



Integrated CPAP System

Patient Manual



Manufacturer

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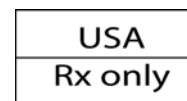
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**NOTICE: The information contained in this document is
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Contents

Precautions for Use.....	1
Inspecting the CPAP Components.....	5
Standard User Modes.....	7
Buttons.....	7
Powering the Everest CPAP Device.....	8
Using AC Line Power.....	8
Using the Optional Battery Pack.....	9
Using the Optional Battery Pack and AC Line Power.....	10
Checking the Battery Pack's Capacity.....	11
Changing Battery Cells.....	12
Using the Optional Mobile Adapter.....	13
Using the Optional Battery Pack and Mobile Adapter.....	14
Starting Therapy.....	16
Humidifier Preheat (Optional Step).....	21
Turning on the Blower.....	22
Stopping Therapy.....	25
Adjusting Patient Settings.....	26
Accessing Patient Settings.....	26
Therapy Session Information.....	28
Cleaning Instructions.....	30
Specifications.....	32
Manufacturer's Declaration.....	34
Limited Warranty.....	37
Troubleshooting.....	39
Appendix 1: Reorder Numbers.....	41

Precautions for Use

This section describes the contraindications, warnings, and cautions associated with use of the Everest® 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 or feature to aid efficient operation of the device.

Indications for Use

The Everest and Everest 2 Integrated CPAP Systems are intended for the therapy of adults over 66 pounds (30 kg) with Obstructive Sleep Apnea (OSA). The devices deliver continuous positive airway pressure (CPAP), which prevents the collapse of the upper airway, thereby preventing obstructions that can interfere with spontaneous breathing.

NOTE: Unless otherwise specified, references to “Everest” throughout this manual refer to both the Everest and Everest 2 Integrated CPAP Systems.

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®2 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).
- In ambient temperatures greater than 95°F (35°C), the CPAP unit must be placed at least 5 feet (1.5m) away from the user.
- Do not block or otherwise obstruct the exhalation ports of the patient interface. Follow the Patient Interface Instructions for your interface.
- This equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- 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 emissions or decreased immunity of the CPAP system.
- The CPAP system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the CPAP system should be observed to verify normal operation.

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.

Caution

- Do not sterilize the CPAP system.
- Power the CPAP system only from the AEIOMed® supplied power supply, optional battery pack, or mobile power supply. Reference Appendix 1 for Reorder Numbers.
- Reference the Everest® Integrated CPAP Patient Manual only after receiving appropriate training in the use of the CPAP system.
- At low CPAP pressures, the flow through the exhalation port may be inadequate to clear all exhaled gas from the airway. Some re-breathing may occur.
- Use patient interface devices with a leak flow rate of at least 12 L/min at 4 cm H₂O.
- Contact your healthcare provider if you experience redness or skin irritation.
- 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 humidity level 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.
- AEIOMed, Inc. recommends replacing the 22 mm 6' Output Hose after 6 months use.
- Use the humidifier only for its intended purpose as described in this manual.
- Use only those accessories provided or recommended by AEIOMed, Inc.
- 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.
- To protect the environment, some parts and accessories of the CPAP system must be disposed of in accordance with local regulations.
- 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.

Contraindications

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

- Bullous lung disease
- Pathologically low blood pressure
- Pneumothorax or pneumomediastinum.

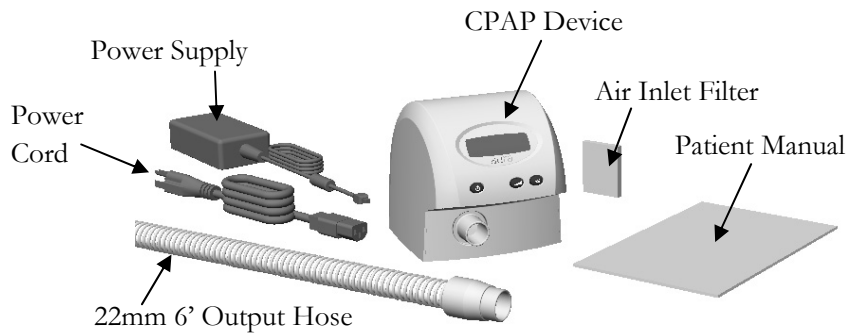
Pneumocephalus has been reported in users using nasal CPAP. Caution should be used when prescribing CPAP for susceptible users such as those with cerebral spinal fluid (CSF) leaks; abnormalities of the cribriform plate; and a prior history of head trauma; and/or pneumocephalus.

