



REMstar®
M Series
USER MANUAL

IMPORTANT!

**Fill in the information below when you receive the
REMstar M Series system.**

Serial No.: _____ (located on the bottom of the device)

System Prescribed for: _____

Date of Purchase or Rental: _____

Pressure Setting: _____ cm H₂O

Mask Type: _____

Mask Size: _____

If you have any questions concerning the system, contact:

- Home Care Company: _____

Telephone Number: _____

- Health Care Professional: _____

Telephone Number: _____

- Respironics, Inc.

1001 Murry Ridge Lane

Murrysville, Pennsylvania

15668-8550 USA

Customer Service

Telephone Number: 1-800-345-6443 or 1-724-387-4000

The REMstar® M Series system is covered by the following patent: 6,622,724. Other patents pending.
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CHAPTER 1: INTRODUCTION

This chapter provides information on:

- System contents
- Intended use
- Warnings, cautions, and contraindications
- System overview
- Glossary and symbol key
- How to contact Respironics

1.1 SYSTEM CONTENTS

Your REMstar M Series system includes the following items:

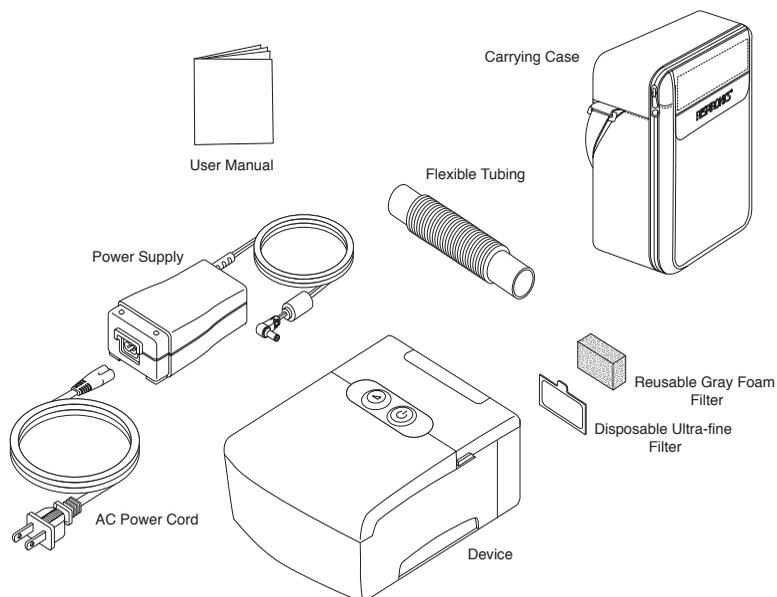


FIGURE 1-1 SYSTEM CONTENTS

Note: *If your system includes a humidifier, you will receive additional items with your package. See the instructions included with your humidifier for more information.*

Note: *If any of the above items are missing, contact your home care provider.*

1.2 INTENDED USE

The Respironics REMstar M Series system is a CPAP (Continuous Positive Airway Pressure) device designed for the treatment of Obstructive Sleep Apnea only in spontaneously breathing patients weighing more than 66 lbs (30 kg).

The device is to be used only on the instruction of a licensed physician. Your home care provider will make the correct pressure settings according to your health care professional's prescription.

1.3 WARNINGS, CAUTIONS, AND CONTRAINDICATIONS

Caution: *US federal law restricts this device to sale by or on the order of a physician.*

1.3.1 WARNINGS

A warning indicates the possibility of injury to the user or the operator.

- This manual serves as a reference. The instructions in this manual are not intended to supersede the health care professional's instructions regarding the use of the device.
- The operator should read and understand this entire manual before using the device.
- 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.

- 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.

- Oxygen supports combustion. Oxygen should not be used while smoking or in the presence of an open flame.
- When using oxygen with this system, a Respironics Pressure Valve must be placed in-line with the patient circuit. Failure to use the pressure valve could result in a fire hazard.
- 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 this device if the room temperature is warmer than 95° F (35° C). If the device is used at room temperatures warmer than 95° F (35° C), the temperature of the airflow may exceed 106° F (41° C). This could cause irritation or injury 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.
- Contact your health care professional if symptoms of sleep apnea recur.
- If you notice any unexplained changes in the performance of this device, if it is making unusual or harsh sounds, if the device or the power supply are dropped or mishandled, if water is spilled into the enclosure, or if the enclosure is broken, 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 for damage or signs of wear. Discontinue use and replace if damaged.
- To avoid electric shock, unplug the device before cleaning it. DO NOT immerse the device in any fluids.
- Using this device at an incorrect elevation setting could result in airflow pressures higher than the prescribed setting. Always verify the elevation setting when traveling or relocating.
- 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.

