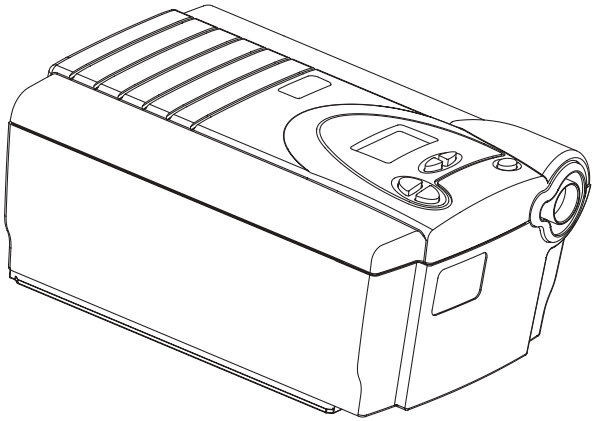
BiPAP® | pro 2

– AND –

BiPAP® | plus



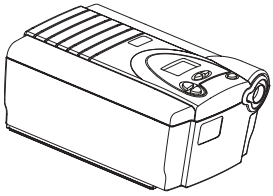
User Manual

This BiPAP system is covered by one or more of the following patents: US Patent Nos. 5,148,802; 5,313,937; 5,433,193; 5,632,269; 5,803,065; 6,029,664; 6,305,374; 6,539,940; 5,239,995; Re 35,295; 5,492,113; 5,551,418; 5,904,141; 5,970,975; and 6,426,689.

Table of Contents

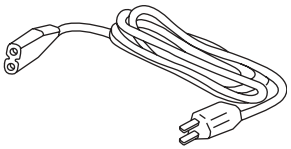
Chapter 1: Package Contents

Your device should include the following items. If any of these items are missing, contact your home care provider.

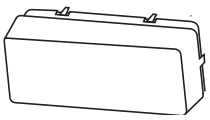


BiPAP Pro 2/BiPAP Plus Device

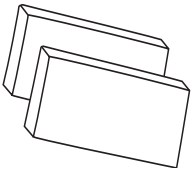
Encore® Pro SmartCard™ (not available with the BiPAP Plus)



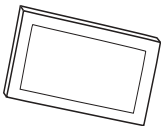
Power Cord



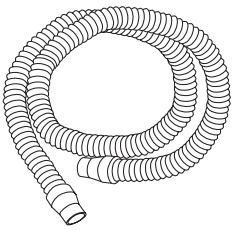
Filter Cap



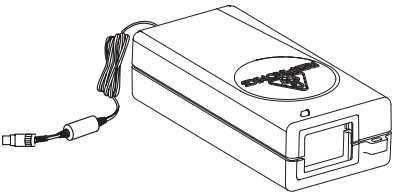
Reusable Gray Foam Filters



Ultrafine Filter



Flexible Tubing
6 ft. (1.83 m) X 22 mm i.d.



External AC Power Supply

CHAPTER 2: WARNINGS AND CAUTIONS

WARNING: Indicates the possibility of injury to the user or operator.

CAUTION: Indicates the possibility of damage to the device.

NOTE: Places emphasis on an operating characteristic.

CAUTION! US federal law restricts this device to sale by or on the order of a physician.

2.1 WARNINGS

- The instructions in this manual are not intended to supersede established medical protocols.
- You should read and understand this entire manual before using the device.
- This device is intended for adult use only.
- This device is not intended for life support.
- The device should be used only with masks and connectors recommended by Respironics or with those recommended by the health care professional or respiratory therapist. A mask should not be used unless the device is turned on and operating properly. The exhalation port(s) associated with the mask should never be blocked.
  Explanation of the Warning: The device is intended to be used with special masks or connectors that have exhalation ports to allow continuous flow of air out of the mask. When the device is turned on and functioning properly, new air from the device flushes the exhaled air out through the mask exhalation port. However, when the device is not operating, enough fresh air will not be provided through the mask, and exhaled air may be rebreathed. Rebreathing of exhaled air for longer than several minutes can in some circumstances lead to suffocation.
- Use only the breathing circuit provided by your home care provider.
- When using a breathing circuit that contains a mask with an integrated exhalation port or a circuit with a separate exhalation device, do not tape, seal, or otherwise block the vent openings. Doing so could result in suffocation.
- If oxygen is used with the device, the oxygen flow must be turned off when the device is not in use.
  Explanation of the Warning: When the device is not in operation and the oxygen flow is left on, oxygen delivered into the tubing may accumulate within the device's enclosure. Oxygen accumulated in the device enclosure will create a risk of fire.

- Contact your doctor if symptoms of sleep apnea recur.
- If you are using oxygen, the device must be equipped with the Respironics Pressure Valve (Part number 302418). Failure to use the Pressure Valve could result in a fire hazard.
- Oxygen supports combustion. Oxygen should not be used while smoking or in the presence of an open flame.
- Do not use the device in the presence of a flammable anaesthetic mixture in combination with oxygen or air, or in the presence of nitrous oxide.
- Do not use the device if the room temperature is above 95° F (35° C). If the device is used at room temperatures above 95° F, the temperature of the airflow may exceed 105° F (41° C), which could cause irritation to your airway.
- Do not operate the device in direct sunlight or near a heating appliance because these conditions can increase the temperature of the air coming out of the device.
- For proper use, the power supply **must** be placed feet down, in the upright position.
- When the device is used with a humidifier, position the humidifier so that the water level in the humidifier is lower than you, and the humidifier is on the same level or lower than the device.
- Do not attempt to wear your mask without the device turned on. Doing so could result in CO_2 rebreathing.
- If you notice any unexplained changes in the performance of the device, if it is making unusual or harsh sounds, if it and/or the power supply has been dropped or mishandled, if the enclosure is broken, or if water has entered the unit, discontinue use and contact your home care provider.
- Repairs and adjustments must be performed by Respironics - authorized service personnel only. Unauthorized service could cause injury, invalidate the warranty, or result in costly damage.
- Periodically inspect electrical cords, cables, and the power supply device for damage or signs of wear.
- To avoid electrical shock, unplug the device before cleaning it.
- Pins of connectors identified with the ESD warning symbol should not be touched. Connections should not be made to these connectors unless ESD precautionary procedures are used. Precautionary procedures include methods to prevent build-up of electrostatic discharge (e.g., air conditioning, humidification, conductive floor coverings, non-synthetic clothing), discharging one's body to the frame of the equipment or system or to earth or a large metal object, and bonding oneself by means of a wrist strap to the equipment or system or to earth.

2.2 Cautions

- The device may only be operated at temperatures between 41° F (5° C) and 95° F (35° C).
- A properly installed, undamaged reusable foam inlet filter is required for proper operation.
- Do not immerse the device or allow any liquid to enter the enclosure or the inlet filter.
- Condensation may damage the device. Always allow the device to reach room temperature before use.

NOTE: Additional warnings, cautions, and notes are located throughout this manual.

2.3 Intended Use

The BiPAP Pro 2 and BiPAP Plus Bi-level systems deliver positive airway pressure therapy for the treatment of adult Obstructive Sleep Apnea (OSA) only.

