



EVEREST[®]3

Integrated CPAP System

Patient Manual

Manufacturer

AEIOMed, Inc.
1313 5th Street SE, Suite 205
Minneapolis, MN 55414 USA
www.aeiomed.com

Phone: 612.455.0550
Toll Free: 866.722.2507
Fax: 612.455.0551

Revision Record

Everest[®] 3 Integrated CPAP System
Patient Manual 101213 Rev A

REF E3PM

Revised: 12-2008

| |
|---------|
| USA |
| Rx only |

Provided for your reference by
cpapXchange.com

© 2008 AEIOMed, Inc., Minneapolis, MN USA
All rights reserved.

AEIOMed[®], Everest[®], HeadRest[®] and DataRest[®] are registered trademarks of AEIOMed, Inc.

NOTICE: The information contained in this document is subject to change without notice.

Contents

| | |
|--|----|
| Precautions for Use | 1 |
| Inspecting the CPAP Components | 6 |
| Description of the Everest 3 Integrated CPAP System..... | 8 |
| Standard User Modes | 8 |
| Buttons..... | 8 |
| Powering the Everest 3 CPAP Device | 9 |
| Using AC Line Power..... | 9 |
| Using the Optional Battery Assembly | 10 |
| Using the Optional Battery Assembly and AC Line Power | 11 |
| Checking the Capacity of the Battery Cell Pack | 12 |
| Changing the Battery Cell Pack..... | 13 |
| Using the Optional Mobile Power Adapter | 14 |
| Using the Optional Battery Assembly and Mobile Adapter | 15 |
| Using the Everest CPAP with a Power Source Connected..... | 16 |
| Starting Therapy | 17 |
| Without Humidifier | 17 |
| With Humidifier | 19 |
| Humidifier Preheat (Optional Step)..... | 22 |
| Using the CPAP with Heated Humidifier and Optional Battery | 23 |
| Turning on the Blower..... | 25 |
| Interface Interrupt Feature (if enabled) | 26 |
| Enabling/Disabling Interface Interrupt..... | 27 |
| Using the Ramp Function | 28 |
| Stopping Therapy | 30 |
| Patient Information Settings | 31 |
| Accessing Patient Settings | 31 |
| Therapy Session Information | 33 |
| Cleaning Instructions..... | 35 |
| Specifications | 37 |
| Manufacturer's Declaration..... | 39 |
| Limited Warranty | 42 |
| Troubleshooting..... | 44 |
| Appendix 1: Reorder Numbers | 48 |

Precautions for Use

This section describes the indications for use, warnings, cautions, and contraindications associated with use of the Everest® 3 Integrated CPAP System. The following guidelines apply to this document:



Indicates the possibility of serious injury or death to yourself or others.



Indicates the possibility of minor injury or damage to the equipment.

NOTE

Indicates a tip, explanation or feature to aid in understanding or efficient operation of the device.

Indications for Use

The Everest 3 Integrated CPAP System is intended for the therapy of adults over 66 pounds (30 kg) with Obstructive Sleep Apnea (OSA). The device delivers continuous positive airway pressure (CPAP), which prevents the collapse of the upper airway, thereby preventing obstructions that can interfere with spontaneous breathing.

Warning

- Caution: Federal law (United States) restricts this device to sale by or on the order of a physician.
- This device is not intended for life support.
- The Everest® 3 Integrated CPAP System must be set up and adjusted by a trained CPAP provider before it can be used for therapy.
- When operating properly, the CPAP system flushes out exhaled air through the vent in the patient interface. Exhaled air could be re-breathed if the CPAP blower is off, not operating properly, or the vent is blocked. Re-breathing exhaled air for longer than several minutes can, in some circumstances, lead to suffocation.
- The air temperature produced by this device can be as much as 10°F higher than the temperature of the room. Exercise caution if the room temperature is warmer than 90°F (32°C).
- Do not block or otherwise obstruct the exhalation ports of the patient interface. Follow the Patient Interface Instructions for your interface.
- Oxygen can only be used in accordance with the Oxygen Use Warnings on the following page.
- Emptying and cleaning the humidifier reservoir daily will help to prevent mold and bacteria growth.
- Use of accessories or a humidifier other than defined in this manual is potentially unsafe.
- The CPAP system is only to be used with the supplied and recommended accessories. Use of accessories not recommended may result in increased electromagnetic emissions or decreased electromagnetic immunity of the CPAP system.
- The CPAP system should not be used adjacent to or stacked with other equipment.
- The CPAP System is not defibrillation proof.

Oxygen Use Warnings

- If oxygen is used with this device, the oxygen flow must be turned off when the device is not in operation.
- Turn the device on before turning oxygen on. This will prevent oxygen from accumulating in the device.
- Do not inject oxygen through the air inlet of the device.
- At a fixed flow rate of supplemental oxygen, inhaled oxygen concentration will vary depending on the pressure settings, patient breathing patterns, mask selection, and leak rate.
- Oxygen use must be accommodated as far down stream as possible from the air outlet side of the CPAP and only as prescribed and set-up by your physician or equipment dealer.

Caution

- Do not sterilize the CPAP system.
- Power the CPAP system only from the AEIOMed® supplied power supply, optional battery assembly, or mobile power adapter. Reference Appendix 1 for Reorder Numbers.
- Reference the Everest® 3 Integrated CPAP Patient Manual only after receiving appropriate training in the use of the CPAP system.
- Use patient interface devices with a leak flow rate of at least 12 L/min at 4 cm H₂O.
- Discontinue use of the CPAP device or humidifier if respiratory irritation occurs.
- Do not introduce liquids or objects into the CPAP device's air inlet/outlet connector.
- Inspect the power cord for signs of wear or damage before each use. Replace the power cord if necessary.
- Reduce the humidifier heat setting if you observe excessive moisture in the flexible tubing.
- For safe operation, place the humidifier lower than the user.

- For proper operation, the humidifier must be level.
- Use the humidifier only for its intended purpose as described in this manual.
- Do not operate the humidifier if any of the parts are damaged, if it is not working properly, or if the humidifier has been dropped or mishandled.
- Do not use the humidifier if the water reservoir is leaking or is damaged in any way. Replace damaged parts before continuing use.
- Do not submerge the humidifier in any fluids; damage may occur.
- The humidifier reservoir must be filled with distilled water to the MAX fill line (see humidifier lid) at the beginning of each therapy session.
- Dry external surfaces before inserting the humidifier reservoir into the humidifier garage.
- AEIOMed, Inc. recommends replacing the 22 mm 6' Output Hose after 6 months use.
- To protect the environment, some parts and accessories of the CPAP system must be disposed of in accordance with local regulations.
- Use only those accessories provided or recommended by AEIOMed, Inc.

