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PROBASICS™
by PMI
Zzz-PAP
Owner's Manual



Model No.: 9S-005 series

Item No. 7501

Please read the instruction manual before use

Contents

| | |
|--|----|
| Important Safeguards..... | 1 |
| 1. Introduction..... | 3 |
| 2. Product Description..... | 4 |
| 3. Installation..... | 5 |
| 4. Operation | 7 |
| 5. Adding the Heated Humidifier..... | 10 |
| 6. Cleaning & Maintenance..... | 10 |
| 7. Troubleshooting | 11 |
| 8. Technical Specifications..... | 12 |
| 9. Note, Caution and Warning Statements..... | 13 |



Provider Mode Instructions (Not for distribution to patients)

(1) To Re-set the Compliance Meter (TM)

1. Press **"MENU"** to select **[TM XXXX.X hr]** menu while in the standby screen.
2. Hold the **"UP"** and **"DOWN"** button, and then simultaneously press the **"MENU"** button for one second. Meanwhile, **[TM XXXX.X hr]** will start blinking and **"CLEAR"** will show on the LCD display.
3. Press **"UP"** or **"DOWN"**. The LCD screen will show **"CLEAR OK"** and the total meter record will be erased so the value becomes 0.0 hr.
4. Press **"MENU"** to confirm the reset function.
5. Press **"START/STANDBY"** button to go back to standby screen or leave the device to automatically go back to standby screen 5 seconds later.

(2) To Set the Prescribed Therapy Pressure

1. Press **"MENU"** to select **[P XX.XcmH₂O]** menu while in the standby screen.
2. Hold the **"UP"** and **"DOWN"** button, and then simultaneously press the **"MENU"** button for one second. Meanwhile, the LCD screen **[P XX.XcmH₂O]** should start blinking to allow you to adjust the therapy pressure from 4 to 18 cm H₂O.
3. Press **"UP"** or **"DOWN"** button to increase or decrease the pressure setting in increments of 0.5 cm H₂O.
4. After selecting the prescribed pressure, press **"MENU"** to confirm.
5. Press **"START/STANDBY"** button to go back to standby screen or leave the device to automatically go back to standby screen 5 seconds later.



Note: Detailed instruction for "Compliance Meter (TM)" and the "Therapy Pressure" are separated because of concerns with renting service management and accidental wrong setting by others. **Please tear off this page from manual before delivering this product to end-user.**

**IMPORTANT SAFEGUARDS
SAVE THESE INSTRUCTIONS
READ ALL INSTRUCTIONS BEFORE USING**

WARNING –

1. **THIS DEVICE IS NOT INTENDED FOR LIFE SUPPORT.** The unit may cease operation due to power interruption but will cause no hazards to the patient. The Probasics Zzz-PAP mini-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 airflow for breathing generated by this device may be as much as 7°C (12.6°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.
4. If this device overheats, it will stop operating and show "Error Message 002" 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) recommended 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 CPAP pressure, some exhaled gas may remain in the mask and be re-breathed.

NOTE –

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



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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 insert any object into any opening or hose.
8. Recommended operating atmospheric condition is above sea level up to 8000 feet, if goes higher than 8000 feet, re-calibration is then required.

LIMITATIONS AND EXCLUSIONS: THE WARRANTY SHALL NOT APPLY TO PROBLEMS ARISING FROM NORMAL WEAR OR FAILURE TO ADHERE TO THE ENCLOSED INSTRUCTIONS. IN ADDITION, THE FOREGOING WARRANTY SHALL NOT APPLY TO SERIAL NUMBERED PRODUCTS IF THE SERIAL NUMBER HAS BEEN REMOVED OR DEFACED; PRODUCTS SUBJECTED TO NEGLIGENCE, ACCIDENT, IMPROPER OPERATION, MAINTANENCE OR STORAGE; OR PRODUCTS MODIFIED WITHOUT PMI'S EXPRESS WRITTEN CONSENT (INCLUDING, BUT NOT LIMITED TO MODIFICATION THROUGH THE USE OF UNAUTHORIZED PARTS OR ATTACHMENTS, PRODUCTS DAMAGED BY REASON OF REPAIRS MADE TO ANY COMPONENT WITHOUT SPECIFIC CONSENT OF PMI; PRODUCTS DAMAGED BY CIRCUMSTANCES BEYOND PMI'S CONTROL; PRODUCTS REPAIRED BY ANYONE OTHER THAN AN AUTHORIZED PMI DEALERS). SUCH EVALUATION SHALL BE SOLELY DETERMINED BY PMI.