1.3.2 CAUTIONS

A Caution indicates the possibility of damage to the device.

- The device may only be operated at temperatures between 41° F (5° C) and 95° F (35° C).
- If this device has been exposed to either very hot or very cold temperatures, allow it to adjust to room temperature before starting therapy.
- 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.
- A properly installed, undamaged reusable foam inlet filter is required for proper operation.
- Tobacco smoke may cause tar build-up within the device, which may result in the device malfunctioning.

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

1.3.3 CONTRAINDICATIONS

When assessing the relative risks and benefits of using this equipment, the clinician should understand that this device can deliver pressures up to 20 cm H₂O. In the event of certain fault conditions, a maximum pressure of 30 cm H₂O is possible. Studies have shown that the following pre-existing conditions may contraindicate the use of CPAP therapy for some patients:

- Bullous Lung Disease
- Pathologically Low Blood Pressure
- Bypassed Upper Airway
- Pneumothorax
- 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. Not for use with patients whose upper airways are bypassed. Contact your physician if you have any questions concerning your therapy.

1.4 SYSTEM OVERVIEW

The REMstar M Series device, shown in Figure 1–2, is a sleep apnea therapy system that delivers Continuous Positive Airway Pressure (CPAP). CPAP maintains a constant level of pressure throughout the breathing cycle.

When prescribed for you, the device provides a special feature to help make your therapy more comfortable. 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.

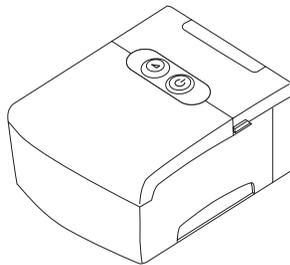


FIGURE 1–2 REMSTAR M SERIES DEVICE

Figure 1–3 illustrates many of the device features, described in the table below.

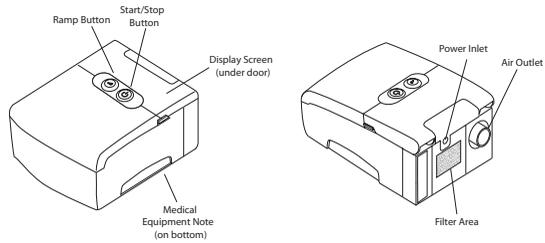


FIGURE 1–3 SYSTEM OVERVIEW

DEVICE FEATURE	DESCRIPTION
Air Outlet	Connect the flexible tubing here.
Display Screen	Shows therapy settings and patient data.
Filter Area	A reusable, gray foam filter must be placed in the filter area to screen out normal household dust and pollens. An optional, white ultra-fine filter can also be used for more complete filtration of very fine particles.
Medical Equipment Note	For ease at airport security stations, there is a note on the bottom of the device stating that it is medical equipment. It may help if you also take this manual with you when you travel.
Power Inlet	Connect the power cord here.
Ramp Button	This button starts or restarts the ramp cycle.
Start/Stop Button	This button starts or stops the airflow.

1.4.1 BREATHING CIRCUIT OVERVIEW

The patient breathing circuit, shown in Figure 1–4, consists of the following:

- 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

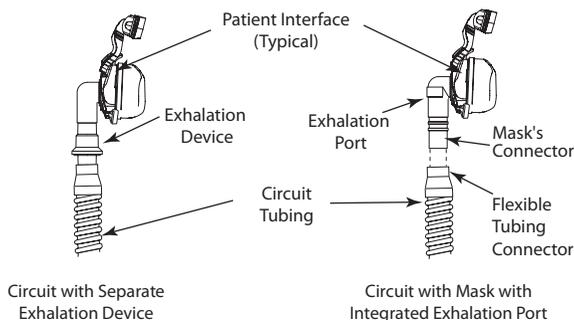


FIGURE 1–4 TYPICAL BREATHING CIRCUITS

Note: *The exhalation port may be part of the interface or may be part of a separate exhalation device, but is required to minimize the potential for CO₂ rebreathing.*