Contraindications

The Everest® 3 Integrated CPAP System is contraindicated in patients with the following conditions:

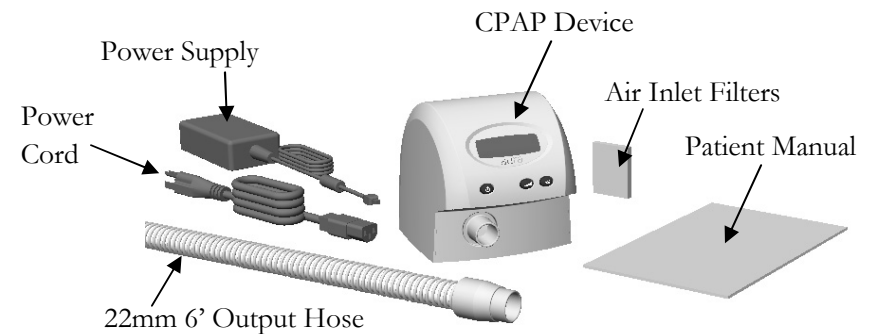
- Bullous lung disease
- Pathologically low blood pressure
- Pneumothorax or pneumomediastinum.
- Pneumocephalus has been reported in some users using nasal CPAP. Caution should be used when prescribing CPAP for susceptible users such as those with cerebral spinal fluid (CSF) leaks; abnormalities of the cribriform plate; and a prior history of head trauma; and/or pneumocephalus.

Inspecting the CPAP Components

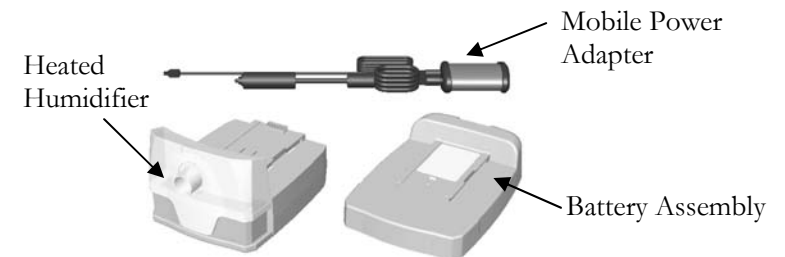
When you receive the Everest® 3 CPAP System package, unpack all items from the travel bag, including the manual, and inspect them to ensure they were not damaged during shipment.

Report any missing or damaged items to your home healthcare provider.

The Everest 3 Integrated CPAP System includes the following items and an accessory pouch (not pictured):



Optional Integrated Components



Refer to Appendix 1 for reorder numbers.

Optional DataRest® Accessories

The DataRest Compliance System makes it easy for your healthcare provider to collect, save, print, and e-mail valuable information collected from the Everest® 3 CPAP device.

The DataRest Compliance System Patient Kit contains the following components:

- Docking Station
- Data Card
- Instruction Manual



The DataRest Compliance System

Refer to the DataRest Compliance System instruction manual or contact your provider for additional information if necessary.

Description of the Everest® 3 Integrated CPAP System

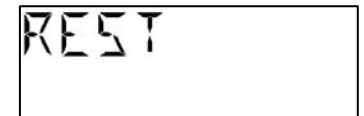
The Everest 3 CPAP System delivers positive pressure from 4 to 20 cm H₂O to the patient, as prescribed by the clinician. The therapeutic pressure is continuous. The display panel presents therapy pressure, settings of the device, and the duration of therapy completed.

Standard User Modes

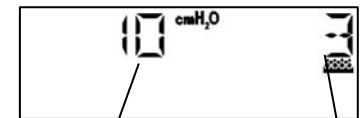
Normal operation consists of 3 states: Off, Standby, and On.

Off: Not connected to a power source. Display is blank.

Standby: Connected to a power source, but the blower is off. "REST" is displayed.



On: Blower is on. The display shows the therapeutic pressure setting. This example shows the setting for the optional humidifier is at 3.



Therapy Pressure Optional Humidifier operating at Setting 3

Buttons



Turns the blower off or on



Manual ramp when the blower is on; in Standby mode it is used to review Patient Settings



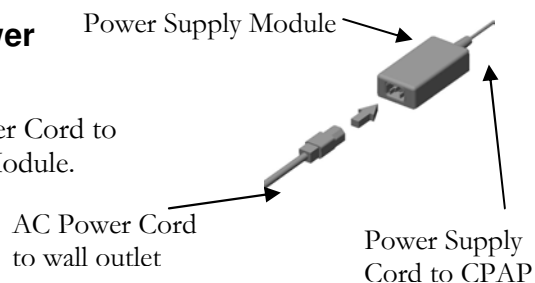
Adjusts the optional humidifier's heater settings when connected; in standby mode it is used to preheat water

Powering the Everest® 3 CPAP Device

The Everest CPAP System offers several choices for powering your CPAP device: AC line power (an electrical wall outlet), optional battery assembly, or optional mobile power adapter (for 12V automotive type receptacles).

Using AC Line Power

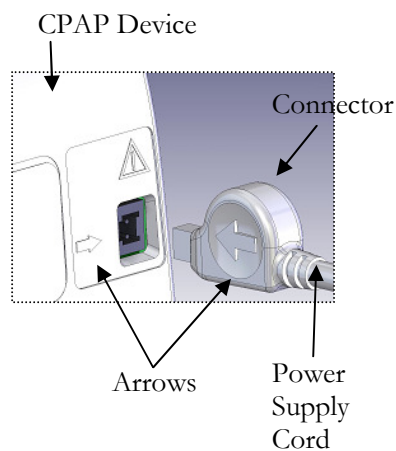
1. Attach the AC Power Cord to the Power Supply Module.



Warning Use only AEIOMed® supplied AC power cord.

2. Insert the AC Power Cord plug into AC line power wall outlet.
3. To attach the Power Supply Cord to the CPAP:

- a. Hold the connector of the Power Supply Cord so the arrow symbol appears on the left side.
- b. Insert the connector into the receptacle on the back of the Everest CPAP device.
- c. The CPAP device is ready for use.



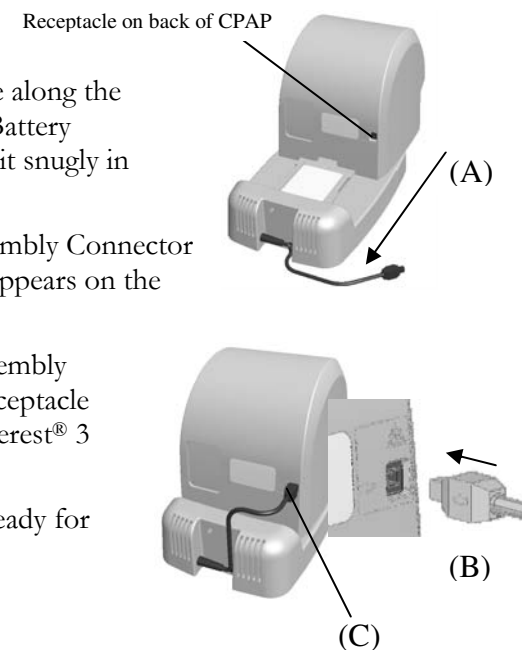
Using the Optional Battery Assembly

Caution Use only the AEIOMed® battery assembly such as may be supplied by your homecare provider.