2.4 Contraindications

Studies have shown that the following pre-existing conditions may contraindicate the use of positive airway pressure therapy for some patients:

- Bullous lung disease
- Pneumothorax
- Pathologically low blood pressure
- Pneumocephalus has been reported in a patient using nasal Continuous Positive Airway Pressure. Caution should be used when prescribing CPAP for susceptible patients such as those with cerebral spinal fluid (CSF) leaks, abnormalities of the cribriform plate, prior history of head trauma, and/or pneumocephalus. (Chest 1989; 96:1425-1426)

The use of positive airway pressure therapy may be temporarily contraindicated if you exhibit signs of a sinus or middle ear infection. This device is not for use with patients whose upper airways are by-passed. Contact your health care professional if you have any questions concerning your therapy.

Chapter 3: Introduction

This chapter contains the following information:

- Definitions for common terms used throughout this manual
- An overview of the device
- An explanation of the symbols used on the device and throughout this manual
- Contact information

3.1 Definitions

The following terms appear throughout this manual:

Apnea	A condition marked by the cessation of spontaneous breathing.
Auto-Off	This feature, when enabled through the Patient Disconnect setting, causes the device to automatically transition from the Operate state to the Standby state whenever the mask is removed from the airway.
Auto-On	The device automatically transitions from the Standby state to the Operate state when you begin breathing (3 consecutive breaths) on the device.
Bi-Flex	A therapy feature that establishes a level of pressure relief taking place at the end of inhalation and at the start of exhalation (*BiPAP Pro 2 only*).
EPAP	Expiratory Positive Airway Pressure
High Priority Alert	Alert signal indicating a condition that requires immediate attention.
IPAP	Inspiratory Positive Airway Pressure
Low Priority Alert	Alert signal indicating an informational message.
Medium Priority Alert	Alert signal indicating a condition that requires operator awareness.
Operate State	The state of the device when the unit and the airflow are both on.
Standby State	The state of the device when the unit is on, but the airflow is off.

OSA	Obstructive Sleep Apnea
Ramp	A feature that may increase patient comfort when therapy is started. The ramp feature reduces the pressure and then gradually increases (ramps) the pressure to the prescription setting, so you can fall asleep more comfortably.
Rise Time	The time it takes for the device to change from EPAP to IPAP. You can adjust this time for your comfort.

3.2 Overview

This system offers several options in how therapy is delivered, so treatment can be personalized to meet your needs. The system delivers two different positive pressure levels: IPAP (Inspiratory Positive Airway Pressure) and EPAP (Expiratory Positive Airway Pressure). Your home care provider will make the correct pressure settings.

When prescribed by your physician, the ramp function allows you to lower the pressure when you are trying to fall asleep. The air pressure will gradually increase until your prescription pressure is reached. You also have the option of not using the ramp feature at all.

Several accessories are available to make your OSA treatment with the BiPAP Pro 2 or BiPAP Plus system as convenient and comfortable as possible. Contact your home care provider to purchase any accessories not included with your system.

The device, shown in Figure 3–1, supplies air pressure through a breathing ciruit.

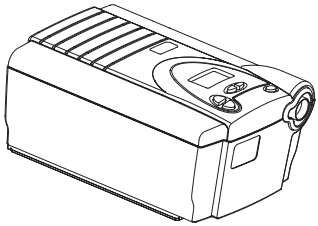


Figure 3–1 The BiPAP Pro 2/BiPAP Plus Device

The circuit, shown in Figure 3–2, consists of:

- Circuit tubing to deliver air from the device to your interface (e.g., mask)
- A mask or other patient interface device to deliver the prescribed pressure to your nose or nose and mouth, depending on which interface has been prescribed for you
- An exhalation device to vent exhaled air from the circuit

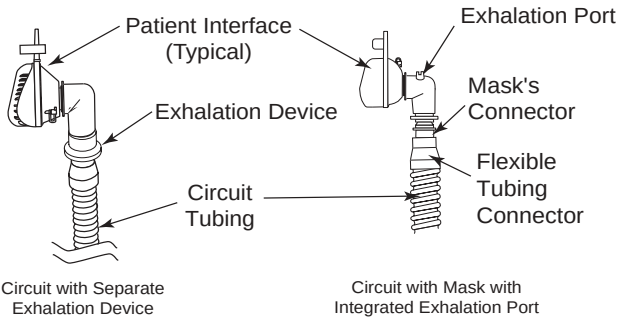


Figure 3–2 Typical Breathing Circuits

NOTE: The exhalation port may be part of the mask or may be part of a separate exhalation device, but is required to minimize the potential for CO_2 rebreathing.

The system senses your breathing effort and changes pressure levels when you inhale and exhale depending on the mode of operation.

WARNING: The device can operate on AC or DC power. The DC power option is not intended as a battery backup.

CAUTION: When DC power is obtained from a vehicle battery, the device should not be used while the vehicle's engine is running.

3.3 Symbols

The symbols shown below are used on the device and throughout this manual.

Symbol	Meaning
	Attention, consult accompanying documents
	DC Power
	Type BF Applied Part
	Class II (Double Insulated)
	European CE Declaration of Conformity
	Notified Body Approval for Standards Compliance
	Canadian/US Certification
	Electrostatic Discharge
IPX1	Drip Proof Equipment
	UL Recognized for Canada and the United States
	TUV Safety Standard Compliance
	No User Serviceable Parts

3.4 How to Contact Respironics

To have your unit serviced, contact your home care provider. If you need to contact Respironics directly, call 1-800-345-6443 or use the following address:

RESPIRONICS®
1001 Murry Ridge Lane
Murrysville, Pennsylvania
15668-8550 U.S.A.

Chapter 4: Controls and Display Features

4.1 Control Panel

The control panel contains the following control buttons, shown in Figure 4–1.

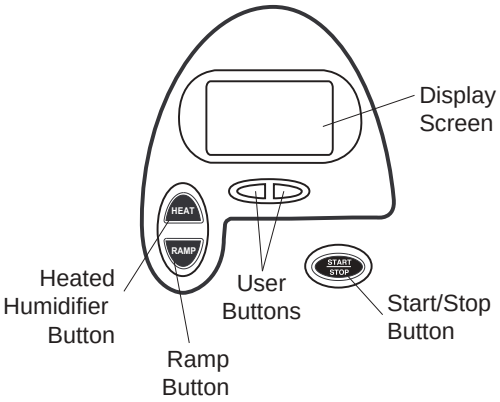


Figure 4–1 Control Panel

START/STOP This button starts or stops the unit's airflow. Press the button in to turn the airflow on and put the device in the Operate state. When the button is turned off, the device is in the Standby state. When in Standby, any ramp in progress is terminated, the alerts are reset (except for the System Errors alert), and the humidifier is turned off. This button is also used to exit the parameter screens.

HEAT When the optional REMstar Heated Humidifier is prescribed, this button controls the humidifier's heater plate setting. Follow the instructions provided with the humidifier. You can also use this button to adjust the settings shown in the user menu screens.

