC61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s)	Mains power quality should be that of atypical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	<5 % UT(>95 % dip in UT)for 0,5 cycle 40 % UT(60 % dip in UT)for 5 cycles 70 % UT(30 % dip in UT)for 25 cycles <5 % UT(>95 % dip in UT)for 5 sec	<5 % UT(>95 % dip in UT) for 0,5 cycle 40 % UT(60 % dip in UT) for 5 cycles 70 % UT(30 % dip in UT) for 25 cycles <5 % UT(>95 % dip in UT) for 5 sec	Mains power quality should be that of atypical commercial or hospital environment. If the user of this device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of atypical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to the application of the test level			

BF symbol, which indicated this product is according to the degree of protecting against electric shock for type BF equipment.

Attention, should read the instructions.

Attention, should read the instructions.

Class II

Disposal of Electrical & Electronic Equipment (WEEE):
This product should be handed over to an applicable collection point for the recycling of electrical and electronic equipment. For more detailed information about the recycling of this product, please contact your local city office, household waste disposal service or the retail store where you purchased this product.

Authorized representative in the European community

Manufacturer

10. NOTE, CAUTION, AND WARNING STATEMENTS

NOTE: Indicate information that you should pay special attention to.

CAUTION: Indicate correct operating or maintenance procedures in order to prevent damage 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.

EMC Warning Statement

This equipment has been tested and found to comply with the limits for medical devices to the EN 60601-1-2:2007. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult the manufacturer or field service technician for help.

This system has been tested and compliance to the following volunteer standards:
FDA

1.2 Intended Use

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

Cautions: Some patients might have pre-existing contraindications for CPAP therapy, or might experience some potential side effects of using CPAP device, please consult your physician if you have any questions concerning your therapy.

2. Product Description

Components including:

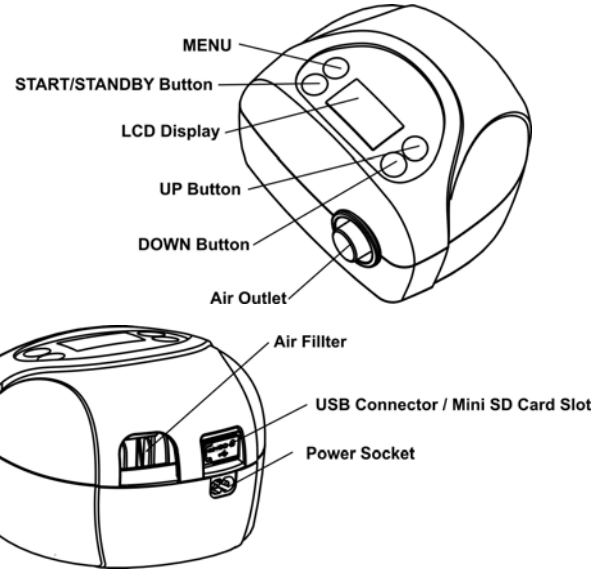
(1) Main CPAP device
(2) Detachable power cord
(3) User manual
(4) Flexible air tubing with 1.8 m length
(5) Full face or nasal mask and headgear straps (Optional, Always use CE certified and 510(k) cleared mask for CPAP)
(6) Carrying bag (optional)
(7) miniSD card and USB cable

⚠ Note 1: ONLY for Physician or Technician to download data. Patient should not use this function.

⚠ Note 2: Only applicable for devices with miniSD card slot.

⚠ Note 3: Please use miniSD card (smaller than 2GB) which comply with SDHC standard. Before using it, please format it to FAT16 to ensure correct data collection.