Note: The battery assembly consists of a charging bay and a removable/replaceable battery cell pack.

Note: Charge the battery assembly for at least 5 hours before the first use.

1. Slide the CPAP device along the notched track of the Battery Assembly, and secure it snugly in place. (A)
2. Hold the Battery Assembly Connector so the arrow symbol appears on the left side. (B)
3. Insert the Battery Assembly Connector into the receptacle on the back of the Everest® 3 CPAP device. (C)
4. The CPAP device is ready for use.



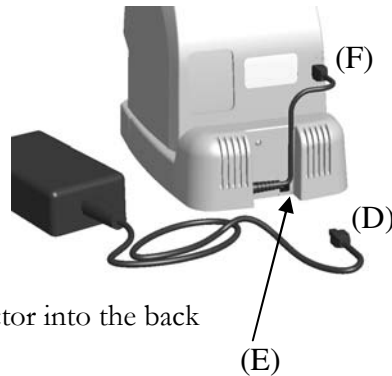
Using the Optional Battery Assembly and AC Line Power

Note: If an electrical outlet is available, use it. This will charge the battery assembly and allow maximum use when AC line power is not available, such as during a power outage. The CPAP device switches automatically to battery power in such events without interrupting your CPAP therapy.

Note: To charge the battery assembly without the CPAP device attached, connect the power supply to the battery assembly.

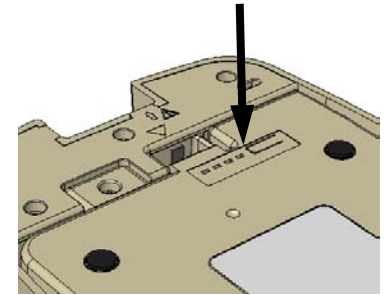
Complete the steps in the section above, *Using the Optional Battery Assembly*.

1. Hold the connector of the power supply so the arrow symbol appears on the bottom. (D)
2. Insert the power supply connector into the receptacle on the back of the battery assembly. (E)
3. Insert the battery assembly connector into the back of the CPAP. (F)
4. Insert the power cord plug into AC line power wall outlet.



Checking the Capacity of the Battery Cell Pack

1. Locate the Key on the bottom of the battery assembly.
2. Press and hold the Key.
3. Observe the number of illuminated lights, which provide an approximate indication of the capacity.



- 0 – 1 lights – Little or no charge remaining.
- 4 lights – Full or near full charge.



Note: For peak performance, AEIOMed® recommends keeping the power supply or mobile adapter connected to the battery assembly even after all 4 lights are illuminated.

Note: Battery life varies depending on the pressure and humidifier settings. Monitoring charge time vs. usage time will help you understand how to optimize battery operation for your system.

Note: Lithium Ion (Li-Ion) batteries such as this one and those used in laptop computers can be charged and discharged either fully or partially repeatedly without noticeable performance loss. However, to get the utmost in runtime throughout the life of your battery, occasionally (e.g. once per month) allow the battery to discharge completely followed by fully charging it for at least 5 hours. Individual results may vary.

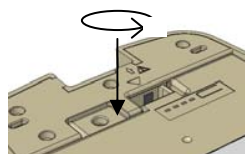
Note: Verify proper disposal requirements of the Li-Ion battery according to local, state, or national laws.

Changing the Battery Cell Pack

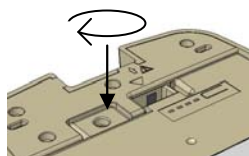
Note: See Appendix 1 to order additional battery assemblies or battery cell packs.

Note: Your battery cell was designed for convenient removal and replacement much like a laptop computer battery. Fully charged spare battery cell packs may be kept on hand and replaced in a matter of minutes.

1. Disconnect any power sources.
2. Detach the Battery Assembly from the CPAP device and humidifier.
3. Locate the battery cell pack screw located on the bottom of the battery assembly. Loosen the screw with a flat blade (or Phillips) screwdriver. The captivated screw is made to remain in place as you loosen it for your convenience.
4. Remove the battery cell pack from the battery assembly.



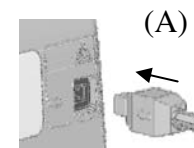
5. Insert the new battery cell into the battery assembly.
6. Tighten the screw.



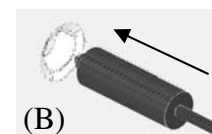
7. Reattach the CPAP components.
8. Reconnect the power connections.
9. Charge for at least 5 hours.

Using the Optional Mobile Power Adapter

Caution Use only the AEIOMed® mobile power adapter and cables such as may be supplied by your homecare provider.



Your mobile power adapter is supplied with two cables: one to connect to your CPAP, and the other to connect to a mobile power receptacle (e.g. 12V automotive/cigarette lighter).



1. Connect both of the cables to the base of the mobile power adapter.
2. Insert the square connector to the back of the CPAP device, making sure to line up the arrows on the left side (similar to connecting Power Supply described previously). (A)
3. Insert the 12V connector into the 12V mobile power receptacle (e.g. cigarette lighter). (B)
4. Ensure the CPAP display turns on indicating that power is being supplied to the CPAP.

Note: Make certain that the cables are securely connected to the power adapter and to the power receptacle. It may be necessary to unplug the cables and reconnect to ensure a good connection.

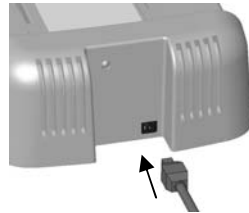
Using the Optional Battery Assembly and Mobile Power Adapter

Note: If a power receptacle for the mobile power adapter is available, use it. This will charge the battery assembly and allow maximum use while traveling.

Note: To charge the battery assembly without the CPAP device attached, use the steps below.

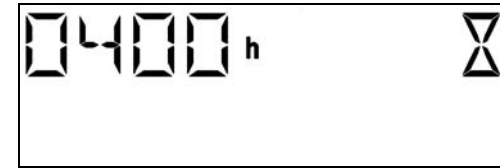
Complete the steps in the section above, *Using the Optional Mobile Power Adapter*.

1. Hold the square connector of the mobile power adapter so the arrow symbol appears on the bottom.
2. Insert the square connector into the receptacle on the back of the battery assembly.
3. Insert the 12V connector into the 12V mobile power receptacle (e.g. cigarette lighter).