RAMP When the airflow is turned on and the ramp function is enabled, this button lowers the airflow pressure, allowing you to fall asleep more easily. You can also use this button to adjust the settings shown in the user menu screens.

USER The left and right user buttons allow you to navigate the display screens.

NOTE: Additionally, if an alert occurs, pressing any of the buttons on the control panel will clear the alert.

4.2 Display Screen

The display allows you to view the measured pressure and displays alert messages. Figure 4–2 shows the device display screen.

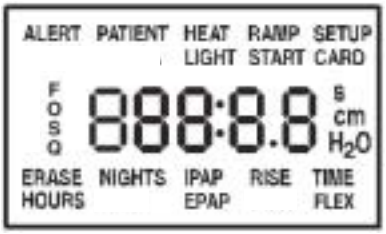


Figure 4–2 Display Screen

The information shown on the display screen is defined as follows:

ALERT — Indicates that the device requires user attention as indicated on the screen.

CARD — Indicates that a SmartCard is inserted and detected (*BiPAP Pro 2 only*).

cm H_2O — Indicates that the alphanumeric digits are displaying a pressure value.

EPAP — Indicates that an EPAP pressure setting is being displayed.

ERASE — Indicates that the user may clear the Therapy Session Counter.

FLEX — Indicates that a Bi-Flex comfort setting is being displayed or is active (*BiPAP Pro 2 only)*.

FOSQ — Indicates that the FOSQ test is active (*BiPAP Pro 2 only)*.

HEAT — Indicates that the humidifier is turned on and/or its setting is displayed.

HOURS	Indicates that the Therapy Hour Meter is being displayed.
IPAP	Indicates that an IPAP pressure setting is being displayed.
LIGHT	Indicates that the control panel LED backlight setting is being displayed or is active.
NIGHTS	Indicates that the session counter is being displayed.
PATIENT	Indicates that a Patient Disconnect alert is active.
RAMP	Indicates that the ramp function is in progress.
RAMP START	Indicates that the ramp starting pressure is being displayed.
RISE TIME	Indicates that a rise time setting is being displayed.

4.3 Breathing Circuit Connection

Figure 4–3 shows where the circuit tubing connects to the device.

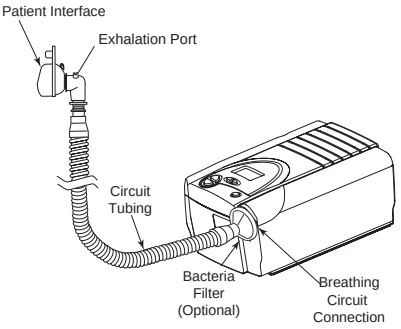


Figure 4–3 Typical Breathing Circuit Connection

4.4 Rear Panel

Figure 4–4 shows the rear panel of the BiPAP Pro 2 and BiPAP Plus.

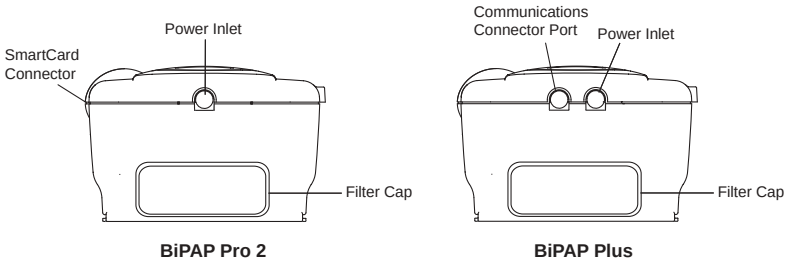


Figure 4–4 Rear Panels

NOTE: The SmartCard Connector is located on the side of the BiPAP Pro 2 unit. There is no SmartCard connector on the BiPAP Plus.

The BiPAP Pro 2 rear panel contains the following:

- A power inlet for connecting either the external AC power supply or a Respironics DC power adapter (when available).
- The filter cap that is removed to inspect the inlet air filters.

The BiPAP Plus rear panel contains the following:

- A communications connector that accepts the Respironics Communications Cable for computer and external communications. (Use only with an IEC 60950 approved computer.)
- A power inlet for connecting either the external AC power supply or a DC power adapter.
- The filter cap that is removed to inspect the inlet air filters.

CHAPTER 5: SETUP

This chapter provides instructions on how to:

- Install the air filters
- Position the device
- Connect the breathing circuit
- Plug the device in using AC or DC power

5.1 INSTALLING THE AIR FILTERS

CAUTION: A properly installed, undamaged foam filter is required for proper operation.

The device uses a gray foam filter that is washable and reusable, and an optional white, ultra-fine filter that is disposable. Two reusable gray foam filters and one disposable ultra-fine filter are supplied with the device.

If your home care provider did not install the inlet air filters, you must install at least the gray foam filter before using the device.

1. Place the gray foam filter on top of the ultra-fine filter (if using the ultra-fine filter).
2. Slide the filters into the air inlet at the rear of the device, and push them down into the recess as shown in Figure 5-1.

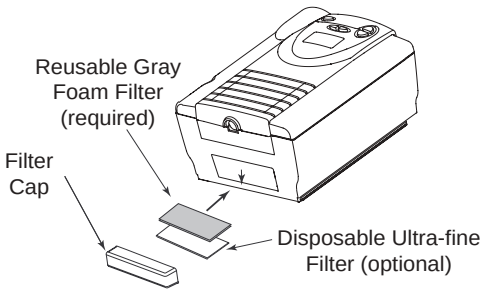


Figure 5–1 Installing the Filters

3. Attach the filter cap as shown in Figure 5–2. Position the cap so that the small opening on the cap is facing down. Insert the caps bottom tabs into the openings below the filter area. Snap the cap into place.

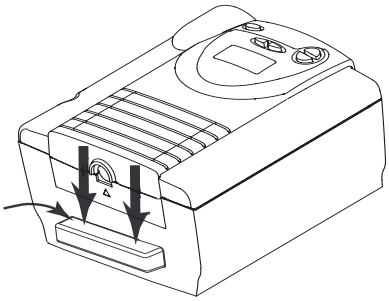


Figure 5–2 Attaching the Filter Cap

NOTE: The filter cap should be installed with the air inlet opening at the bottom.

See Chapter 9 to clean or replace the filters.

5.2 Where to Place the Device

Place the device on its base somewhere within easy reach of where you will use it. Make sure that the air inlet on the rear of the unit is not blocked. Place the unit on a hard, flat surface. If you block the air flow around the device, it may not work properly.

WARNING: If using an external humidifier, position the humidifier so the water level is lower than you, and the humidifier is on the same level or lower than the device. See the humidifier instructions for complete setup information.

5.3 Connecting the Breathing Circuit

To connect your breathing circuit to the device, complete the following steps:

1. Connect one end of the circuit tubing to the outlet of the bacteria filter (if using one) and connect the inlet of the bacteria filter to the large connector on the device as shown in Figure 5–3.

   If you are not using a bacteria filter, connect the end of the circuit tubing directly to the outlet connector on the device.

NOTE: Follow the recommendations of your home care provider for using the optional bacteria filter.