Inspecting the CPAP Components

When you receive the Everest® CPAP System package, unpack all items, 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.

Both the Everest and Everest 2 Integrated CPAP Systems include the following items and an accessory pouch (not pictured):



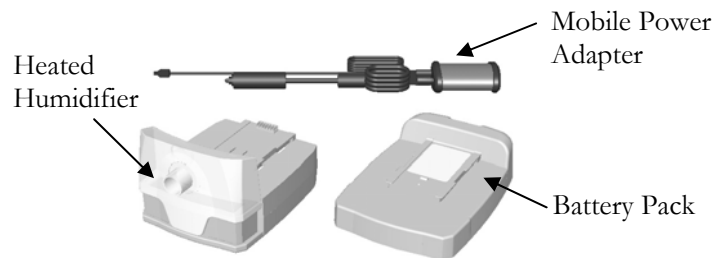
Optional DataRest™ Accessories

The DataRest Patient Kit contains the following additional components:

- DataRest Docking Station
- DataRest Data Card

Refer to DataRest Docking Station Instructions for Use for more information.

Optional Integrated Components



Refer to Appendix 1 for reorder numbers.

Description of the Everest® and Everest 2 Integrated CPAP Systems

The CPAP Systems deliver positive pressure from 4 to 20 cmH₂O to the patient, as prescribed by the clinician. The therapeutic pressure is continuous. The display panel presents delivered pressure, settings of the device, and the duration of therapy completed.

Standard User Modes

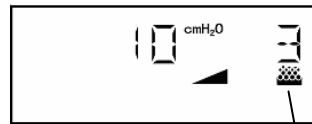
Normal operation consists of 3 states: Off, Standby, and On.

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

Standby: Connected to a power source, but the blower is off. The user can view compliance.



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



Optional Humidifier operating at Setting 3

Buttons



Turns the blower off or on



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



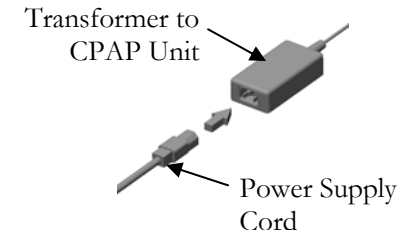
Adjusts the optional humidifier's heater settings when connected

Powering the Everest® CPAP Device

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

Using AC Line Power

Attach the power cord to the power supply.

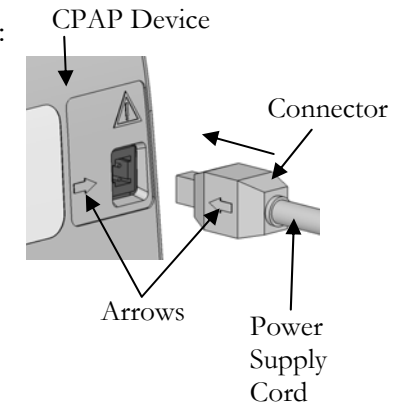


Warning! Use only AEIOMed® supplied power cord.

Insert the power cord plug into AC line power.

To attach the power cord to the CPAP:

1. Rotate the power supply's connector of the power supply so the arrow symbol appears on the left side.
2. Insert the connector into the receptacle on the back of the Everest CPAP device.
3. The CPAP device is ready for use.

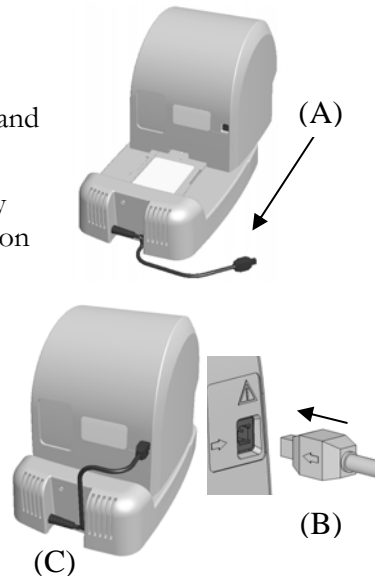


Using the Optional Battery Pack

Caution! Use only the AEIOMed® battery pack supplied by your homecare provider.