Using the Everest® 3 CPAP with a Power Source Connected

When a power source is connected to the Everest 3 CPAP device, the CPAP displays the total number of therapy hours[♦] and a flashing hourglass symbol for 3 seconds.



Following the initial display of the therapy hours, the CPAP device is in Standby mode—the CPAP is ready, the blower is off, and the display shows the following:



Note: If the CPAP loses power while delivering therapy, it will immediately resume delivering therapy as soon as power is restored (the CPAP will skip the initial therapy hours and Standby screens)

[♦] Therapy hours = operating time at therapy pressure, as monitored by the device. Ramp time and Interface Interrupt time are not included in therapy time.

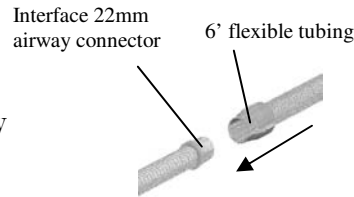
Starting Therapy

Without humidifier:

1. Make sure that the CPAP device is connected to a power source. (If necessary, refer to *Powering the Everest® CPAP Device*.)
2. Ensure the display is in Standby mode. “REST” is displayed.



3. Attach the patient interface 22 mm airway connector to the 6' flexible tubing.
4. Position the patient interface (mask), according to the instructions accompanying the patient interface selected by your care provider.



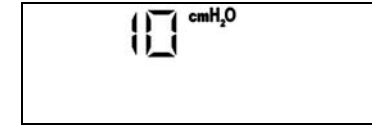
Example of the HeadRest® with Nasal Seal

5. Press the on/off button.



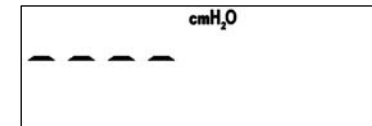
Warning Turn on the CPAP blower as quickly as possible after positioning the patient interface. Exhaled air could be re-breathed if the CPAP blower is off. Re-breathing exhaled air for longer than several minutes can, in some circumstances, lead to suffocation.

6. The blower will turn on, and the display will show the therapeutic pressure setting.



7. Check that the hose and patient interface have a tight seal and that there is no excessive air leaks around the interface when positioned on face.

Note: If you remove or do not securely position the patient interface, the CPAP will automatically reduce the pressure in approximately 1-60 seconds (depending on therapy pressure and interface type). This is called Interface Interrupt (refer to *Interface Interrupt Feature*). It occurs when your patient interface (mask) is removed from your face and the air leak is excessive. The display will indicate that the therapy pressure has been reduced due to the Interface Interrupt function.



Secure the interface and the pressure will increase to the prescribed level when you resume breathing (the display will indicate therapy pressure).

Note: If the device is left off the face for more than one hour, it will shut off the blower and enter Standby mode. To resume device therapy, you must press the on/off button to initiate the CPAP blower.

With humidifier:

The optional heated humidifier relieves nasal dryness and irritation in patients by adding moisture to the airflow.

Warning The humidifier reservoir should be filled to the MAX fill line (see humidifier lid) with distilled water at the start of each therapy session.

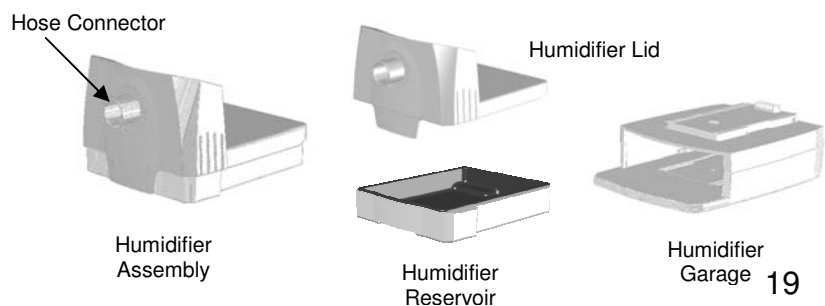
Warning If moisture collects in the hose (sometimes referred to as rainout), adjust the humidity setting. Reducing the humidity setting usually stops the collection of moisture.

Warning Do not spill water into the CPAP air outlet port.

Warning Keep objects out of the humidifier garage when the reservoir is not installed.

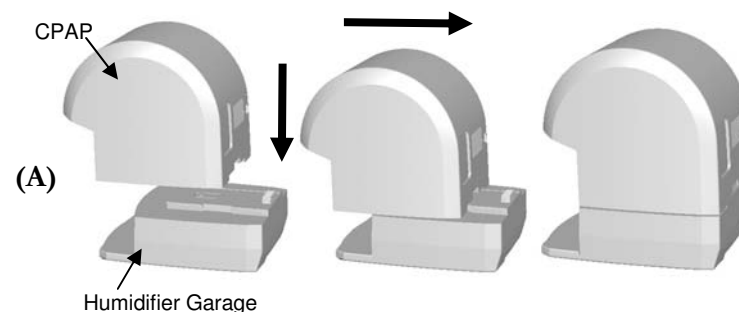
Caution Do not submerge the humidifier in any type of liquid; damage may occur.

Caution Dry external surfaces before inserting the humidifier reservoir into the humidifier garage.



To attach the humidifier to the CPAP:

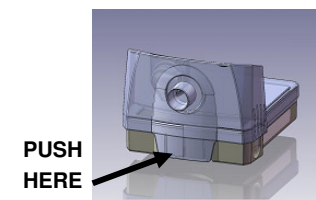
1. Remove the humidifier assembly from the humidifier garage.
2. Attach the humidifier garage to the bottom of the CPAP device (A).



To fill the reservoir:

Note: Refer to “Humidifier Patient Guide”, instructional video DVD, or AEIOMed website (www.aeiomed.com) for additional information.

3. Ensure the humidifier lid is securely seated on the reservoir bottom. The clear lid has slots that fit tightly over the tabs, protruding from the rear of the reservoir bottom.
4. Ensure that the clear lid is securely attached to the humidifier reservoir bottom. Push the front of the latch as shown, to fully engage the humidifier lid with the reservoir bottom.
5. Turn the humidifier reservoir so that the hose connector is facing up.



6. Fill the humidifier reservoir with distilled water to the MAX line.

7. Wipe off excess water from the outside of the humidifier reservoir. Take care to wipe off any moisture that may be on the electrical contacts of the reservoir.

8. Place the reservoir in the humidifier garage, and slide it firmly into position. Ensure humidifier is fully seated in garage (reservoir should 'click' into place when fully seated).

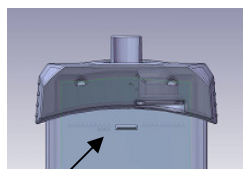
9. Ensure that the silicone adapter is connected to the clear lid tightly at the humidifier hose connector. The flat edge of the silicon adapter should be aligned with the top side of the humidifier.