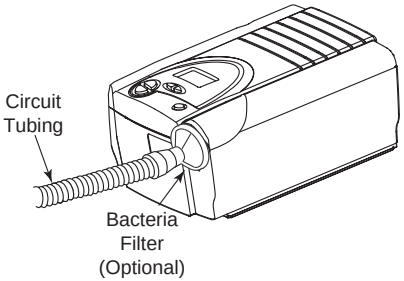


Figure 5–3 Connecting the Tubing to the Outlet

2. Connect the tubing to the mask:

   A. If you are using a mask with a built-in exhalation port, connect the mask's connector to the circuit tubing, as shown in Figure 5–4.

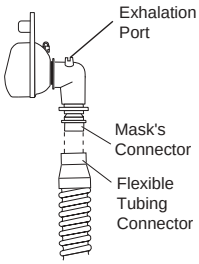


Figure 5–4 Connecting a Mask with a Built-In Exhalation Port

B. If you are using a mask with a separate exhalation device, connect the open end of the circuit tubing to the exhalation device as shown in Figure 5–5. Position the exhalation device so that the vented air is blowing away from your face.

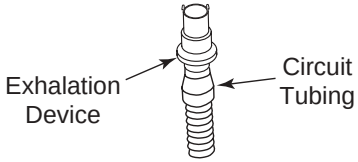


Figure 5–5 Connecting an Exhalation Device

Connect the mask's connector to the exhalation device, as shown in Figure 5–6. See the mask instructions for complete setup information.

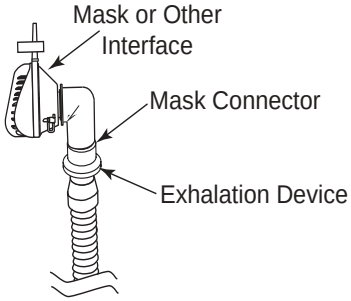


Figure 5–6 Connecting the Mask

WARNING: The exhalation device is designed to exhaust CO_2 from the patient circuit. Do not block or seal the ports on the exhalation device.

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3. Attach the headgear to the mask. See the instructions that came with your headgear.

5.4 Complete Setup

Figure 5–7 shows the completed breathing circuit setup for the device.

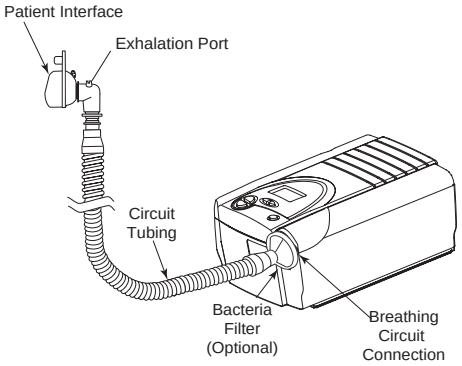

Figure 5–7 Complete Breathing Circuit

5.5 Plugging the Unit In

You can use AC or DC power to operate the device.

WARNING: The DC power option is not intended as a battery backup when using AC power.

WARNING: For proper use, the power supply **must** be placed feet down, in the upright position, as shown in Figure 5–8.

5.5.1 Using AC Power

Complete the following steps to operate the device using AC power:

1. Plug the pronged end of the AC power supply's cord into an electrical outlet.
2. The external AC power supply features a cord retainer to provide strain relief for the AC power cord. Wrap the cord around the AC power supply's cord retainer, using the wire tie supplied with your power supply.

WARNING: Never plug the AC power supply into an outlet that is controlled by a wall switch.

WARNING: Route the wires to avoid tripping.

3. Leaving a small amount of slack in the cord, connect the cord on the other side of the power supply to the power inlet on the device, as shown in Figure 5–8. The power cord has a locking connector. To properly plug in the cord:
   a. Pull the locking mechanism back.
   b. Push the connector into place.
   c. Release the lock.

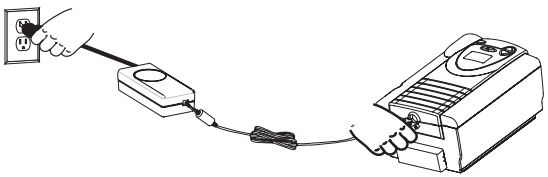

Figure 5–8 Plugging in the AC Power Supply

4. Ensure that all connections are secure.

NOTE: If you need to disconnect the power cord from the device, slide the locking connector back before removing the power cord.

5.5.2 Using DC Power

You can operate the device on DC power by using the Respironics DC power adapter accessory (when available). See the DC power adapter instructions for more information.

CAUTION: Only use the Respironics DC power adapter available from your home care provider. Use of any other system may cause damage to the device or the vehicle.

CAUTION: When DC power is obtained from a vehicle battery, the device should not be used while the vehicle's engine is running. Damage to the device or the vehicle may occur.

CHAPTER 6: OPERATING THE DEVICE

This chapter explains how to start the device and change the settings.

6.1 STARTING THE DEVICE

1. Plug in the device to an AC or DC power source to power up the unit. A confirmation alarm sounds, and the control panel buttons light up.

NOTE: If the alarm does not sound or the buttons do not light up, the device requires servicing. Contact your home care provider.

Several screens appear initially during this step:

a. The first screen that appears is the Self Test screen, shown in Figure 6–1. This is the internal test performed by the device.

Figure 6–1 Self Test Screen

b. The next screen displays the software version, as shown in Figure 6–2:

Figure 6–2 Software Version Screen

NOTE: Version 1.0 shown in Figure 6–2 is an example. Your device may have a different software version installed.

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c. The third screen to appear is the Blower Hours screen, which displays the blower hours time meter:

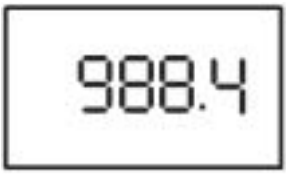

Figure 6–3 Blower Hours Screen

NOTE: The control panel is inactive during these first three screens. Each of these screens appears for approximately 1-3 seconds.

---

d. The next screen that appears is the Standby screen, shown in Figure 6–4. This indicates that the device is in the Standby state. The screen displays the number of therapy hours.

Figure 6–4 Standby Screen

2. Press the **Start/Stop** button to put the device into the Operate state. The Monitoring screen, shown in Figure 6–5, appears.

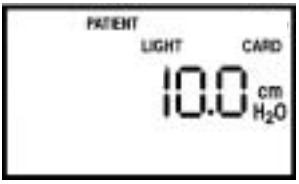

Figure 6–5 Monitoring Screen

Both the Monitoring and the Standby screens display the **PATIENT**, **FLEX**, and **LIGHT** icons if these features are enabled. Additionally, the **CARD** icon displays if a SmartCard is inserted (*BiPAP Pro 2 only)*. The Monitoring screen also displays the actual measured pressure.

3. Put on your mask assembly when the air starts to flow.
4. Make sure that no air is leaking from your mask into your eyes. If it is, adjust the mask and headgear until the air leak stops. See the instructions that came with your mask for more information.

NOTE: A small amount of mask leak is normal and acceptable. Correct large mask leaks or eye irritation from an air leak as soon as possible.