1.5 GLOSSARY

The following terms and acronyms appear throughout this manual:

TERM/ACRONYM	DEFINITION
Active State	The state of the device when power is applied, the airflow is on, and the device is capable of providing therapy.
Altitude	Allows the user to modify the altitude setting. Can be set to 1, 2, or 3 corresponding to low, medium, and high altitudes, respectively.
Apnea	A condition marked by the cessation of spontaneous breathing.
BPM	Breaths Per Minute
Compliance Check Value	Represents a code used by the provider to determine the accuracy of reported therapy data.
CPAP	Continuous Positive Airway Pressure
Hours of Patient Use	The total amount of time that the blower has been on .
LPM	Liters Per Minute
OSA	Obstructive Sleep Apnea

TERM/ACRONYM	DEFINITION
Patient Data Mode	The display mode in which the patient can view certain stored information, such as session count.
Patient Setup Mode	The display mode in which the patient can change patient-adjustable device settings such as the ramp starting pressure.
Ramp	A feature that may increase patient comfort when therapy is started. The ramp feature reduces pressure and then gradually increases the pressure to the prescription setting so patients can fall asleep more comfortably.
Safe State	The state in which the device does not provide therapy. The device enters this state if a fault is detected.
Standby State	The state of the device when power is applied but the airflow is turned off.
Therapy Hours	The total amount of time that the blower is on and patient breathing is detected.

1.6 SYMBOL KEY

The following symbols appear on the device and power supply:

SYMBOL	DEFINITION
	Consult accompanying instructions for use.
	DC Power
	Type BF Applied Part
	Class II (Double Insulated)
IPX1	Drip Proof Equipment
	Electrostatic Discharge
	Canadian/US Certification
	TUV Safety Standard Compliance
	UL Recognized for Canada and the United States
	No User Serviceable Parts

1.7 HOW TO CONTACT RESPIRONICS

To have your device serviced, contact your home care provider. If you need to contact Respiroics directly, call the Respiroics Customer Service department at 1-800-345-6443 (US and Canada only) or 1-724-387-4000.

You can also use the following address:

Respiroics
1001 Murry Ridge Lane
Murrysville, Pennsylvania
15668-8550 USA

Visit Respiroics web site at: www.respiroics.com

CHAPTER 2: DEVICE CONTROLS AND DISPLAYS

This chapter describes the device's control buttons and displays, patient circuit connections, and rear panel connections.

2.1 CONTROLS AND DISPLAYS

Figure 2–1 shows the two primary control buttons on the REMstar M Series device.

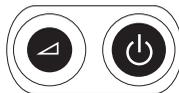


FIGURE 2–1 PRIMARY CONTROL BUTTONS

These buttons are described below.

BUTTON	DESCRIPTION
	Ramp – When the airflow is on, this button allows you to activate or restart the ramp function. Ramp lowers the airflow pressure and then gradually increases it, allowing you to fall asleep more easily.
	Start/Stop – This button starts the device's airflow and places the device in the Active state, or stops the airflow, and places the device in Standby. You can also press this button to exit any setting screen.

If you do not want to modify the settings that your home care provider has set for you, you only need these two buttons to start and stop therapy and do not need to use the display buttons located under the device cover door.

Figure 2–2 shows the device display and navigation buttons that are under the cover door.



FIGURE 2–2 DISPLAY BUTTONS

The display buttons are described below:

BUTTON	DESCRIPTION
	Allows you to access the Data screens. Also allows you to navigate to the previous screen when in the Data or Setup mode.
	Allows you to access the Setup screens. Also allows you to navigate to the next screen when in the Data or Setup mode.
	Allows you to decrease the settings on the patient setup screens.
	Allows you to increase the settings on the patient setup screens.

The device's display screen shows the prescribed or ramping pressure and patient data. See Chapter 4 for instructions on navigating the display screens.

Figure 2–3 provides a view of the entire device control panel, with the cover door open.

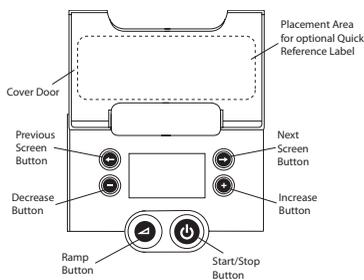


FIGURE 2–3 DEVICE CONTROL PANEL

2.1.1 CONTROL PANEL INACTIVITY

Some screens have time-out periods. The screen's timer starts when the screen is initially displayed and is restarted whenever a button is pressed. The screen times out after one minute if there is no activity and returns to the Standby screen.