THE FOREGOING WARRANTY IS EXCLUSIVE AND IN LIEU OF ALL OTHER EXPRESS WARRANTIES, IF ANY, INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, AND SHALL NOT EXTEND BEYOND THE DURATION OF THE EXPRESS WARRANTY PROVIDED HEREIN AND THE REMEDY FOR VIOLATIONS OF ANY IMPLIED WARRANTY SHALL BE LIMITED TO REPAIR OR REPLACEMENT OF THE DEFECTIVE PRODUCT PURSUANT TO THE TERMS CONTAINED HEREIN. PMI SHALL NOT BE LIABLE FOR ANY CONSEQUENTIAL OR INCIDENTAL DAMAGES WHATSOEVER.

THIS WARRANTY SHALL BE EXTENDED TO COMPLY WITH STATE/PROVINCIAL LAWS AND REQUIREMENTS.

ALL PRODUCTS LEAVE OUR WAREHOUSE IN BRAND NEW CONDITION. IT IS THE CUSTOMER'S RESPONSIBILITY TO EXAMINE ALL SHIPMENTS FOR DAMAGE IMMEDIATELY UPON ARRIVAL. COUNT THE PACKAGES AND SIGN FOR SAFE DELIVERY. SIGN ONLY FOR WHAT YOU RECEIVE. IF MERCHANDISE IS DAMAGED CALL CARRIER AND SECURE DAMAGE INSPECTION REPORT YOU HAVE 15 DAYS TO SECURE DAMAGE REPORTS OTHERWISE YOU MAY LOSE YOUR PRIVILEGE OF FILLING A CLAIM FOR LOSS OR DAMAGE.

LIMITED WARRANTY

PMI WARRANTS THIS PRODUCT TO BE FREE FROM DEFECTS IN MATERIALS AND WORKMANSHIP.

PLEASE NOTE: THE WARRANTY BELOW HAS BEEN DRAFTED TO COMPLY WITH FEDERAL LAW APPLICABLE TO PRODUCTS MANUFACTURED AFTER JULY 4, 1999.

THIS WARRANTY IS EXTENDED ONLY TO ORIGINAL PURCHASER/USER OF OUR PRODUCTS.

PMI WARRANTS ITS PRODUCTS TO THE ORIGINAL PURCHASER TO BE FREE FROM DEFECTS IN MATERIAL AND WORKMANSHIP FOR TWO YEARS. IF WITHIN SUCH WARRANTY PERIOD ANY SUCH PRODUCT SHALL BE PROVEN TO BE DEFECTIVE, SUCH PRODUCT SHALL BE REPAIRED OR REPLACED, AT PMI'S OPTION. THIS WARRANTY DOES NOT INCLUDE ANY LABOR OR SHIPPING CHARGES INCURRED IN REPLACEMENT PART INSTALLATION OR REPAIR OF ANY SUCH PRODUCT. PMI'S SOLE OBLIGATION AND YOUR EXCLUSIVE REMEDY UNDER THIS WARRANTY SHALL BE LIMITED TO SUCH REPAIR AND/OR REPLACEMENT. FOR WARRANTY SERVICE, PLEASE CONTACT THE DEALER FROM WHOM YOU PURCHASED YOUR PMI PRODUCT. IN THE EVENT YOU DO NOT RECEIVE SATISFACTORY WARRANTY SERVICE, PLEASE WRITE DIRECTLY TO PMI AT THE ADDRESS ON THE BACK PAGE. PROVIDE DEALER'S NAME, ADDRESS, MODEL NUMBER, DATE OF PURCHASE, INDICATE NATURE OF THE DEFECT AND, IF THE PRODUCT IS SERIALIZED, INDICATE THE SERIAL NUMBER.