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5. If you are using the device while sleeping, try placing the tubing from the device over your headboard. This may reduce tension on the mask.
6. Relax. Take normal, relaxed breaths through your nose.

NOTE: If you are having trouble with your mask, see Chapter 8, *Troubleshooting*, for some suggestions.

6.2 Changing the Device Settings

You can view the measured pressure on the device display screen.

Additionally, you can view and modify the following settings by pressing and holding the **Ramp** button while the device is in Standby:

- Flex (*BiPAP Pro 2 only)*
- Rise Time
- Ramp start pressure
- LED backlight
- Answers to FOSQ test questions (*BiPAP Pro 2 only)*
- Patient Disconnect

You can also view and modify the Humidifier heat setting by pressing and holding the **Heat** button until the Humidifier Setting screen appears.

6.2.1 Changing the Humidifier Setting

If you are using the REMstar Heated Humidifier with your device, you can adjust the humidifier heat setting by completing the following steps:

1. From either the Standby or Monitoring screen, press and hold the **Heat** button for approximately 4 seconds. The Humidifier Setting screen appears, as shown in Figure 6–6.

Figure 6–6 Humidifier Setting Screen

2. Press the **Heat** button to increase the humidifier setting, or press the **Ramp** button to decrease the setting. You can adjust the setting from **1** to **5**. The change takes effect immediately as you adjust the setting.
3. Exit this screen by pressing the **Left** or **Right User** buttons or the **Start/Stop** button.

   For additional information on using a humidifier with the device, see Chapter 10.

6.2.2 Navigating the User Display Screens

You can navigate the rest of the user display screens by pressing the **Left** and **Right User** buttons.

You can change the settings on any of the display screens by pressing the **Heat** and **Ramp** buttons to increase or decrease the setting.

You can exit any of the user display screens by pressing the **Start/Stop** button.

Figure 6–7 shows how to navigate the user display screens.

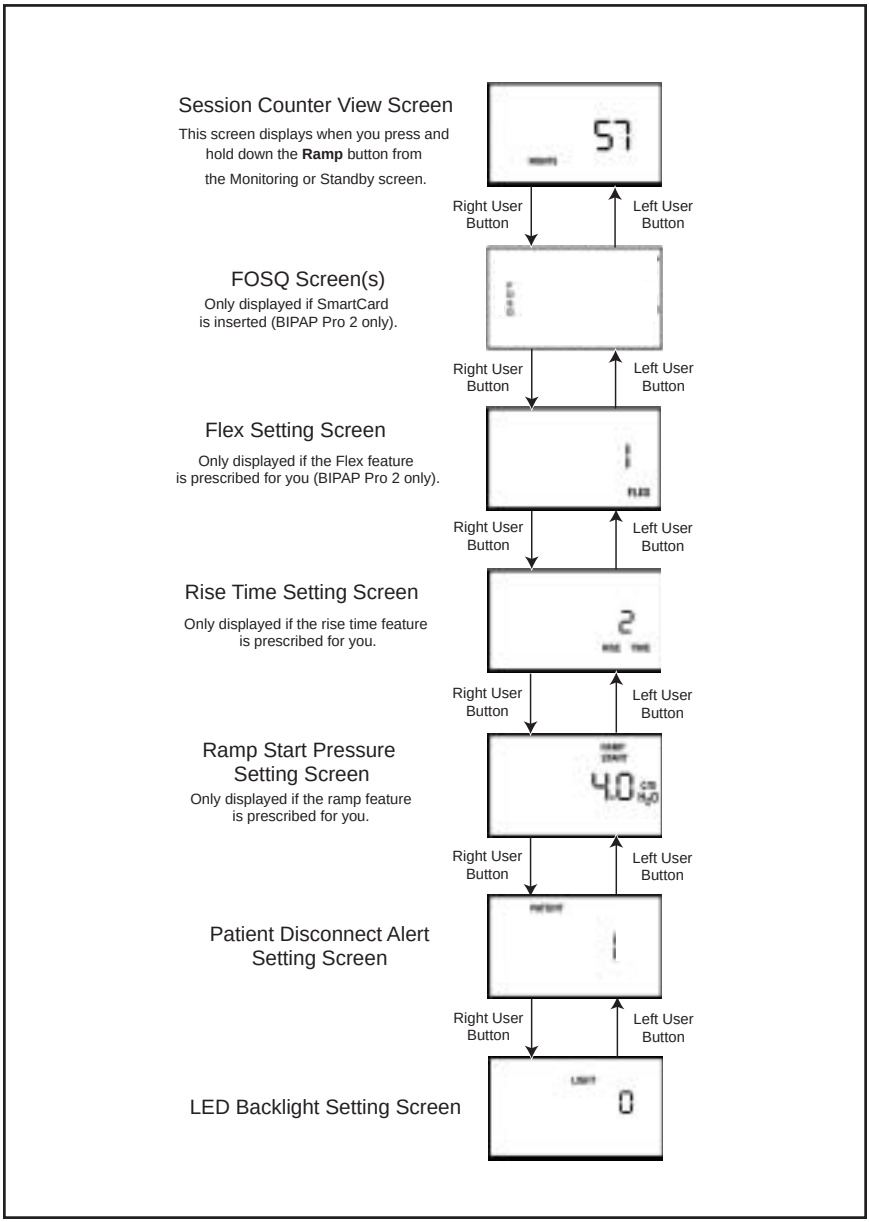

Figure 6–7 Navigating the User Display Screens

6.2.2.1 Viewing the Session Counter

From the Monitoring or Standby screen, you can press and hold the **Ramp** button for several seconds to access the Session Counter View screen, shown in Figure 6–8.

Figure 6–8 Session Counter View Screen

This screen allows you to view the session counter, which tracks the number of sessions in which the device has provided therapy.

6.2.2.2 Viewing the FOSQ Screens (BiPAP Pro 2 only)

The FOSQ test is a "quality of life" questionnaire designed specifically for people with sleep disorders. The results allow health care professionals to see how therapy has improved the quality of your life. By completing the questionnaire periodically, you can provide valuable information about the effectiveness of your treatment. The BiPAP Pro 2 has the ability to record your answers on the SmartCard for later review by your health care professional. Contact your home care provider for further instructions.

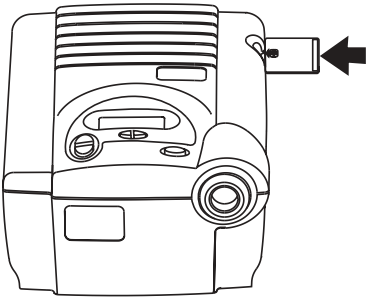

Figure 6–9 Installing the SmartCard

IMPORTANT! If your health care professional or home care provider instructs you to complete the questionnaire, he or she will provide you with the instructions and the questions, and you will enter your answers into the device. Make sure the SmartCard is installed before answering the questions.

NOTE: These screens only display if you are using a BiPAP Pro 2 device with a SmartCard inserted.

NOTE: Your home care provider may ask you to periodically remove the SmartCard and send it to him or her for evaluation.