2.2 REAR PANEL

Figure 2–4 shows the REMstar M Series device's rear panel (without a humidifier).

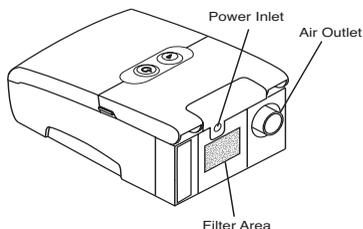


FIGURE 2–4 REAR PANEL

The rear panel contains the following:

- A filter area where each filter supplied with your device should be inserted.
- A DC power inlet where the power cord is connected (see Chapter 3, *Setup*, for complete information on supplying power to the device).
- The air outlet port where the breathing circuit's flexible tubing is attached.

CHAPTER 3: SETUP

This chapter provides instructions on how to:

- Install the air filters
- Position the device
- Connect the breathing circuit
- Supply power to the device

3.1 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. The reusable filter screens out normal household dust and pollens, while the optional ultra-fine filter provides more complete filtration of very fine particles. The gray reusable filter must be in place at all times when the device is operating. The ultra-fine filter is recommended for people who are sensitive to tobacco smoke or other small particles.

Two reusable gray foam filters and one disposable ultra-fine filter are supplied with the device.

If your filters are not already installed when you receive your device, you must at least install the reusable gray foam filter before using the device.

To install a filter:

1. If you are using the optional disposable white ultra-fine filter, insert it into the filter area first, mesh-side facing in, towards the device.
2. Insert the gray foam filter into the filter area as shown in Figure 3–1.

Note: *If you are not using the white disposable filter, simply insert the gray foam filter into the filter area.*

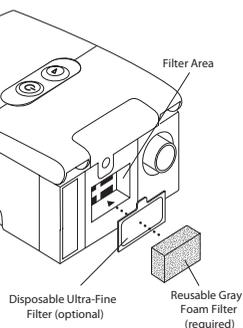


FIGURE 3–1 INSTALLING THE AIR FILTER

Note: See Chapter 7, *Cleaning and Maintenance*, for information on how to clean or replace the air filters.

3.2 WHERE TO PLACE THE DEVICE

Place the device on a firm, flat surface somewhere within easy reach of where you will use it. Make sure the filter area on the back of the device is not blocked by bedding, curtains, or other items. Air must flow freely around the device for the system to work properly. Make sure the device is away from any heating or cooling equipment (e.g., forced air vents, radiators, air conditioners).

3.3 CONNECTING THE BREATHING CIRCUIT

To use the system, you will need the following accessories in order to assemble the recommended circuit:

- Respiroics interface (e.g., nasal mask) with integrated exhalation port (or Respiroics interface with a separate exhalation device such as the Whisper Swivel® II)
- Respiroics 6 ft. (1.83 m) flexible tubing
- Respiroics headgear (for the patient interface)

Warning: *If the device is used by multiple persons (e.g., rental devices), a low-resistance, main flow bacteria filter should be installed in-line between the device and the circuit tubing to prevent contamination.*

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

1. Connect the flexible tubing to the air outlet on the back of the device, as shown in Figure 3–2.

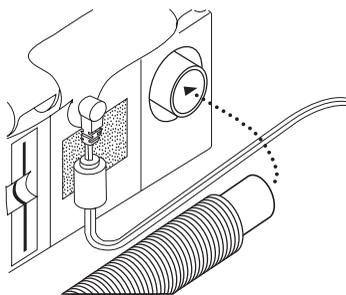


FIGURE 3–2 CONNECTING THE FLEXIBLE TUBING

Note: *If required, connect a bacteria filter to the device air outlet, and then connect the flexible tubing to the outlet of the bacteria filter.*

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 flexible tubing, as shown in Figure 3–3.