PMI WILL USE A RETURN AUTHORIZATION. THE DEFECTIVE UNIT OR PARTS MUST BE RETURNED FOR WARRANTY INSPECTION USING THE SERIAL NUMBER, WHEN APPLICABLE, AS IDENTIFICATION WITHIN 30 DAYS OF RETURN AUTHORIZATION DATE. DO NOT RETURN PRODUCTS TO PMI WITHOUT PRIOR CONSENT. C.O.D. SHIPMENTS WILL BE REFUSED: PLEASE REPAY SHIPPING CHARGES.

1. Introduction

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

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 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 preventing the OSA.

This device is a micro-processor controlled continuous positive airway pressure device. 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.

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



EN 60601-1
EN 60601-1-2
EN 55011 Class B
IEC 61000-4-2
IEC 61000-4-3
IEC 61000-4-4
IEC 61000-4-5
IEC 61000-4-6
IEC 61000-4-8
IEC 61000-4-11
EN 61000-3-2 Class A
EN 61000-3-3

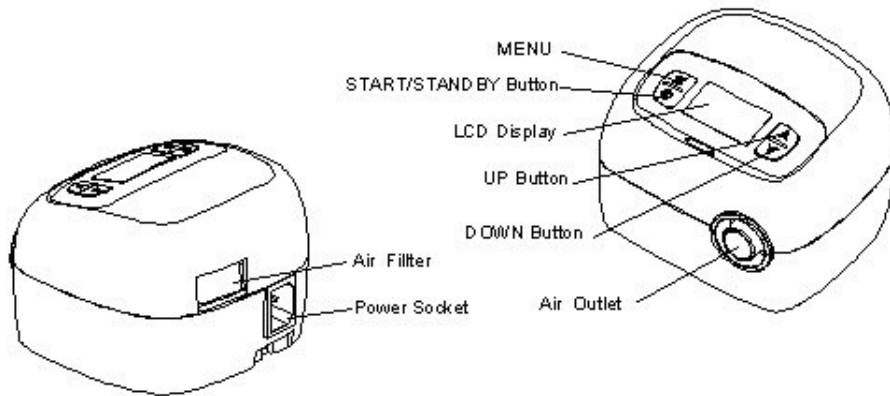
1.2 Intended Use

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

2 Product Description

Components include:

- (1) Main CPAP device
- (2) Detachable power cord
- (3) User manual
- (4) Flexible, 6' long corrugated air tubing
- (5) Carrying bag



BF symbol, which indicates this product is designed to protect against electric shock for type BF equipment.



Attention, should read the instructions.



Grounding terminal



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.

9. 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 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.

Error / Warning Messages show in LCD.

| Message type | Definition | Message in LCD |
|---|---|------------------|
| Error: Primary function can't execute. | Error for system's settings abnormal | Error 001 |
| | Error for flow generator failure | Error 002 |
| Warning: | The allowed maximum time of the meter is reached | Warn 001 |
| | The allowed maximum time of the meter is nearly reached | Warn 002 |