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

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



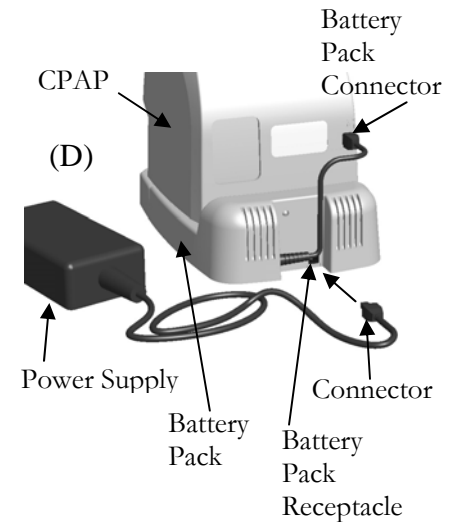
Using the Optional Battery Pack and AC Line Power

Note: If an electrical outlet is available, use it. This will charge the battery pack 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.

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

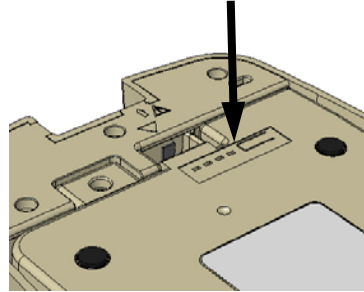
Complete the steps in the section above, *Using the Optional Battery Pack*.

1. Rotate the connector of the power supply so the arrow symbol appears on the bottom. (D)
2. Insert the connector into the receptacle on the back of the battery pack.
3. Insert the battery pack connector into the back of the CPAP.
4. Insert the power cord plug into AC line power.



Checking the Battery Pack's Capacity

1. Locate the Key on the bottom of the battery pack.
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 pack even after all 4 lights are illuminated.

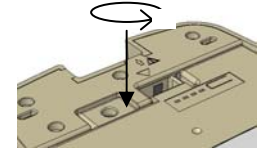
Note: Battery life varies depending on the pressure and humidifier settings. Monitoring charge time vs. usage time will help you understand how to optimize battery operation for your system.

Note: Occasionally (once per month), allow the battery to discharge completely followed by fully charging it for at least 5 hours. This can help keep the battery operating close to its maximum capacity as it ages. Individual results may vary.

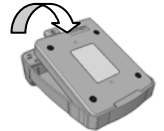
Changing Battery Cells

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

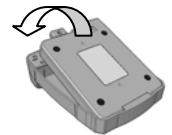
1. Detach the Battery Pack from the CPAP device and humidifier.
2. Disconnect any power sources.
3. Locate the battery cell screw located on the bottom of the battery pack. Loosen the screw with a flat blade screwdriver. The battery pack will retain the screw as you loosen it.



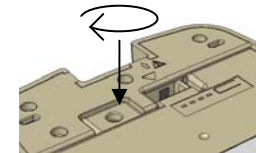
4. Remove the battery cell from the battery pack.



5. Insert the new battery cell into the battery pack.



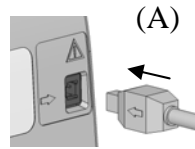
6. Tighten the screw.



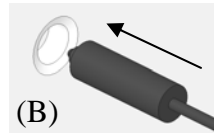
7. Reattach the CPAP components.
8. Reconnect the power connections.

Using the Optional Mobile Power Adapter

Caution! Use only the AEIOMed® mobile power adapter and cables available from 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.



1. Connect both cables to the mobile power adapter base.
2. Attach the square connector to the back of the CPAP device, making sure to line up the arrows on the left side. (A)
3. Connect the oblong cable into the power adapter. (B)
4. Plug the assembled adapter into the mobile power receptacle.
5. Ensure the CPAP display powers on.

Note: If you have any problems, try unplugging the cables and reconnecting them, to make sure that you have a good connections.

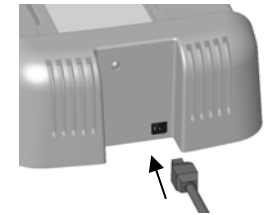
Using the Optional Battery Pack and Mobile Power Adapter

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

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

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

1. Insert the mobile power adapter square connector into the receptacle at the back of the battery pack, making sure to line up the arrow symbols on the bottom.
2. Connect the second cable to the mobile power receptacle.