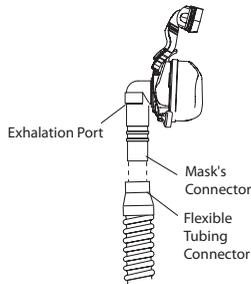


FIGURE 3–3 CONNECTING A MASK WITH BUILT-IN EXHALATION PORT

- b. If you are using a mask with a separate exhalation device, connect the open end of the flexible tubing to the exhalation device as shown in Figure 3–4. Position the exhalation device so that the vented air is blowing away from your face. Connect the mask's connector to the exhalation device.

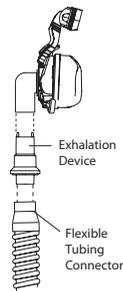


FIGURE 3–4 CONNECTING A MASK WITH A SEPARATE EXHALATION DEVICE

Warning: *The exhalation device (e.g., Whisper Swivel II) or exhalation port (on masks with an integrated exhalation port) is designed to exhaust CO₂ from the patient circuit. Do not block or seal the ports on the exhalation device.*

Warning: *If you are using a full face mask (i.e., a mask covering both your mouth and your nose), the mask must be equipped with a safety (entrainment) valve.*

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

3.4 SUPPLYING POWER TO THE DEVICE

You can power the device using AC or DC power.

Caution: *If this device has been exposed to either very hot or very cold temperatures, allow it to adjust to room temperature before beginning the following setup procedures.*

Warning: *Route the wires to avoid tripping.*

Warning: *This device is activated when the power cord is connected. Pressing the  button turns the airflow on or off.*

Important! *If you are using your device with a humidifier, refer to the instructions included with your humidifier for details on how to power the device and humidifier.*

3.4.1 USING AC POWER

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

1. Plug the socket end of the AC power cord into the power supply, as shown in Figure 3–5.

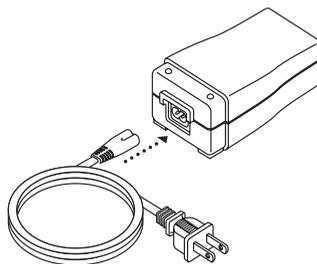


FIGURE 3–5 CONNECTING THE POWER CORD TO THE POWER SUPPLY

2. Plug the pronged end of the AC power cord into an electrical outlet that is not controlled by a wall switch.
3. Plug the power supply cord's connector into the power inlet on the back of the device, as shown in Figure 3–6.

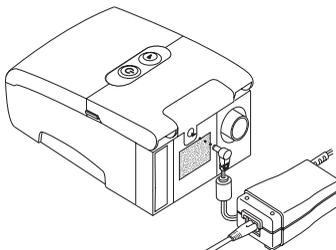


FIGURE 3–6 CONNECTING THE POWER SUPPLY CORD TO THE DEVICE

4. Ensure that all connections are secure.

Important! *To remove AC power, disconnect the power supply cord from the electrical outlet.*

Warning: *Inspect the power cord often for any signs of damage. Replace a damaged power cord immediately.*

3.4.2 USING DC POWER

The Respironics DC Power Cord can be used to operate this device in a stationary recreational vehicle, boat, or motor home. The Respironics DC Battery Adapter Cable when used with the DC Power Cord, enables the device to be operated from a 12 VDC free-standing battery.

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 vehicle or the device may occur.*

Caution: *Only use a Respironics DC Power Cord and Battery Adapter Cable. Use of any other system may cause damage to the device or vehicle.*

Refer to the instructions supplied with the DC Power Cord and adapter cable for information on how to operate the device using DC power.

3.5 COMPLETE ASSEMBLY EXAMPLE

Figure 3-7 shows an example of how a complete assembly will look, with breathing circuit connected and power applied to the device.

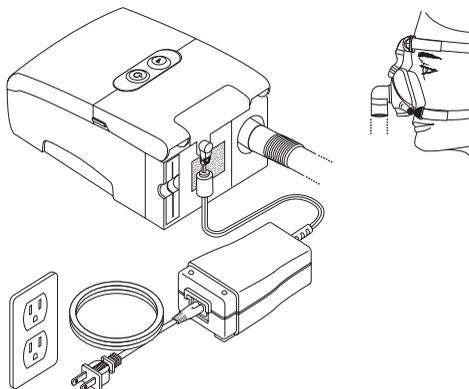


FIGURE 3-7 FINAL ASSEMBLY EXAMPLE

Figure 3-8 shows an example of how you should route your tubing and situate your device on your night stand for the best setup possible. This will help prevent the device from falling off your night stand or table.