To view the FOSQ screens, complete the following steps:

1. From the Session Counter View screen, press the **Right User** button. The first FOSQ screen appears, shown in Figure 6–10.

Figure 6–10 FOSQ Screen - Part 1

2. The screen in Figure 6–11 allows you to choose whether or not you want to answer the FOSQ questionnaire. Choose one of the following options:
   - Press the **Right User** button to move to the next screen if you do **not** want to answer the FOSQ questionnaire.

   - OR -

   - Press the **Heat** or **Ramp** buttons to access the second FOSQ screen, shown in Figure 6–11, if you want to answer the questionnaire.

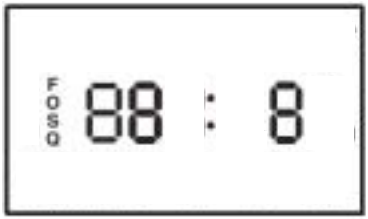

Figure 6–11 FOSQ Screen - Part 2

3. Once in the second FOSQ screen, use the **Heat** and **Ramp** buttons to change your answers to the questions. Use the **Left** and **Right User** buttons to navigate the questions. The **Left User** button takes you to the previous question, while the **Right User** button takes you to the next question.

4. Once you have reached the last question, press the **Right User** or **Start/Stop** button to save your FOSQ answers. The first FOSQ screen will appear on the display.

NOTE: If the **Left User** button is pressed on the first question, the answers are not saved and the first FOSQ screen displays again. Additionally, if the SmartCard is removed while either FOSQ screen is displayed, the FOSQ answers are discarded and the next parameter screen is displayed.

6.2.2.3 Changing the Flex Setting (BiPAP Pro 2 Only)

The Flex setting allows you to adjust the level of air pressure relief that you feel when you exhale during therapy.

NOTE: The Flex feature is not prescribed for all users. If the screen shown in Figure 6–12 does not appear on your display, you cannot adjust this setting.

To change the Flex setting, complete the following steps:

1. From the Session Counter View screen or the FOSQ screen (if applicable), press the **Right User** button. The Flex Setting screen appears, as shown in Figure 6–12.

Figure 6–12 Flex Setting Screen

2. To increase or decrease the Flex setting, press the **Heat** or **Ramp** button until the correct setting appears. You can choose from **1** to **3**.

NOTE: It is recommended that you start with the minimum setting of 1, which provides the least relief. Levels 2 and 3 progressively increase the pressure relief.

6.2.2.4 Changing the Rise Time Setting

Rise time is the time it takes for the device to change from EPAP to IPAP. You can adjust the rise time to find the setting that provides you with the most comfort.

NOTE: The rise time feature is not prescribed for all users. If the screen shown in Figure 6–13 does not display, you cannot adjust this setting.

To change the rise time setting, complete the following steps:

1. From the Session Counter View screen or the FOSQ screen (if applicable), press the **Right User** button to access this screen, shown in Figure 6–13.

Figure 6–13 Rise Time Setting Screen

2. Increase or decrease the rise time setting from **0** to **3** by pressing the **Heat** or **Ramp** button until you find the right setting. A setting of **0** is the fastest rise time, while **3** is the slowest.

6.2.2.5 Changing the Ramp Starting Pressure

The device is equipped with an optional ramp feature. This feature will reduce the pressure and then gradually increase (ramp) the pressure to the prescription pressure setting so you can fall asleep more comfortably.

NOTE: The ramp feature is not prescribed for all users. If the screen shown in Figure 6–14 does not appear on your display, you cannot adjust this setting.

To change the ramp starting pressure setting, complete the following steps:

1. From either the Flex or Rise Time Setting screens, press the **Right User** button to access the Ramp Start Setting screen appears, as shown in Figure 6–14.

Figure 6–14 Ramp Start Setting Screen

2. Press the **Heat** or **Ramp** button to increase or decrease the ramp starting pressure as needed. You can adjust the setting from 4.0 cm H_2O to your EPAP setting. The setting increases or decreases in 0.5 cm H_2O increments.

6.2.2.6 Changing the Patient Disconnect Setting

To change the Patient Disconnect alert setting, complete the following steps:

1. From the Ramp Start Setting screen, press the **Right User** button to access the Patient Disconnect Setting screen, shown in Figure 6–15.

Figure 6–15 Patient Disconnect Setting Screen

2. You can turn the patient disconnect audible alert on or off by using the **Heat** or **Ramp** buttons to select **0** to disable the alert or **1** to enable the alert.

NOTE: Setting the Patient Disconnect parameter to **1** also enables the Auto-Off feature, which causes the unit to automatically change from the Operate state to the Standby state whenever the mask is removed from the airway.

WARNING: If your physician indicates that the Patient Disconnect alert is necessary for you, do not disable it.

6.2.2.7 Changing the LED Backlight Setting

When airflow is turned on and the device is in the Operate state, you can turn the control panel lighting behind the buttons on or off using the LED backlight setting.

NOTE: The lights are always on when the airflow is off and the unit is in Standby.

To change the LED backlight setting, complete the following steps:

1. From the Patient Disconnect Setting screen, press the **Right User** button to access the LED Backlight Setting screen, shown in Figure 6–16.

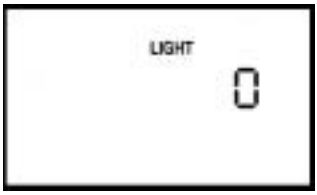

Figure 6–16 LED Backlight Setting Screen

2. Press the **Heat** or **Ramp** button to select a new setting. A setting of **1** means the light is on, while **0** means the light is off.

CHAPTER 7: DEVICE ALERTS

This chapter describes the device alerts and what you should do if an alert occurs.

7.1 INTRODUCTION

The device provides three alert levels: high, medium, and low priority.

High Priority	These alerts require immediate operator response. The alert signal consists of a high priority sound. The display has the message **ALERT** at the top of the screen.
Medium Priority	These alerts require prompt operator response. The alert signal consists of a medium priority sound. The display has the message **ALERT** at the top of the screen.
Low Priority	These alerts require operator awareness. The alert signal consists of a low priority sound. The display has the message **ALERT** at the top of the screen.

Some audible alerts are self-cancellable. This means that the alert sound stops when the cause of the alert is corrected.

7.1.1 OVERVIEW OF ALERT BEHAVIOR

Alert conditions are signalled by the device in two ways: a sound and a display message. Each signal type behaves differently depending on the type of alert.

7.1.1.1 ALERT SOUNDS BEHAVIOR

1. **High Priority Sounds**

   There are two possible high priority sounds:

   - **High Priority** – The sound repeats a pattern of three beeps followed by a pause and then two more beeps until a button is pressed. This pattern is indicated in Section 7.3 as • • • • •
   - **Continuous** – An audible alert sounds continuously. This pattern is indicated in Section 7.3 as ▬

2. **Medium Priority Sound**

   The medium priority sound repeats a pattern of two beeps with a short interval between each set of beeps until a button is pressed. This pattern is indicated in Section 7.3 as • • ••

3. **Low Priority Sound**

   The low priority sound repeats a pattern of two beeps with a longer interval between each set of beeps until a button is pressed This pattern is indicated in Section 7.3 as • • ••

7.1.1.2 Display Behavior

For high, medium, and low priority alerts, the display shows **ALERT** and the name of the alert.