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

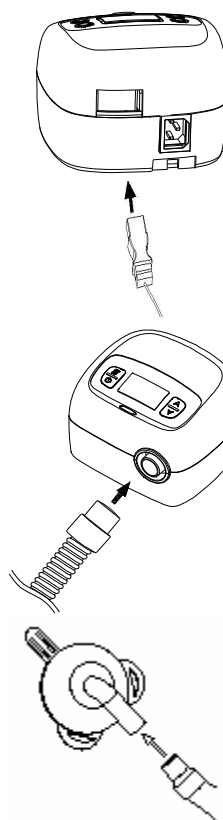
8. Technical Specifications

| Item | | Specifications |
|------------------------|-------------|---|
| Mode of Operation | | Continuous |
| Pressure Range | | 4 -18 cmH ₂ O (adjustable in 0.5 cmH ₂ O increment) |
| Ramp Time | | 0 - 45 minutes (adjustable in 5-minute increment) |
| Altitude Compensation | | Level 1~8 for 0 ~ 8000 ft. (manual setting) |
| 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 ₂ O, 1 meter distance |
| Power Input | | 100-240 VAC, 50/60 Hz, 0.5-0.3A |
| 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 |
| Air Tubing | | Flexible reinforced corrugated plastic, 6' |
| Classification: | | Class I 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.

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 PMI or your Wholesale Source 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 is also served 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. Be sure to then assemble the mask and headgear according to the manufacturer's instruction manual.

3.3 WARNING & CAUTION

WARNING: This CPAP 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 CPAP 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 CPAP machine will stop and show message “**Error 002**”, after cooling down, please re-connect the power cord to reset the machine.

WARNING: When the CPAP is not in operation, oxygen may accumulate within the CPAP device enclosure, and it may create the risk of fire. This warning applies to most of the CPAP models.

WARNING: This device SHOULD NOT be used if the room temperature is warmer than 35°C (95°F) to prevent the temperature of air delivered to nasal mask over 40°C (104°F).

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

WARNING: Recommended operating atmospheric condition is above sea level up to 8000 feet, if goes higher than 8000 feet, re-calibration is then required.

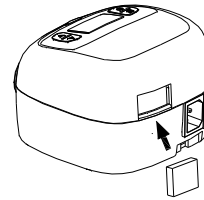
CAUTION: At low pressures, some exhaled gas may remain in the mask and be re-breathed.

CAUTION: Make sure the environment around the machine is dry and clean. Dust and foreign particles may affect the treatment. Keep the air inlet on the back 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 electro-magnetic interference with mobile phones, please increase the distance between devices.

6.3 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.

7. 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. |

5. Adding a Humidifier

Probasics Zzz-PAP CPAP device can be used with the Zzz-PAP integrated Heated Humidifier which is available from your 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 Probasics Zzz-PAP Heated Humidifier instruction manual for complete setup information.



NOTE: When the Probasics Zzz-PAP CPAP device is used with the integrated Heated Humidifier, the power supply runs from the wall power outlet to the rear of the heated humidifier base. Then the jumper cord connects from the humidifier base to the rear of the CPAP unit.

6. Cleaning & Maintenance

6.1 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 CPAP outlet for this can cause the system to malfunction.

6.2 Tubing and Mask

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

1. Disconnect the air tubing from the air outlet of the device.
2. Disconnect the mask.
3. Use a mild detergent (prepare the detergent according to manufacturer's recommendations). And wash both the inside and outside of the tubing.
4. Rinse thoroughly and make sure the tubing is completely dry before reconnecting for the next use.
5. 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.

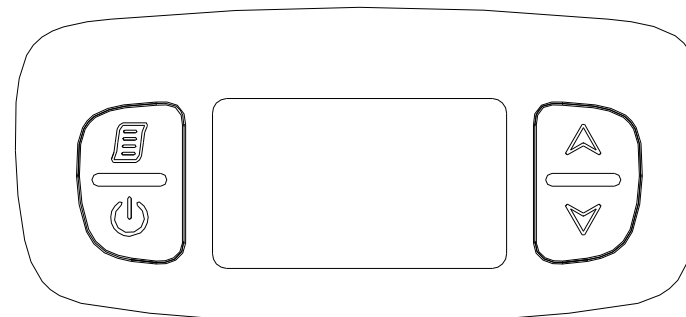
4 Operation



NOTE: Always read the operating instruction before use.

4.1 Control Panel Description

Buttons 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 cmH₂O]** in cmH₂O unit.