⚠ **CAUTION :** Patient should not connect the device to the personal computer for data downloading. This may cause the CPAP system failure



9. Technical Specifications

Item		Specifications
Power Supply		Universal power supply, AC100-240V, 50/60 Hz, 0.5-0.3A
Pressure Range		4-20 cmH_2O (adjustable in 0.5 cmH_2O increment)
Initial Pressure		3-19 cmH_2O (adjustable in 0.5 cmH_2O increment)
Maximum Pressure		5-20 cmH_2O (adjustable in 0.5 cmH_2O increment)
Minimum Pressure		4-19 cmH_2O (adjustable in 0.5 cmH_2O increment)
Ramp Time		0-45 minutes (adjustable in 5-minute increment)
Ramp Starting Pressure		3-19 cmH_2O (adjustable in 0.5 cmH_2O increment)
Operating Altitude		Up to 8,000 ft (2,438 m) when the pressure is set at 4-18 cmH_2O but limit to 5,000ft (1,524m) when the pressure is set at 18.5 - 20 cmH_2O
Dimensions (W x D x H)		14.5 x 13.0 x 10.0 cm or 5.7” x 5.1” x 3.9”
Weight		Approximately 800 g or 1.76 lb
Sound Level		30 dBA at 10 cmH_2O, 1 meter distance
Environment	Temperature	Operating: +5°C to +35°C (+41°F to +95°F) Storage: -15°C to 50°C (+5°F to +122°F) Shipping: -15°C to 70°C (+5°F to +158°F)
	Humidity	Operating: 15%RH to 95%RH non-condensing Storage: 10%RH to 90%RH non-condensing Shipping: 10%RH to 90%RH non-condensing
Classification:		Class II Type BF, Applied Parts Nasal Mask Not suitable for use in the presence of a flammable anesthetic mixture IPX0: Enclosed equipment without protection against ingress of water Continuous operation.

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

8. 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 Causes	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 regularly. 3. Contact your equipment provider for repair.
Data can not be copied to the miniSD card	1. miniSD card is full. 2. miniSD card is not inserted correctly. 3. Data on the miniSD card is corrupted.	1. Ensure the miniSD card has enough capacity. 2. Ensure the miniSD card is inserted into the slot. 3. Format the card.

Error / Warning Messages show in LCD.

Message type	Definition	Message in LCD
Error: Primary function can't execute.	Error for abnormal system settings	Error 001
	Error for flow generator failure	Error 002
	Error for abnormal timer setting or timer failure	Error 003
	Error for flow sensor failure	Error 004
Warning:	Out of system memory	Warn 001
	System memory is nearly full	Warn 002
	miniSD card module communication failure	Warn 003
	Remove the miniSD card while data is being processed	Warn 004
	miniSD card is full	Warn 005

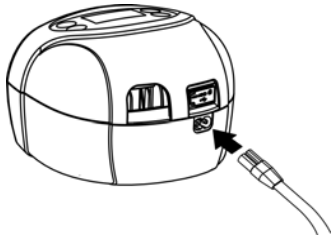
NOTE: When the warning message appears, contact your physician or equipment provider to download the memory data and reset the meter.

3. Installation

3.1 Unpacking

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

3.2 Setting Up



1) 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 ("**STANDBY**" sign appears in LCD display)

⚠ **NOTE: The plug can also be used to disconnect the device.**

2) Connect one end of the air tubing firmly onto the air outlet of the CPAP.

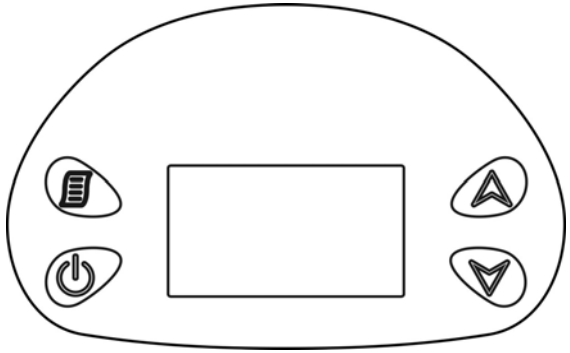
3) Connect the other end of the air tubing to the mask system. Putting on the mask and headgear according to the mask instruction manual.

4. Operation

NOTE: Always read the operating instruction before use.