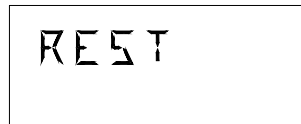


Using the Everest[®]2 CPAP with a Power Source Connected

When a power source is connected to the Everest 2 CPAP device, the CPAP displays the total number of therapy hours[▲] and a flashing hourglass symbol for 3 seconds. Your clinician or homecare provider may request that you report these hours.



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:



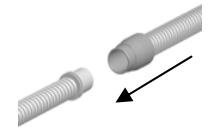
Note: If the CPAP loses power while delivering therapy, it will immediately resume delivering therapy as soon as power is restored (the CPAP will skip the initial therapy hours and Standby screens)

[▲] Therapy hours = operating time at therapy pressure, as monitored by the device.

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.



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.

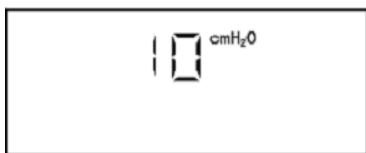


Example of the HeadRest[®] with Nasal Seal

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 is on, and the display shows the therapeutic pressure setting.
7. 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 device will automatically reduce the pressure in approximately 60 seconds. This is called Interface Interrupt. It occurs when your patient interface (mask) is not securely positioned on your face and the air leak is excessive. Secure the interface and the pressure will increase to the prescribed level when you resume breathing.


Note: If you do not breathe with a correctly positioned patient interface within one hour, the device will shut off the blower and enter Standby mode.


With humidifier:

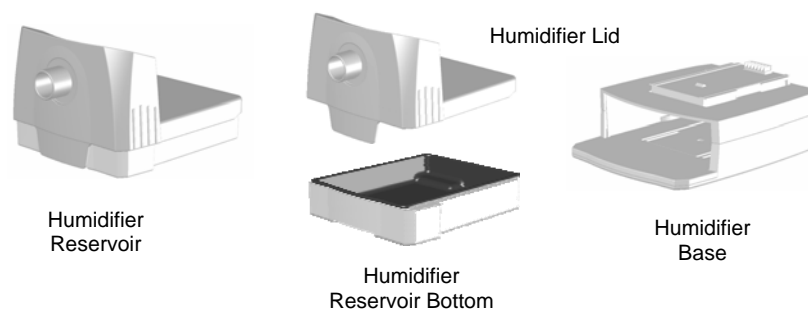
 **Warning!** The humidifier reservoir must be filled to the MAX fill line (see humidifier lid) with distilled water at the start of each therapy session.

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

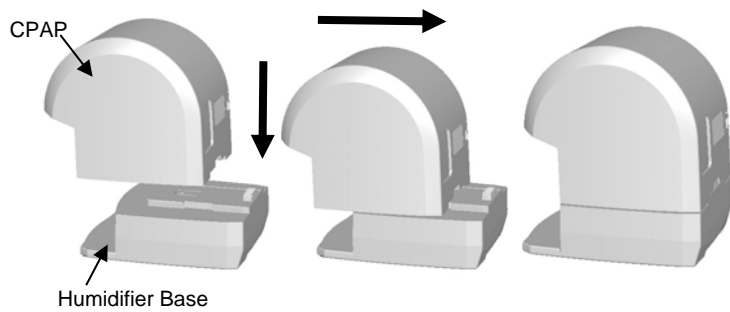
The optional heated humidifier relieves nasal dryness and irritation in patients by adding moisture to the airflow.

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

 **Warning!** Do not spill water into the CPAP air outlet connector.

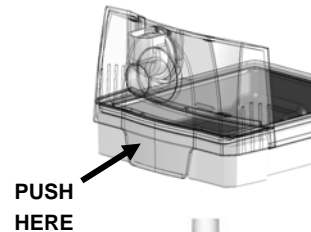


1. Remove the humidifier reservoir from the humidifier base.
2. Attach the humidifier base to the bottom of the CPAP device.



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 below, to fully engage the humidifier lid with the reservoir bottom.