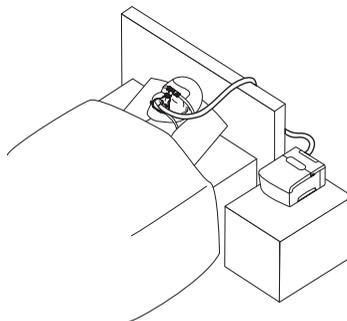


FIGURE 3-8 RECOMMENDED DEVICE AND TUBING PLACEMENT

CHAPTER 4: DEVICE OPERATION

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

4.1 STARTING THE DEVICE

1. Plug the device in to an AC or DC power source. The Start/Stop  and the Ramp  buttons light up. The Software Version screen, shown below, momentarily appears. The number that appears on your screen will be different from the number shown below.

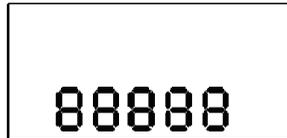


FIGURE 4-1 SOFTWARE VERSION SCREEN

2. The next screen to appear is the Standby screen, which displays the cumulative therapy hours. When you first begin using this device, the number shown will be zero, but as you use it, the number shown here will increase. Your provider may ask you for this number.



FIGURE 4-2 STANDBY SCREEN

3. When you press the Start/Stop button  to turn on the airflow, the Active Display screen displays, as shown below.

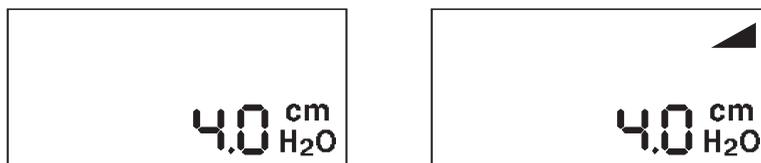


FIGURE 4-3 THE ACTIVE DISPLAY—WITHOUT RAMP (LEFT) AND WITH RAMP (RIGHT)

The Active Display screen shows the prescribed or ramping pressure. If the ramp feature is enabled by your health care provider, the Ramp symbol also appears as described below:

SYMBOL	DESCRIPTION
	If the Ramp feature is enabled, you can initiate it by pressing the Ramp button. When the ramp function is active, the Ramp symbol displays on the Active Display screen, as shown above.

4. Put on your mask assembly when the air starts to flow.
5. 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 provided 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.*

6. 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.

Note: *If you are having trouble with your mask, refer to the instructions supplied with the mask.*

4.2 USING THE RAMP FEATURE

The optional Ramp feature can be enabled or disabled by your home care provider.

This feature reduces the air pressure when you are trying to fall asleep. Then it gradually increases (ramps) the pressure until your prescription setting is reached, allowing you to fall asleep more comfortably.

If ramp is enabled on your device, after you turn on the airflow, press the Ramp button  on the top of the device. You can use the Ramp button as often as you wish during the night.

Note: *If the ramp feature is disabled, nothing will happen when you press the Ramp button.*

4.3 CHANGING THE DEVICE SETTINGS

You can view the prescribed or ramping pressure on the Active Display screen, as well as the following information on the Patient Data screens:

- Hours of Patient Use
- Session Counter (number of sessions greater than 4 hours)
- Compliance Check Value

Additionally, you can view and modify the following settings on the Patient Setup screens:

- Altitude
- Ramp Starting Pressure (if enabled by your home care provider)

Note: *You can view your therapy usage hours on the Standby screen each time you turn on the device.*

4.3.1 NAVIGATING THE DISPLAY SCREENS

Use the  button to navigate to the next screen and the  button to navigate to the previous screen. Use the Plus (+) and Minus (-) buttons to adjust the settings on the Patient screens.

4.3.1.1 VIEWING THE PATIENT DATA SCREENS

Press the ← button to enter the Data screens. Figure 4–5 shows how to navigate the Patient Data screens.