4.1 Control Panel Description

Button arrangement on control panel and main use of the buttons:



START/STANDBY

- To start the treatment, simply press the ***"START/STANDBY"*** button. To stop the treatment, press the ***"START/STANDBY"*** button again. The display will switch between ***[STANDBY]*** and Therapy Pressure ***[XX.X cmH$_2$O]*** in cmH$_2$O unit *or* ***[APAP]***.

MENU

- Press the ***"MENU"*** button to enter the setting mode when device is in standby mode. The adjustment setting includes mode selection, ramp time selection, ramp starting pressure, therapy pressure adjustment, initial pressure adjustment, maximum pressure adjustment, minimum pressure adjustment, alarm ON/OFF, clock alarm and clock setting, compliance meter, and total operating meter. When each setting's value has been changed, press ***"MENU"*** for confirmation and press ***"MENU"*** again for next setting selection. Please refer to 4.2 Function Description section for detailed information.

UP

Press the ***"UP"*** button to increase the value.

DOWN

Press the ***"DOWN"*** button to decrease the value.

7.2 Tubing and Mask

The tubing and mask should be checked and cleaned regularly. Please refer to the cleaning instruction packaged with the accessories.

1. Disconnect the air tubing from the air outlet of the device.
2. Remove the air tubing and headgear straps from the mask.
3. Wash the mask system according to the instructions supplied with it.
4. Wash the air tubing in warm water using mild detergent. Rinsed thoroughly, hang and allow to dry.
5. Before next use, assemble the mask and headgear according to the mask user instructions.
6. All items of the mask and air tubing are subject to normal wear and tear and may eventually be replaced. Replace the mask and the air tubing if they are damaged.

CAUTION: Do not use blench, chlorine-, alcohol-, or aromatic-based (including all scented oils), moisturizing or antibacterial soaps to clean the cushion, mask, air tubing. These solutions may cause hardening and reduce the life of the product.

CAUTION: Do not wash or dry the mask or air tubing at a temperature above 70°C (160°F)

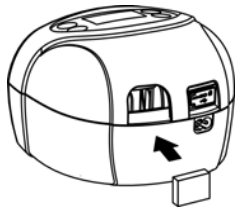
WARNING: Do not use any cleaner containing fragrance or conditioners as they will leave a residue.

WARNING: The mask must not be re-used by another person. This is to avoid the risk of cross-infection.

7.3 Air Filter

The air filter should be cleaned at least once every two weeks or more often if this device is operated in a dusty environment and replaced with a new one every six months.

CAUTION: Dirty air filter may cause high operating temperatures that affect device performance. Ensure the air filter is cleaned and fitted at all times.

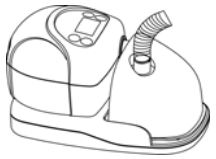


1. Remove the dirty filter from the enclosure on the rear of the device.
2. Wash the filter in warm water with a mild detergent, and rinse with water. Allow the filter to air dry completely before reinstalling. Do not use a filter that is not completely dry. If the filter is torn, replace it.
3. Reinstall the filter.

NOTE: Please follow national requirements to dispose the unit properly.

5. Adding a Humidifier

804 APAP device can be used with the integrated heated humidifier (9S-006500) which is available from the home care provider. The heated humidifier may reduce nasal dryness and irritation by providing adequate moisture and heat to the airflow. Please refer to the integrated heated humidifier (9S-006500) instruction manual for complete setup information



NOTE: When 804 APAP device is used with the heated humidifier, its power supply is from the power socket outlet of the heated humidifier. Do not connect the power cord to APAP device and plug into main electrical outlet.

6. Using the miniSD Card to Collect Data

If physicians need to review the usage data, they may ask you to use the miniSD card to copy data from the device, and to return the card to them. Data that is copied to the miniSD Card is still stored and available on the device.