5. Turn the humidifier 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 connector on the reservoir bottom.



8. Place the reservoir in the humidifier base, and slide it into position.

9. Check that the silicone seal is connected to the clear lid tightly at the CPAP air outlet.



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

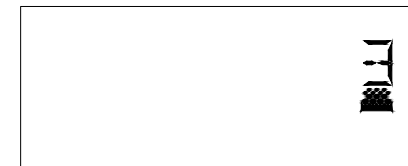


11. Attach the patient interface airway connector to the 6' flexible tubing.

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.



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 battery run-time will be significantly reduced to less than 50% of the expected battery run-time. Two battery packs may be used together to increase battery run-time.

Note: The overheating sensor shuts off the heating element of the humidifier if there is no water.

Humidifier Preheat (Optional Step)

Preheating the humidifier 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. Press the humidifier button for the number display.



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.


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.

The blower is on, and the display shows the prescribed 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 60 seconds. This is called Interface Interrupt. It occurs when your patient interface (mask) is not securely positioned on your face and the air leak is excessive. Secure the interface and

the pressure will increase to the prescribed level when you resume breathing.

If you do not breathe with a correctly positioned patient interface within one hour, the device will shut off the blower and enter Standby mode.

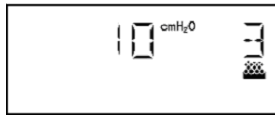
Note: The CPAP device recalls the humidity setting during therapy. The next time you begin therapy, the CPAP will use this same humidifier setting.

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 *Adjusting Patient 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.



After the ramp time is complete, the ramp icon will disappear from the display screen.

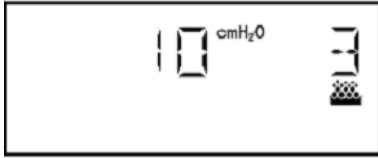
Note: Pressing the ramp button during pressure delivery will not affect the pressure delivered. If you wish to stop the gradual pressure increase of the ramp function you must turn off the device. The next time the blower is turned on it will deliver the prescribed therapy pressure.

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. To restart the ramp, press the ramp button.

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 (shown below).



4. Empty any remaining water from the humidifier reservoir.
5. Rinse the humidifier reservoir 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.

Adjusting Patient 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

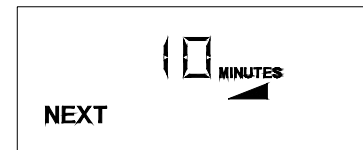
1. Make sure the device is in Standby mode. The CPAP device must have power, and the blower must be off.



2. Press the middle button.



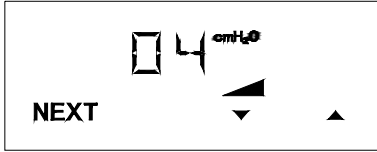
The display shows the duration in minutes for the pressure to ramp from the starting pressure to the prescribed pressure setting.



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.

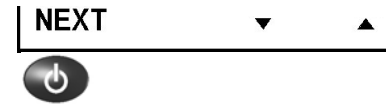
NOTE: If the up and down arrows are not visible on the display your clinician has not allowed you to change the starting ramp pressure.

Therapy Session Information

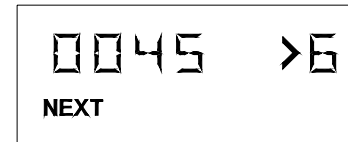
1. The display shows the number of therapy sessions equal to or longer than 8 hours. You cannot adjust the value on this screen.



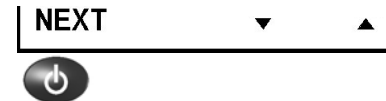
2. Press the NEXT button.



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.



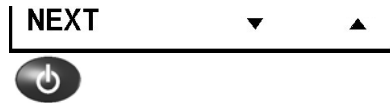
4. Press the NEXT button.



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

The cases of the Everest® and Everest 2 Integrated CPAP devices are durable and do not require special cleaning or maintenance.

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 pack, or battery charger 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. In addition, periodically remove the air inlet filter and rinse it with warm running water. Dry the filter thoroughly before reinstalling it in CPAP device.

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, separate the plastic lid from the reservoir bottom, and rinse with warm water and mild liquid dishwashing soap.



Do not immerse the reservoir bottom in liquid. Clean daily, and fill with distilled water.