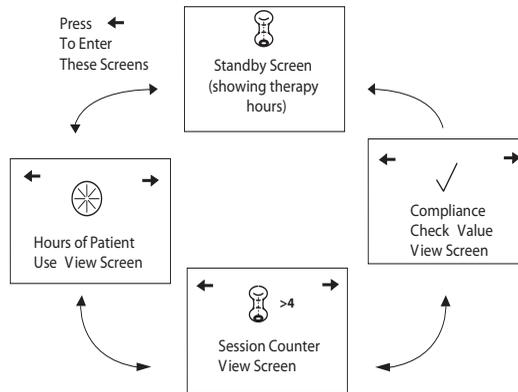


FIGURE 4–4 NAVIGATING THE PATIENT DATA SCREENS

Press the ← button to scroll forward through these screens, or press the → button to scroll through the screens in the reverse order.

From any of these screens, press the Start/Stop button  to return to the Standby screen.

Note: After one minute of inactivity, the Data mode automatically times out and returns to the Standby screen.



1. **Hours of Patient Use View Screen**

This screen shows you the total number of hours that the blower has been active. Your home care provider may periodically ask for this information.



2. **Session Counter View Screen**

This screen shows you the number of sessions greater than four hours. Your home care provider may periodically ask for this information.



3. **Compliance Check Value View Screen**

This screen shows you the Compliance Check Value, which typically is a different number from the one shown here. Your home care provider may periodically ask for this information.

4.3.1.2 VIEWING AND MODIFYING THE PATIENT SETUP SCREENS

Press the → button to enter the Setup screens. The figure below shows how to navigate the Patient Setup screens.

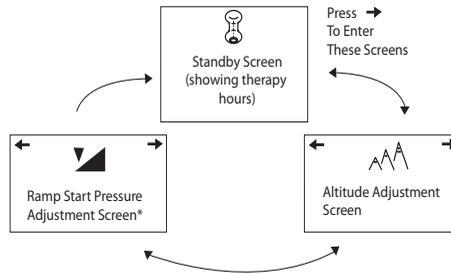


FIGURE 4-5 NAVIGATING THE PATIENT SETUP SCREENS.
(*NOTE: THE RAMP SCREEN APPEARS ONLY IF THE RAMP FEATURE IS ENABLED.)

Press the → button to scroll forward through these screens, or press the ← button to scroll through the screens in the reverse order.

From any of these screens, press the Start/Stop button  to return to the Standby screen.

Note: *After one minute of inactivity, the Setup mode automatically times out and returns to the Standby screen.*



1. **Altitude Adjustment Screen**

You can adjust the altitude setting by pressing the Plus (+) or Minus (-) buttons to increase or decrease the setting to 1, 2, or 3. Use these guidelines to find the setting best for you:

- 1 = less than 2500 ft. (<762 m)
- 2 = 2500 to 5000 ft. (762 m to 1524 m)
- 3 = 5000 to 7500 ft. (1525 m to 2286 m)

Note: Elevations over 7500 ft. (2286 m) may affect the accuracy of the pressure. Your home care provider can verify the pressure setting with a water column manometer.

Warning: If you set the manual altitude setting incorrectly, the pressure may be too high or too low, depending on your location.



2. **Ramp Starting Pressure Adjustment Screen**

You can increase or decrease the ramp starting pressure in 0.5 cm H₂O increments by pressing the Plus (+) or Minus (-) buttons. The default setting is 4 cm H₂O. You can adjust the setting from 4 cm H₂O to the CPAP pressure setting.

Note: This screen appears only if the ramp feature is enabled by your home care provider.

4.4 REPORTING YOUR THERAPY BY PHONE

Your provider may ask you to report certain therapy values by telephone. To do so, follow the steps below in order:



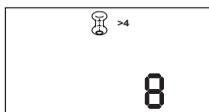
1. With the device in standby mode (the power is on but the blower is off), open the cover door. The Standby screen will display your total therapy hours (a sample is shown on the left).

Give the provider the value for **total therapy hours**, as shown on your screen.



2. Press the left arrow button ← to advance to the hours of patient use screen (a sample is shown on the left).

Give the provider the value for **hours of patient use**, as shown on your screen.



3. Press the left arrow button ← to advance to the total sessions > 4 screen (a sample is shown on the left).

Give the provider the value for **total sessions > 4**, as shown on your screen.



4. Press the left arrow button ← to advance to the compliance check value screen (a sample is shown on the left).

Give the provider the **compliance check value**, as shown on your screen.

Press the left arrow button ← again to return to the Standby screen.

5. If you are using the device with the optional humidifier, your provider may ask you to read the humidifier setting as shown on the humidifier dial. For more information about the humidifier, see page 6-1.