1. Insert the miniSD Card when the device is in standby mode.
2. Data copying starts automatically when the miniSD Card is inserted into the slot.
3. The ***[Card]*** message is displayed on the LCD while data is being copied.
4. The ***[OK Card]*** message is displayed on the LCD when copying has finished.
5. Remove the miniSD Card and mail it to the clinician.
6. The miniSD Card should be stored in the plastic card case when not in use. The miniSD card does not need to be uninstalled for the device to work properly.

⚠**CAUTION:** Do not remove the miniSD card until ***[OK Card]*** message is displayed on the LCD, or data copied to the card may be corrupted or missing.

7. Cleaning & Maintenance

7.1 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 performed by an authorized service agent. Don't drop any foreign object into the air tube or air outlet.

4.2 Function Description

(1) Ramp Time (only CPAP mode)

Ramp time function allows the user to fall asleep with a lower, more comfortable pressure and helps them gradually become accustomed to increasing treatment pressure. The second selection of pressing ***"MENU"*** is ***[Ramp XX MIN]***. When the ***"MENU"*** setting is in ***[Ramp XX MIN]*** mode, press ***"UP"*** or ***"DOWN"*** button to set the preferred ramp time and press ***"MENU"*** for confirmation. There are 10 adjustable levels, 0, 5, 10, 15, 20, 25, 30, 35, 40 and 45 minutes.

(2) Ramp Starting Pressure (only CPAP mode)

Press ***"MENU"*** button to select ***[Ramp P XX.X]*** menu, press ***"UP"*** or ***"DOWN"*** button to set the preferred ramp starting pressure and press ***"MENU"*** for confirmation. The ramp starting pressure can be changed from 3 cmH_2O to "Therapy Pressure – 1" cmH_2O. For example, if your therapy pressure is 10 cmH_2O, the maximum ramp starting pressure you can select is 9 cmH_2O.

(3) Therapy Pressure (only CPAP mode)

Press ***"MENU"*** button to select ***[P XX.XcmH₂O]*** menu, you can view the current pressure setting displayed in cmH_2O unit. Therapy pressure is adjustable only by the provider, a respiratory therapist or physician.

NOTE: The therapy pressure is to only be prescribed by a physician.

(4) Low Pressure Auto Off (only CPAP mode)

Press ***"MENU"*** button to select ***[LOW P on/off]*** menu, you can view if the Low Pressure Auto Off setting is enabled and the device will be automatically turned off while detecting a large leak for 3 minutes. This setting is adjustable only by the provider, a respiratory therapist or physician.

(5) Initial Pressure (only APAP mode)

Press ***"MENU"*** button to select ***[Init. XX.XcmH₂O]*** menu, you can view the current pressure setting displayed in cmH_2O unit. Initial pressure is adjustable only by the provider, a respiratory therapist or physician.

NOTE: The initial pressure is to only be prescribed by a physician.

(6) Maximum Pressure (only APAP mode)

Press ***"MENU"*** button to select ***[Max. XX.XcmH₂O]*** menu, you can view the current pressure setting displayed in cmH_2O unit. Maximum pressure is adjustable only by the provider, a respiratory therapist or physician.

NOTE: The maximum pressure is to only be prescribed by a physician.

(7) Minimum Pressure (only APAP mode)

Press ***"MENU"*** button to select ***[Min. XX.XcmH₂O]*** menu, you can view the current pressure setting displayed in cmH_2O unit. Minimum pressure is adjustable only by the provider, a respiratory therapist or physician.

NOTE: The minimum pressure is to only be prescribed by a physician.

(8) Compliance Meter

Press ***"MENU"*** button to select ***[CM XXXX.X hr]*** menu, the compliance meter records the total therapy hours for the device. The compliance meter should be re-set only by the provider, a respiratory therapist or by a physician.

(9) Alarm

Press ***"MENU"*** button to select ***[Alarm on/off]*** menu, press ***"UP"*** or ***"DOWN"*** button to set the alarm on or off. When alarm is turned on, the audible alarm will activate with warning messages showed on the LCD display. Set alarm off for mute the audible alarm.