MENU

- Press the **"MENU"** button to enter the setting mode when device is in standby mode. The adjustment setting includes ramp time selection, therapy pressure adjustment, altitude compensation, and compliance 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 select the increasing value.



DOWN

Press the **"DOWN"** button to select the decreasing value.

4.2 Function Description

(1) Ramp Time

Ramp time function allows user to fall into sleep with a lower, comfortable pressure and helps users gradually accustomed to increasing treatment pressure. The first 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) Therapy Pressure

Press "MENU" button to select [P XX.XcmH₂O] menu, you can view the current pressure setting displayed in cmH₂O 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.

(3) Altitude Compensation

Press "MENU" button to select [Alt X] menu, press "UP" or "DOWN" button to set the preferred altitude compensation level from 1 to 8. The level should be set depending on your elevation above sea level. Once the preferred level has been selected, press "MENU" for confirmation.

NOTE: Users can operate the Probasics Zzz-PAP at a wide range of altitudes within 0~8000 ft. The altitude function provides a method of accuracy pressure output at high altitude. Users must follow the table below to select correct altitude setting depending on your elevation above sea level. The device will automatically regulate airflow output to achieve the targeted pressure per the setting. Otherwise, the wrong altitude setting will cause inaccurate pressure output. There are eight altitude compensation levels. The level should be set depending on your elevation above sea level. The table below represents proper settings to be used by the altitude range of where the device is being used.

| Altitude Setting | Altitude (Imperial) | Altitude (Metric) |
|------------------|---------------------|-------------------|
| 1 | 0 ~ 1000 ft | 0 ~ 304 m |
| 2 | 1001 ~ 2000 ft | 305 ~ 609 m |
| 3 | 2001 ~ 3000 ft | 610 m ~ 914m |
| 4 | 3001 ~ 4000 ft | 915 m ~ 1219m |
| 5 | 4001 ~ 5000 ft | 1220 m ~ 1524m |
| 6 | 5001 ~ 6000 ft | 1525 m ~ 1829m |
| 7 | 6001 ~ 7000 ft | 1830 m ~ 2134m |
| 8 | 7001 ~ 8000 ft | 2135 m ~ 2438m |

(4) Total Compliance Meter (TM)

Press "MENU" button to select [TM XXXX.X hr] menu, the total compliance meter records the total number of hours that the device has been active. The meter should only be re-set by the provider, a respiratory therapist or by a physician.

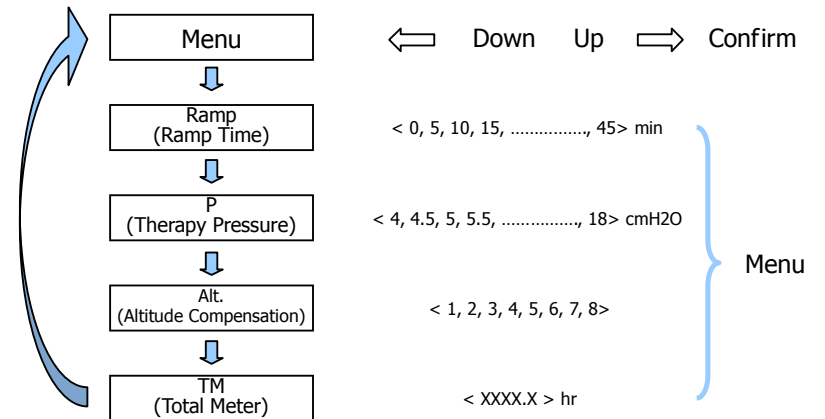
(5) Turn off the Device

Remove the power cord from the electrical outlet, and disconnect power cord from the power socket on the back of the device, or if using the Heated Humidifier, turn off the Humidifier power switch at the rear of the humidifier base.

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 within 5 seconds.

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 provider mode, providers, respiratory therapists and physicians may refer to the separate "Provider Mode Instructions".