Clean the humidifier base by using a soft cloth dampened with warm water and mild liquid dishwashing soap. Dry with a cloth, or allow to air dry.

CAUTION: Do not clean the humidifier components in the dishwasher.

CAUTION: Do not submerge the heated humidifier base or garage assembly in liquid.

Specifications

CPAP Physical Characteristics

CPAP Device Weight:	2.2 lbs (1.00 kg)
CPAP Device Dimensions:	4.8 in X 5.0 in X 5.0 in (11.4 cm X 12.7 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

Battery Physical Characteristics

Battery Weight:	1.58 lbs (0.73 kg)
Battery Life:	11 hours @ 10 cm H ₂ O without humidifier
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:	19.4 Vdc nominal. 12 to 15.5 Vdc
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Power Supply Characteristics

100-240 VAC, 50-60Hz, 19Vdc

CPAP Performance

Working pressure range:	4 to 20 cmH ₂ O
Accuracy of Set Pressure Display:	±1 cmH ₂ O or ±10%, whichever is greater
Accuracy of Time Display:	± 1 second
Maximum system shutdown pressure:	30 cmH ₂ O
Operating Atmospheric Pressure Range:	700 to 1060 mbar (525 to 795 mmHg) up to 11,000 feet
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 level:	31 dbA Sound pressure measured in compliance with Clause 26 of EN 17510-1:2002

EN 60601-1 Compliance

Protection against electric shock:	Class II Type BF
Degree of Protection against ingress of water:	IPX1 Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.


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	±2, 4, 6 kV contact ±8 kV air	N/A. The CPAP System does not have conductive surfaces. ±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	±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 IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 10 KHz to 100 MHz*	Recommended Separation Distance $d = 1.17 \sqrt{P}$ $d = 0.35 \sqrt{P}$ 80 MHz to 800MHz $d = 0.70 \sqrt{P}$ 800MHz to 2.5 GHz where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> 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: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m* 26 MHz to 2.5 GHz*	
		* Compliance level adjusted to meet FDA limits.	

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.

- 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.
- 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® and/or Everest 2 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 pack 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 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

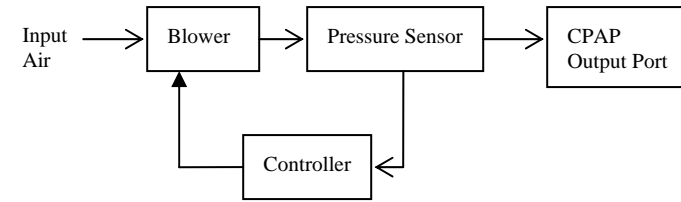
PARTICULAR PURPOSE ARE LIMITED TO TWO YEARS. SOME STATES DO NOT ALLOW THE EXCLUSION OR LIMITATION OF INCIDENTAL OR CONSEQUENTIAL DAMAGES, SO THE ABOVE LIMITATION OR EXCLUSION MAY NOT APPLY TO YOU. THIS WARRANTY GIVES YOU SPECIFIC LEGAL RIGHTS, AND YOU MAY ALSO HAVE RIGHTS WHICH VARY FROM STATE TO STATE.

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 our 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.	Use another power outlet. Test another device with this outlet.
	Battery is depleted.	Check the battery pack's capacity. Charge if necessary.
CPAP shuts off.	Hose disconnected from the device.	Reconnect the hose.
"LBAT" 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.
"UNIT SHUT DOWN" 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.

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.

USA
Rx only

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

REF

Manufacturer Catalog (Model) Number

Appendix 1: Reorder Numbers

Item	REF
Everest [®] CPAP	EV1
Everest 2 CPAP	EV2
Power Supply Assembly	PSA
Everest Heated Humidifier	HH1
Humidifier Lid Replacement	LID1
Everest Battery	BAT1
Battery Cell Replacement	CELL1
22mm 6' Output Hose	6FH
Mobile Power Adapter	MPA
Filter Media 2 Pack Assembly	FP2
HeadRest [®] with Nasal Seal	HRML
Patient Manual	E2PM
Medium Nasal Seal	MNS
Large Nasal Seal	LNS
Extra-Large Nasal Seal	XLNS

AEIOMed® Everest® and Everest 2
Integrated CPAP Systems
Patient Manual
Part Number 101011 Rev B
REF E2PM
Revised: 06-2007

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