(10) Clock Alarm

Press ***"MENU"*** button to select ***[Clock Alarm on/off]*** menu, press ***"UP"*** or ***"DOWN"*** button to set the clock alarm on or off. When clock alarm is set on, the display will show the time on the left side. Press ***"UP"*** or ***"DOWN"*** button to set the time to wake you up. Once the clock alarm is activated, press the start/standby button to mute the audible alarm.

(11) Clock

Press ***"MENU"*** button to select ***[Clock XX:XX]*** menu, press ***"UP"*** or ***"DOWN"*** button to set the current time.

(12) Turn off the Device

Remove the power cord from the electrical outlet, and disconnect power cord from the power socket on the back of device.

NOTE: Once the setting is confirmed, press *"MENU"* button. Otherwise, the device will automatically go back to standby without saving the modification if no action is taken in 5 seconds.

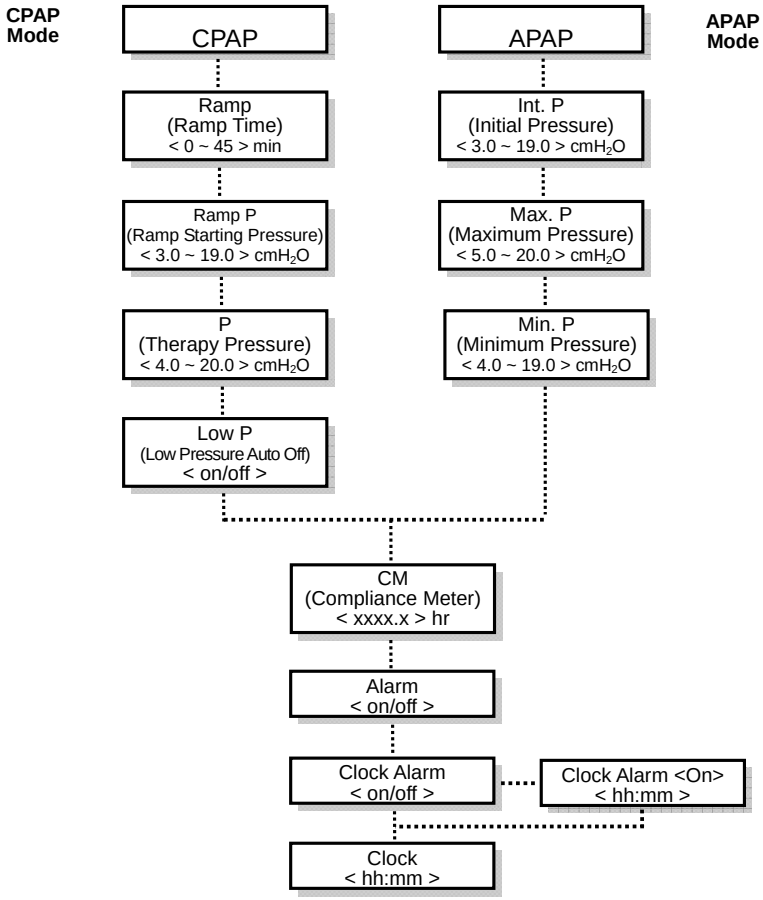
(13) Event Indication

While the device is on standby mode, press ***UP"*** and ***"DOWN"*** button at the same time to see the latest data of Apnea Index (AI), Hypopnea Index (HI) ,Snoring Index (SI) and Flow Limitation Index (FI) on the display. Press ***"MENU"*** button to show each index in sequence. To go back to standby mode, press ***"START/STANDBY"*** button.

NOTE: Once the device is re-started, all the indexes will be re-calculated. Index data can only be viewed by respiratory therapists or physicians by using APAP Compliance playback software.

4.3 Flowchart of Menu settings

Enter the user's menu mode by pressing the "***MENU***" button.



In each setting, when the preferred value has been selected, press ***"MENU"*** for confirmation and press ***"MENU"*** again to enter next selection.

NOTE: For physicians, please refer to a separated "Physician's Additional Instruction" page.