10. Connect one end of the 6' 22 mm flexible tubing to the humidifier connector.

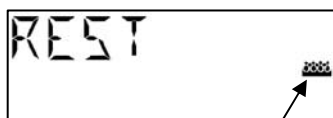
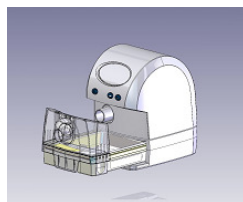
11. Attach the patient interface airway connector to the 6' flexible tubing.

12. Check the lower right-hand corner of the CPAP display for the humidifier symbol:

13. Pressing the humidifier button adjusts the heat settings for the humidifier. Humidifier settings range from minimum heat temperature/humidity (1) to maximum temperature/humidity (5).



MAX Line



Humidifier Symbol



Note: The humidifier symbol without a number above it indicates that the humidifier is connected, but the heat setting is off.

Note: Pressing the humidifier button when the humidifier is not connected does not change the humidifier setting.

Note: The humidifier can be used with the mobile power adapter or the battery. If the battery is used to power the CPAP and the humidifier, without AC line power or mobile power sources, the humidifier heat setting will be automatically reduced to prolong battery life.

Note: During battery operation, the humidifier heat may turn-off when approaching low battery condition to extend overall therapy usage.

Note: The humidifier contains an overheat sensor that will shut off the heating element of the humidifier if there is an over temperature condition (e.g. reservoir is empty).

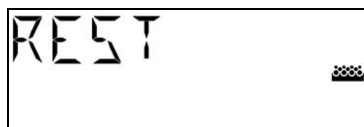
Humidifier Preheat (Optional Step)

Preheating the water in the reservoir provides immediate humidification of the air when the blower is turned on.

Warning Do not wear the patient interface while using preheat, since the blower is off. Exhaled air could be re-breathed. Re-breathing exhaled air for longer than several minutes can, in some circumstances, lead to suffocation.

1. Ensure that the CPAP has power and the blower is off.

2. Check the display for the humidifier icon in the lower right-hand corner.



3. Repeatedly press the humidifier button for the number display. Settings range from minimum temperature/humidity (1) to maximum temperature/humidity (5).



The display shows the humidifier setting.



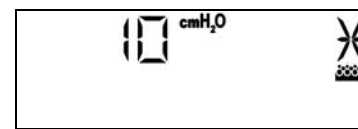
4. Allow the humidifier to preheat for 15-20 minutes. The heat will remain on until the blower is turned off after therapy.

Using the Everest 2 CPAP with the Heated Humidifier and Optional Battery

When the Everest® 3 CPAP and Heated Humidifier are connected to AC line power, the CPAP and Humidifier will function normally as described in the patient manual. When powered by the optional battery assembly however, the device recognizes the loss of AC line power and will enter *Enhanced Energy Management* mode (EEM). EEM extends the life of the optional integrated battery.

Enhanced Energy Management humidification will have the following characteristics that deviate from general AC power usage:

- The CPAP will not offer preheat. If the unit changes from AC power to battery power during preheat, the function is suspended until out of battery mode. When returning to AC power, the unit will resume at previous setting.
- The CPAP will offer only one humidification setting, noted with an asterisk (*) above the humidifier symbol.



- When humidifier shuts off, asterisk symbol will disappear and CPAP will continue therapy without humidification.



- Pressing the humidifier button will toggle between humidification 'on' and 'off.'
- The humidifier will automatically shut off after 5 hours of therapy.

Note: After the Everest 3 CPAP device is disconnected from AC line power it will take 20-40 seconds for recognition of battery use. Following device recognition of battery mode power, the device enters *Enhanced Energy Management* mode and will run the humidifier for a maximum 5-hour period. After this period the humidifier will shut-off, but the CPAP will continue to run on battery power for an estimated 3 hours at 20 cm H₂O prior to battery depletion.

Turning on the Blower

1. Ensure that the CPAP device has power, the blower is off, and the preheated humidifier is active.

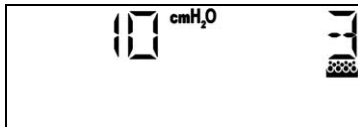


2. Position the patient interface (mask), according to the instructions accompanying the patient interface selected by your care provider.
3. Press the on/off button.



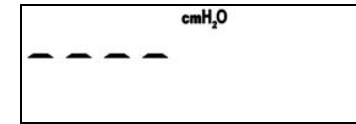
Warning Turn on the blower as quickly as possible after positioning the patient interface. Exhaled air could be re-breathed if the CPAP blower is off. Re-breathing exhaled air for longer than several minutes can, in some circumstances, lead to suffocation.

When the blower is on, the display shows the therapeutic pressure setting. Check that the hose and patient interface have a tight seal and that there is no excessive air leak.



Note: If you remove or do not securely position the patient interface, the CPAP will automatically reduce the pressure in approximately 1-60 seconds (depending on therapy pressure and interface type). This is called Interface Interrupt (refer to *Interface Interrupt Feature*). It

occurs when your patient interface (mask) is removed from your face and the air leak is excessive. The display will indicate that the therapy pressure has been reduced due to the Interface Interrupt function.



Secure the interface and the pressure will increase to the prescribed level when you resume breathing (the display will indicate therapy pressure).

- Note:** If the device is left off the face for more than one hour, it will shut off the blower and enter Standby mode. To resume device therapy, you must press the on/off button to initiate the CPAP blower.
- Note:** The CPAP device recalls the humidity setting during therapy. The next time you begin therapy or turn on preheat, the CPAP will use the same humidifier setting.

Interface Interrupt Feature (if enabled)

The Everest® 3 CPAP will automatically reduce therapy pressure when it detects that the interface has been removed or has an excessive interface leak (within 1-60 seconds, depending on therapy pressure setting and interface type). This feature is intended to minimize disruption to the user or bed partner (e.g. reduce noise when taking a bathroom break). The Interface Interrupt feature also detects when the interface is returned to position on the face and breathing is restored (shortly after the interface is repositioned) and will restore CPAP to previous therapy pressure.

Note: If the Interface Interrupt occurs during normal therapy (indicated by the display showing four dashes instead of

the therapy pressure), please make sure all connections to the CPAP are secure and that no excessive leaks have been introduced. If this feature does not seem to be working properly, please contact Clinician or DME for possible adjustment (reference Troubleshooting table for additional information).

Enabling/Disabling Interface Interrupt

For Everest® 3 CPAP models, the default setting will have Interface Interrupt disabled, and this can only be changed by the clinician. Once the setting is selected, the value is saved within the device and does not change when powered off.