7.2 What to Do When an Alert Occurs

The following example applies to most alert conditions. Follow these steps unless otherwise directed by the alert table that follows.

1. Listen to the alert sound.
2. Look at the display for text.

Figure 7–1 Sample Alert Display

   The word **ALERT** appears at the top of the screen to indicate an alert. Additional codes and icons may also appear depending on the type of alert.

3. Press any button to silence the alert.
4. Look up the alert in the table in Section 7.3 and perform the action specified.

7.3 Alert Summary Table

The following table summarizes the high priority, medium priority, and low priority alerts.

Alert	Display Message	Audible Indicator	Device Action	Possible Cause	Patient Action
System Error	ALERT icon flashes and system error code ("Exx") displays	● ● ● ● ● or ▬	Shuts down and blower cannot be restarted.	Device failure.	Press any button to silence the alarm. Remove power from the device. Restore power. If the alarm continues to occur, contact your home care provider.
Card Error (BiPAP Pro 2 only)	CARD icon flashes and card error code ("Cxx") displays	● ● ● ●	Operates	A problem exists with the Smart Card inserted in the SmartCard connectivity slot. The card may be inserted upside down or backwards.	Press any button to silence the alarm. Confirm that the card is properly inserted. If the alarm continues to occur, remove the SmartCard from the device and contact your home care provider.
Patient Disconnect	ALERT and PATIENT icons flash	● ● ● ●	Operates	Patient circuit is disconnected or has a large leak.	Press any button to clear the alarm. Reconnect the patient circuit or correct the leak. If the alarm continues, contact your home care provider.
Prescription Complete (BiPAP Pro 2 only)	ALERT, CARD, and cm H_2O icons flash	● ● ● ●	Operates	Prescription SmartCard inserted into device. Audible alert sounds when prescription has been successfully written to the device.	No action needed.

CHAPTER 8: TROUBLESHOOTING

This chapter describes problems that you may experience with your device or mask and provides possible solutions.

Problem	Why It Happened	What To Do
The device does not operate when you press the **Start/Stop** button.	There's no power at the outlet or the device is unplugged. Otherwise, the problem is in the device.	Check the outlet power and verify that the device is plugged in. If the problem continues, call your home care provider.
The air out of the mask is much warmer than usual.	The inlet filters may be dirty. The device may be operating in direct sunlight or near a heater.	Clean or replace the inlet air filters as described in Chapter 9. Make sure the unit is away from bedding or curtains that could block the flow of air around the device. Make sure the unit is away from direct sunlight and heating equipment. If the problem persists, contact your home care provider.
The mask feels uncomfortable to wear.	This could be due to improper headgear adjustment or improper mask fitting.	Check the headgear adjustment as described in the headgear instructions. Refer to your mask instructions to make sure the mask is properly fitted. If the problem continues, contact your home care provider for a refitting or a different size mask.

Problem	Why It Happened	What To Do
There is significant air leakage around the mask.	This could be due to improper headgear adjustment or improper mask fitting.	Check the headgear adjustment as described in the headgear instructions. Refer to your mask instructions to make sure the mask is properly fitted. If the problem continues, contact your home care provider for a refitting or a different size mask.
Redness occurs when the mask cushion comes in contact with the skin.	This could be due to improper mask fitting or improper mask cleaning.	Be sure to rinse the mask thoroughly after cleaning to remove residue. See the mask cleaning instructions for detailed information. If the problem continues, contact your home care provider for a refitting or a different size mask.
Redness occurs when the mask cushion accessory comes in contact with the skin.	Irritation or allergic reaction to the mask material.	Use a barrier between your skin and the mask, such as 3M's Microfoam® or Squibb's Duoderm®. Refer to your mask instructions for additional information.
Sore or dry eyes.	The mask may not be positioned correctly, or the mask is not properly fitted.	Check the headgear adjustment as described in the headgear instructions. Refer to your mask instructions to make sure the mask is properly fitted. If the problem continues, contact your home care provider for a refitting or a different size mask.

Problem	Why It Happened	What To Do
There are unexplained changes in the performance of the device.	The device or power supply has been dropped or mishandled, or water has been spilled onto or into the device or the power supply.	Discontinue use. Contact your home care provider or Respironics for directions on how to have your device serviced. Please have the serial number ready when you call.
A patient disconnect alarm occurs.	The tubing has become disconnected from the system.	Press any button to silence the alarm. Reconnect the tubing and press the **Start/Stop** button to restart the airflow. If the airflow does not restart, the device may not be operating correctly. Contact your home care provider or Respironics for directions on having the unit serviced. Please have your serial number ready when you call.
The mask feels uncomfortable to wear.	This could be due to improper headgear adjustment or improper mask fitting.	Check the headgear adjustment as described in the headgear instructions. Refer to your mask instructions to make sure the mask is properly fitted. If the problem continues, contact your home care provider for a refitting or a different size mask.

Problem	Why It Happened	What To Do
Runny nose.	Nasal reaction to the air flow.	Call your health care professional.
The device's display is erratic.	The device or power supply has been dropped or mishandled, or the device or power supply is in an area with high EMI emissions.	Unplug the device and the power supply. Relocate the device to an area with lower EMI emissions.
A SmartCard error occurs (*BiPAP Pro 2 only*).	The SmartCard is not inserted properly. It may be inserted upside down or backwards.	Remove the SmartCard and reinsert it so that the printed side of the card is facing up and the end with the arrow goes into the device first. If the error message appears again, contact your home care provider or Respironics for directions on having your device serviced. Please have your serial number ready when you call.

Chapter 9: Cleaning and Maintenance

This chapter provides information on how to clean and maintain your system.

9.1 Cleaning the Device

Before cleaning or performing any routine maintenance, always make sure the device is not operating and disconnect the device from the power source.

NOTE: The following cleaning instructions are for the device only. To clean the accessories, refer to each accessory's instruction sheet.

CAUTION: Do not immerse the device or allow any liquid to enter the enclosure, inlet filter, or any openings.

Clean the front panel and exterior of the enclosure as needed using a cloth dampened with water and a mild detergent. Allow the device to dry completely before plugging in the power cord.

Gently wash the reusable circuit tubing in a solution of warm water and a mild detergent. Rinse thoroughly and allow to air dry.

9.2 Cleaning or Replacing the Inlet Filters

The device has two removable filters at the air inlet. The gray foam filter is washable and reusable. The optional white, ultra-fine filter is disposable. The gray foam filter should be cleaned at least once every two weeks under normal usage and replaced with a new one every six months. The white ultra-fine filter is disposable and should be replaced after 30 nights of use or sooner if it appears dirty. **Do not** attempt to clean the ultra-fine filter. It will damage the filter.

NOTE: Dirty inlet filters may cause high operating temperatures and may affect device performance. Regularly examine the inlet filters as needed for integrity and cleanliness.