Note: If your CPAP is updated by a prescription created by the PC Compliance software, the Interface Interrupt setting will automatically reset to disable. If this needs to be enabled, the clinician must manually set this or prescription updates cannot be used.

Note: When the Interface Interrupt Feature is disabled, the device will not offer ‘true compliance,’ as therapy session information will record when the device is powered up independent of when the device is actively being used.

Using the Ramp Function

The ramp gradually increases the pressure setting, allowing you to become accustomed to the positive pressure, so that you may ease into the therapy while falling asleep.

Note: If your clinician has instructed you to adjust your ramp starting pressure, refer to *Patient Information Settings*.

1. The CPAP’s blower is on:

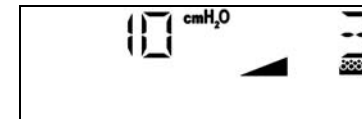


Note: You must start the blower before selecting the ramp function. You should adjust your patient interface at the full therapy pressure setting.

2. Press the ramp button.

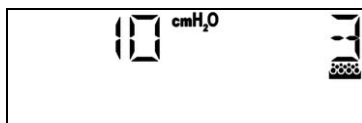


The pressure drops to a reduced level and the display shows the ramp symbol. During ramp, the pressure gradually increases to the prescribed pressure level.



Note: The actual pressure delivered during ramp is not shown on the CPAP display.

Once therapy pressure is reached, the ramp icon will disappear from the display screen.



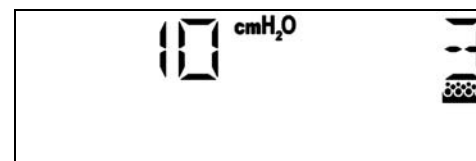
Note: Pressing the ramp button during ramped pressure delivery will not affect the pressure delivered. If you wish to stop the gradual pressure increase of the ramp function you must turn off the device. The next time the blower is turned on it will deliver the prescribed therapy pressure.

Note: Interface Interrupt is not active during ramp.

Note: In the event of power loss during ramp, the CPAP will resume at the full prescribed pressure as soon as power is restored.

Stopping Therapy

The blower is on and the display shows the prescribed pressure setting:



1. Remove the patient interface (mask).
2. Press the on/off button.



3. The blower is off, and the device is in Standby mode ("REST" is displayed).



4. Remove the humidifier reservoir from the humidifier garage.
5. Empty any remaining water from the humidifier reservoir, rinse thoroughly, and allow it to air dry.

Note: The humidifier shuts off when the blower is stopped. However, the CPAP remembers your humidity setting and will use that value the next time you start therapy.

Patient Information Settings

You will typically use the settings configured by your clinician, and will not need to adjust them. You may access patient settings to report therapy session information to your clinician.

Note: When adjusting patient settings, ignore the symbols on the buttons. Instead, the symbol above the button reflects what will occur when you push the button.

Note: Patient Settings consist of viewing therapy session information and ramp settings.

Accessing Patient Settings

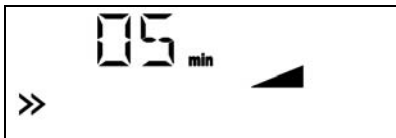
1. Make sure the device is in Standby mode. The CPAP device must have power, and the blower must be off.



2. Press the middle button.



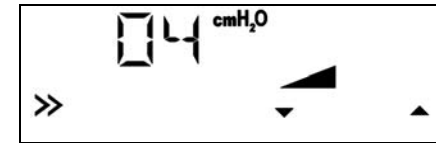
The display shows the approximate duration in minutes for the pressure to ramp from the starting pressure to the prescribed pressure setting (a value of 00 min means ramp is disabled).



3. Press the ">>" (NEXT) button.



The display shows the starting pressure for the ramp



4. Adjust the starting pressure using the buttons under the up and down symbols.

NOTE: If the up and down arrows are not visible on the display, your clinician has not allowed you to change the starting ramp pressure.

5. Press the ">>" (NEXT) button to access therapy session.



Therapy Session Information

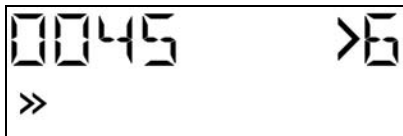
1. The display shows the number of therapy sessions equal to or longer than 8 hours. You cannot adjust the value on this screen.



2. Press the “>>” (NEXT) button.



3. The display shows the number of therapy sessions equal to or longer than 6 hours (but less than 8 hours). You cannot adjust the value on this screen.



4. Press the “>>” (NEXT) button.



5. The display shows the number of therapy sessions equal to or longer than 4 hours (but less than 6 hours). You cannot adjust the value on this screen.



6. Press the “>>” (NEXT) button.



7. The device is back in Standby mode and ready for operation.



Cleaning Instructions

If the case becomes dirty:

- (1) Disconnect power from the unit.
- (2) Use a soft cloth dampened with warm water and mild liquid dish washing soap to clean it.
- (3) Dry the device thoroughly before reconnecting the power source.

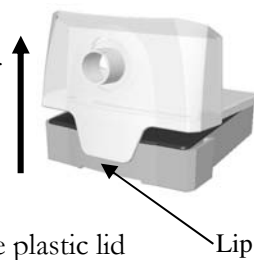
Warning


- Unplug the CPAP device before cleaning it.
- Do not submerge the CPAP device, heated humidifier assembly, battery assembly, battery charger or power supply in liquid.
- Prevent water from entering any of the device's openings.
- Do not use harsh or abrasive cleaning agents to clean any CPAP components.
- Do not sterilize the CPAP device.
- Do not place cleaning materials, such as a cloth or liquid, into the CPAP air inlet or air outlet connector.


Replace the foam air inlet filter periodically. To remove filter, gently tug filter at the center. To replace, insert the new filter and push along its edges to seat in place.


Clean the flexible tubing weekly by washing it in warm water with mild liquid dishwashing soap. Allow the tubing to air dry thoroughly before use.


To clean the humidifier reservoir lid:


1. Hold the reservoir with the bottom of it facing you.
2. Use both hands and position thumbs  under the lip.
3. Push upward on the lip to separate the plastic lid from the reservoir bottom.
4. Rinse the plastic lid with warm water and mild liquid dishwashing soap.
5. Clean the humidifier garage by using a soft cloth dampened with warm water and mild liquid dishwashing soap.
6. Dry with a cloth, or allow to air dry.

 **CAUTION** Do not clean the humidifier components in the dishwasher otherwise damage to humidifier may occur.

 **CAUTION** Do not submerge the heated humidifier garage assembly in liquid or damage may occur.

 **CAUTION** Do not immerse the reservoir bottom in liquid. Clean daily.

 **CAUTION** Dry external surfaces before inserting the humidifier reservoir into the humidifier base.

 **CAUTION** There are no user serviceable parts. Any service or repair must be done by authorized personal only.

Specifications

CPAP Physical Characteristics

| | |
|--|--|
| CPAP Device Weight: | 2.2 lbs (1.00 kg) |
| CPAP Device Dimensions: | 5.0 in X 6.0 in X 5.0 in (12.7 cm X 15.2 cm X 12.7 cm) |
| Air Outlet Connector Port Dimensions: | 22-mm diameter |

Humidifier Physical Characteristics

| | |
|---|--|
| Humidifier Weight: | 0.97 lb (0.44 kg) |
| Humidifier Dimensions: | 6.14 in X 3.45 in X 5.25 in (15.6 cm X 8.8 cm X 13.3 cm) |
| Humidifier Operating Volume: | 0 to 240 ml |
| Humidifier Output: At H5 setting, 4 - 20 cmH ₂ O | ≥ 10 mg/L (Applies to AC or Mobile Power usage) |

Battery Physical Characteristics

| | |
|---|--|
| Battery Weight: | 1.58 lbs (0.72 kg) |
| Battery Life (from fully charged): | 11 hours @ 10 cm H ₂ O without humidifier (Result will vary depending on ambient conditions) |
| Charging Requirement: | Use only AEIOMed-supplied charger, reference Appendix 1 |
| Battery Dimensions: | 7.9 in X 2.0 in X 5.44 in (20.1 cm X 5.08 cm X 13.8 cm) |

Mobile Power Adapter Characteristics

| | |
|------------------------------------|-------------------------------------|
| Mobile Power Adapter Input: | 13.5 Vdc nominal. 12 to 15.5 Vdc |
|------------------------------------|-------------------------------------|

Power Supply Characteristics

| | |
|--------------------------|----------------------|
| AC Supply Input: | 100-240 VAC, 50-60Hz |
| AC Supply Output: | 19Vdc, 2.6 Amp |

CPAP Performance

| | |
|--|---|
| Working pressure range: | 4 to 20 cmH ₂ O |
| Accuracy of Pressure Setting: | ±1 cmH ₂ O or ±10%, whichever is greater |
| Accuracy of Time Display: | ± 1 second |
| Maximum system shutdown pressure: | 30 cmH ₂ O |
| Ramp Time Duration: | ± 25% time variance |
| Operating Temperature Range: | 40 to 104 °F (5 to 40 °C) |
| Storage Temperature Range: | -30 to 150 °F (-34 to 66 °C) |
| Operating Humidity Range: | 10% to 95% relative humidity, non-condensing |
| Storage Humidity Range: | 10% to 95% relative humidity, non-condensing |
| Sound Pressure Level: | ≤ 28 dbA with Heated Humidifier ≤ 22 dbA without Heated Humidifier Sound pressure measured in compliance with Clause 26 of EN 17510-1:2007. |
| Altitude Range: | 0-8000 feet |

EN 60601-1 Compliance

| | |
|---|---|
| Protection against electric shock: | Class II Type BF |
| Degree of Protection against ingress of water: | IPX1 |
| Use of Flammable Gasses: | Equipment not suitable for use in the presence of a flammable anesthetic mixture or with nitrous oxide. Oxygen can be used only as prescribed in the Oxygen Use Warning section of this manual. |

Manufacturer's Declaration

| Table 201: Electromagnetic Emissions | | |
|---|------------|--|
| The CPAP System is intended for use in the electromagnetic environment specified below. The customer or the user of the CPAP System should ensure that it is used in such an environment. | | |
| Emissions Test | Compliance | Electromagnetic Environment—Guidance |
| RF Radiated Emissions CISPR 11 | Group 1 | The CPAP System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF Conducted Emissions CISPR 11 | Class B | The CPAP System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| Harmonic Emissions IEC 61000-3-2 | Class A | |
| Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3 | Complies | |


| Table 202: Electromagnetic Immunity | | | |
|---|--|--|---|
| The CPAP System is intended for use in the electromagnetic environment specified below. The customer or the user of the CPAP System should ensure that it is used in such an environment. | | | |
| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment—Guidance |
| Electrostatic Discharge (ESD) IEC 61000-4-2 | $\pm 2, 4, 6$ kV contact ± 8 kV air | N/A. The CPAP System does not have conductive surfaces. $\pm 2, 4, 6, 8$ kV 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 IEC 61000-4-4 | ± 2 kV for power supply lines ± 1 kV for input/output lines | ± 2 kV for power supply lines ± 1 kV for input/output lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | ± 1 kV differential mode ± 2 kV common mode | $\pm 0.5^*$, 1 kV differential mode ± 2 kV common mode | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11 | $< 5\% U_T$ ($> 95\%$ dip in U_T) for 0.5 cycle $40\% U_T$ (60% dip in U_T) for 5 cycles $70\% U_T$ (30% dip in U_T) for 25 cycles $< 5\% U_T$ ($> 95\%$ dip in U_T for 5 sec) | $< 5\% U_T$ ($> 95\%$ dip in U_T) for 0.5 cycle $40\% U_T$ (60% dip in U_T) for 5 cycles $70\% U_T$ (30% dip in U_T) for 25 cycles $< 5\% U_T$ ($> 95\%$ dip in U_T for 5 sec) | Mains power quality should be that of a typical commercial or hospital environment. If the user of the CPAP System requires continued operation during power mains interruptions, it is recommended that the CPAP System be powered from the battery. |
| Power Frequency (50/60 Hz) Magnetic Field IEC 61000-4-8 | 3 A/m | 3 A/m | Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment. |

NOTE: U_T is the A.C. mains voltage before application of the test level.

* Compliance level adjusted to meet FDA limits.

Table 204: Electromagnetic Immunity

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

| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment—Guidance |
|--|----------------------|---|--|
| Portable and mobile RF communications equipment should be used no closer to any part of the CPAP System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. | | | |
| Conducted RF | 3 Vrms | 3 Vrms | Recommended Separation Distance $d = 1.17 \sqrt{P}$ |
| IEC 61000-4-6 | 150 kHz to 80 MHz | 10 KHz to 100 MHz* | |
| Radiated RF | 3 V/m | 10 V/m* | $d = 0.35 \sqrt{P}$ 80 MHz to 800MHz |
| IEC 61000-4-3 | 80 MHz to 2.5 GHz | 26 MHz to 2.5 GHz* | $d = 0.70 \sqrt{P}$ 800MHz to 2.5 GHz |
| | | * Compliance level adjusted to meet FDA limits. | 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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ¹ should be less than the compliance level in each frequency range. ² 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.

1 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 CPAP System is used exceeds the applicable RF compliance level above, the CPAP System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the CPAP System.