1. Make sure the device is not operating, and disconnect the power cord from the wall outlet or DC source.
2. As shown in Figure 9–1, remove the filter cap by gently pressing down on the top panel and pulling the cap out, away from the device.

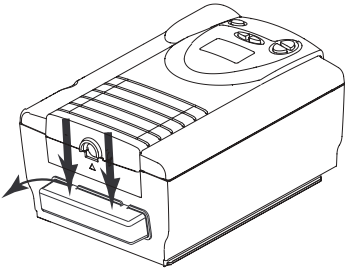

Figure 9–1 Removing the Filter

3. Remove the filters from the enclosure as shown in Figure 9–2. The top filter is the reusable gray foam filter. The bottom filter is the optional disposable, white, ultra-fine filter.

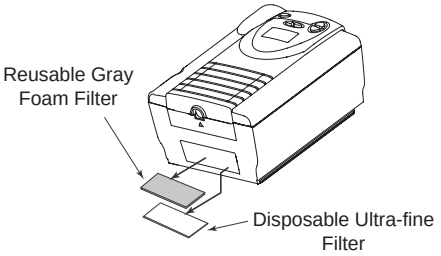

Figure 9–2 Removing the Air Filters

4. Check the filters to see if they are dirty or torn.
5. If needed, wash the gray foam filter in warm water and a mild detergent. Rinse the filter thoroughly to remove all detergent residue. Allow the filter to completely dry before reinstalling it. If the gray foam filter is torn, replace it.
6. If the ultra-fine filter is dirty or torn, replace it.
7. Reinstall the filters, with the ultra-fine filter on the bottom. Slide the filters into the air inlet at the rear of the device and push them down into the recess.
8. Replace the filter cap.

Contact your home care provider to order additional filters.

NOTE: To clean the breathing circuit accessories, refer to each accessory's instruction sheet.

CHAPTER 10: ACCESSORIES

There are several accessories you can use with the device.

10.1 ADDING A HUMIDIFIER

The REMstar Heated Humidifier and REMstar Integrated Humidifier are available from your home care provider. The humidifiers may reduce nasal dryness and irritation by adding moisture (and heat, if applicable) to the airflow.

CAUTION: For safe operation, the humidifier must always be positioned below the circuit connection at the mask and the air outlet on the device. The humidifier must be level for proper operation.

Refer to the humidifier instructions for complete setup information.

10.2 ADDING OXYGEN TO THE DEVICE

Oxygen may be added to the mask connection. Please note the warnings listed below when using oxygen with the device.

WARNING: If you are using oxygen, your device must be equipped with the Respironics Pressure Valve (Part number 302418). Failure to use the Pressure Valve could result in a fire hazard.

WARNING: Oxygen accelerates fires. Keep the device and the O_2 containers away from heat, open flames, any oily substance, or other sources of ignition. Do not smoke in the area near the device or the O_2 container.

WARNING: When using oxygen with your device, the oxygen supply must comply with the local regulations for medical oxygen.

WARNING: When using oxygen with this system, turn the device **on** before turning the oxygen on. Turn the oxygen **off** before turning the device off. This will prevent oxygen accumulation in the device.

CHAPTER 11: SPECIFICATIONS

ENVIRONMENTAL

	Operating	Storage
Temperature	41° F to 95° F	-4° F to 140° F
Relative Humidity	15 to 95% (non-condensing)	15 to 95% (non-condensing)
Atmospheric Pressure	83 to 102kPa (5600 feet to sea level)	

PHYSICAL

Dimensions: 9.75" L x 6.625" W x 4.4" H

Weight: Less than 7 lbs.

ELECTRICAL

AC Voltage Source: 100 to 240 V, 50/60 Hz

DC Voltage Source: 12 V (when operated with the external DC power supply)

AC Current: 1.25 A maximum

DC Current: 3.0 A maximum

Protection against electric shock: Class II

Degree of protection against electric shock: Type BF Applied Part

Degree of protection against harmful ingress of water:
Device: Ordinary Equipment, IPX0
AC Power Supply (Reorder number 1012832): Drip Proof, IPX1
DC Power Adapter (when available): Drip Proof, IPX1

Modes of Operation: Continuous

Electromagnetic Compatibility: The device meets the requirements of EN 60601-1-2, second edition (2001).

Fuses: There are no user-replaceable fuses.

Pressure

Output: 4 to 25 cm H_2O (BiPAP Pro 2)
4 to 20 cm H_2O (BiPAP Plus)

Control Accuracy

Parameter	Range	Accuracy
IPAP	4 to 25 cm H_2O (BiPAP Pro 2)* 4 to 20 cm H_2O (BiPAP Plus)	± 1.5 cm H_2O**
EPAP	4 to 25 cm H_2O (BiPAP Pro 2)* 4 to 20 cm H_2O (BiPAP Plus)	± 1.5 cm H_2O**
Ramp Duration	0 to 45 minutes	± 10% of the setting
Rise Time	0 to 3***	± 25%****

* Limited to 20 cm H_2O when in Bi-Flex mode.

** Dynamic pressure accuracy is measured at the patient end of the circuit with a Whisper Swivel II and varying flow conditions.

*** The range of values correspond to tenths of seconds (0 to 3 corresponds to 0.1 to 0.4 seconds).

**** Measured at the patient end of circuit with a Whisper Swivel II exhalation device and no patient flow.

Disposal

When necessary, dispose of the device and accessories in accordance with local regulations.

APPENDIX A: EMC INFORMATION

GUIDANCE AND MANUFACTURER'S DECLARATION - ELECTROMAGNETIC EMISSIONS

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

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF conducted emissions CISPR 11	Group 1, Class B	This device 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 radiated emissions CISPR 11	Group 1, Class B	This device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

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

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±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 supply mains ±1 kV for input/ output lines	Mains power quality should be that of a typical home or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV for common mode	Mains power quality should be that of a typical home 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 home or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

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

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Power frequency (50/ 60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	If the pressure deviates more than is indicated in the device specification, it may be necessary to position the device further from sources of power frequency magnetic fields. The power frequency magnetic field should be measured in the intended installation location to ensure that it is sufficiently low.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

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

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz 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,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

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

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.

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

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and This Device

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

Rated Maximum Power Output of Transmitter W	Separation Distance According to Frequency of Transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	2.3

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

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

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

Limited Warranty

Respironics, Inc. warrants that the system shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of two (2) years from the date of sale by Respironics, Inc. to the dealer. If the product fails to perform in accordance with the product specifications, Respironics, Inc. will repair or replace – at its option – the defective material or part. Respironics, Inc. will pay customary freight charges from Respironics, Inc. to the dealer location only. This warranty does not cover damage caused by accident, misuse, abuse, alteration, and other defects not related to material or workmanship.

Respironics, 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 any warranty of merchantability or fitness for the particular purpose – are limited to two years. Some states do not allow limitations on how long an implied warranty lasts, so the above limitation may not apply to you. This warranty gives you specific legal rights, and you may also have other rights which vary from state to state.

To exercise your rights under this warranty, contact your local authorized Respironics, Inc. dealer or contact Respironics, Inc. at:

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