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

Limited Warranty

AEIOMed, Inc. warrants the Everest®3 Integrated CPAP units to be free of defects in materials and workmanship and will perform in accordance with the product specifications for a period of 2 years from the date of sales by AEIOMed, Inc. to the dealer. The battery assembly is similarly warranted for a period of 1 year, and the mobile power adapter is warranted for 3 years from the date of sales by AEIOMed, Inc. to the dealer.

If the product fails to perform in accordance with the product specifications, AEIOMed, Inc. will repair or replace, at its option, any materials or parts of the Everest 3 Integrated CPAP system, which, upon AEIOMed’s examination appear defective. This does not cover damages caused by accident, misuse, abuse, alteration, and other defects not related to material or workmanship. AEIOMed, Inc. will pay customary freight charges from AEIOMed, Inc. to dealer location only.





AEIOMED, INC. 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.

THIS WARRANTY IS GIVEN IN LIEU OF ALL OTHER EXPRESS WARRANTIES. IN ADDITION, ANY IMPLIED WARRANTIES, INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR THE PARTICULAR PURPOSE ARE LIMITED TO TWO YEARS. 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. THIS WARRANTY GIVES YOU SPECIFIC LEGAL RIGHTS, AND YOU MAY ALSO HAVE RIGHTS WHICH VARY FROM STATE TO STATE.

To qualify for repair, replacement, or refund, the defective device must be returned to AEIOMed, Inc. within 30 days after the discovery of the defect. Any repair, replacement, or refund obligation would not apply if the device has been repaired or otherwise altered in a facility not authorized in writing by AEIOMed, Inc. To exercise your rights under this warranty, contact your local, authorized AEIOMed, Inc. dealer or AEIOMed, Inc. at 1313 5th Street SE, Minneapolis, MN 55414, 1-866-722-2507 or 1-612-455-0550.

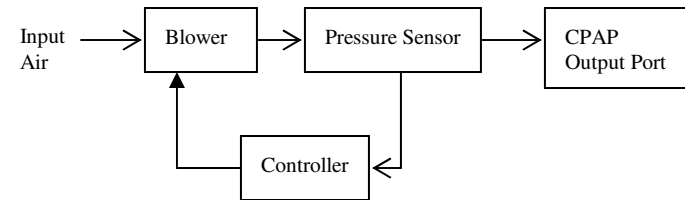
Troubleshooting

| Problem | Probable Cause | Solution |
|---|--|---|
| Discomfort due to a feeling of high pressure. | CPAP device pressure may be set too high. | <ol style="list-style-type: none"> 1. Breathe slowly through your nose with your mouth closed. 2. Use the ramp pressure, if available. 3. If the pressure remains problematic, contact your homecare provider. |
| Nose or throat irritation. | Dry air. | Connect a humidifier to the CPAP device, or add humidity to the room. Contact your provider. |
| | Dirty air filter. | Change and/or clean the air inlet filter. |
| CPAP device display is blank when connected to power. | Power source is not properly connected. | Check all power connections. |
| | AC power may not be active. | <ul style="list-style-type: none"> • Use another power outlet. • Confirm outlet is not controlled by a wall switch. |
| | | Test another device with this outlet. |
| | Battery is depleted. | Check the battery assembly's capacity. Charge if necessary. |
| CPAP shuts off. | <ul style="list-style-type: none"> • Hose disconnected from the device. • The interface was off or dislodged and a high leak was experienced for an extended period of time, enabling the Interface Interrupt feature and shutting off unit. | <ul style="list-style-type: none"> • Reconnect the hose. • Ensure interface adjustments allow proper sealing of the interface to minimize leaks. • Press on the On/Off button to resume at therapeutic pressure. |

| Problem | Probable Cause | Solution |
|---|--|---|
| Low Battery Symbol appears on the display.  | Battery is depleted. | Charge the battery. |
| No airflow from the CPAP system. | Device motor failure; or, electronics failure. | Contact the provider's technical service department. |
| Fault Symbol appears on the display.  | Device detects an operating error. | Note code on display. Unplug and reconnect the power source. If error message continues, contact provider's technical service department. |
| Heat setting cannot be adjusted/shows asterisk symbol (Battery Operation).  | When using humidification on battery power, the CPAP will offer only one humidification setting, noted with an asterisk (*) above the humidifier symbol. | N/A |
| Humidifier heat shuts off (Battery Operation).  | During battery operation, the humidifier heat may turn-off when approaching low battery condition to extend overall therapy usage. | <ul style="list-style-type: none"> Check and/or charge battery prior to nightly usage |
| Heated Humidifier shuts off or is erratic. | Moisture on electrical connector. | Remove and dry connectors – allow to air dry prior to use. |
| Pressure too low | The Interface Interrupt feature is enabled and a high leak was experienced for an extended period; the pressure is reduced until the leak is corrected. | <ul style="list-style-type: none"> Ensure interface adjustments allows proper sealing to minimize leaks |

| | | |
|---|---|--|
| Pressure increases rapidly when interface is removed and then reduces pressure. | This is normal, the device detects within 1-60 seconds that the interface is off and lowers the pressure. | Ensure interface adjustments allow proper sealing to minimize leaks. |
| Pressure increases rapidly when interface is removed, then replaced. | This is normal, the device senses that the interface is being put on and goes from a low pressure to prescribed pressure. | N/A |

Pneumatic Functional Diagram



Symbols



CPAP Output Port



Attention: Consult Accompanying Documents

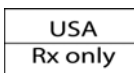


Type BF Applied Part

TYPE BF

IPX1

Ingress of Water. Protection provided against vertical dripping.



CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.

REF

Manufacturer Catalog (Model) Number



CE Mark For Europe

Appendix 1: Reorder Numbers

| Item | REF |
|------------------------------|-------|
| Everest® 3 CPAP | EVE3 |
| Power Supply Assembly | PSA3 |
| Everest 3 Heated Humidifier | HH3 |
| Humidifier Lid Replacement | LID3 |
| Everest Battery Assembly | BAT1 |
| Battery Cell Replacement | CELL1 |
| 22mm 6' Output Hose | 6FH |
| Mobile Power Adapter | MPA |
| Filter Media 2 Pack Assembly | FP3 |
| Patient Manual | E3PM |
| Headrest® with Nasal Seal | HRML |
| Medium Nasal Seal | MNS |
| Large Nasal Seal | LNS |
| Extra-Large Nasal Seal | XLNS |

AEIOMed Everest[®] 3 Integrated CPAP
System
Patient Manual
Part Number 101213 Rev A
 REF E3PM
Revised: 12-2008

AEIOMed, Inc.
1313 5th Street SE, Suite 205
Minneapolis, MN 55414 USA

Web Site: www.aeiomed.com
Phone: 612.455.0550
Toll Free: 866.722.2507
Fax: 612.455.0551