CHAPTER 5: ALERTS AND TROUBLESHOOTING

This chapter describes the device alerts and also provides troubleshooting information for issues you may run into when using the device.

5.1 DEVICE ALERTS

The device provides high priority alerts. These alerts require immediate operator response. The alert signal consists of a high priority flashing pattern consisting of a continuous, bright-to-off, two-flash pattern (indicated in the following table as: $\diamond\diamond$ $\diamond\diamond$ $\diamond\diamond$).

ALERT SUMMARY TABLE

The following table summarizes the high priority alerts.

ALERT	VISUAL INDICATOR	DEVICE ACTION	POSSIBLE CAUSE	PATIENT ACTION
System Error	Backlights: $\diamond\diamond$ $\diamond\diamond$ $\diamond\diamond$ The following symbol displays to indicate that service is required: 	The device enters the "Safe state" in which the device power remains on, but the airflow is disabled.	Device failure	Remove the power supply cord from the device to remove power. Contact your home care provider.

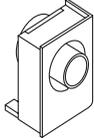
5.2 TROUBLESHOOTING

The table below lists some of the problems you may experience with your device or mask and possible solutions to those problems.

PROBLEM	WHY IT HAPPENED	WHAT TO DO
<p>Nothing happens when you apply power to the device. The backlights on the buttons do not light.</p>	<p>There's no power at the outlet or the device is unplugged.</p>	<p>If you are using AC power, check the outlet power and verify that the device is properly plugged in. Make sure the AC power cord is connected correctly to the power supply and the power supply cord is securely connected to the device's power inlet. If the problem continues to occur, contact your home care provider. Return both the device and power supply to your provider, so they can determine if the problem is with the device or power supply.</p> <p>If you are using DC power, make sure your DC power cord and battery adaptor cable connections are secure. Check your battery. It may need recharged or replaced. If the problem persists, check the DC cord's fuse following the instructions supplied with your DC cord. The fuse may need to be replaced. If the problem still occurs, contact your home care provider.</p> <p>If you are using a humidifier, make sure you follow the instructions for applying power that are provided with your humidifier.</p>
<p>The device does not operate when you press the  button. The airflow does not turn on.</p>	<p>There may be a problem with the blower.</p>	<p>Make sure the device is powered correctly, following the instructions on the previous page. If the button backlights turn on when you apply power, but the airflow does not turn on, there may be a problem with your device. Contact your home care provider for assistance.</p> <p>Note: <i>When the device is functioning correctly, after you press the Start/Stop button , the airflow turns on after a slight delay. This brief delay is normal.</i></p>

PROBLEM	WHY IT HAPPENED	WHAT TO DO
<p>The device's display is erratic.</p>	<p>The device or power supply has been dropped or mishandled, or the device or power supply is in an area with high Electromagnetic Interference (EMI) emissions.</p>	<p>Unplug the device and the power supply. Reapply power to the device. If the problem continues, relocate the device to an area with lower EMI emissions (e.g., away from electronic equipment such as cellular phones, cordless phones, computers, TVs, electronic games, hair dryers, etc.).</p> <p>If the problem still occurs, contact your home care provider for assistance.</p>
<p>Device Resets/Reboots</p> <p>The device shuts down and restarts automatically during therapy. (This is unlikely to occur.)</p>	<p>The device comes installed with troubleshooting software that automatically monitors performance.</p>	<p>Such a reset poses no danger to the patient and assures that the patient receives prescribed therapy throughout the night. If there is a possibility of damage to the device, the device will shut down permanently. The product will then display the following system alert symbol  to indicate that the device must be returned to the home care provider for service.</p>

PROBLEM	WHY IT HAPPENED	WHAT TO DO
<p>The device has fallen off your table or night stand.</p>	<p>The device may not have been properly seated on the night stand, or the placement of the tubing may have caused the device to fall.</p>	<p>Always make sure your device is placed on a hard, flat surface so the rubber feet on the bottom of the device can adhere to the surface (make sure there is no fabric under the device). The device (and humidifier, if using) must be level for proper operation.</p> <p>Also, place the device away from the edge of the night stand or table, so it doesn't accidentally get knocked off the table.</p> <p>If you are using a humidifier with the device, make sure that the device and humidifier are placed below your head and mask, so that any condensation in the tubing drains back into the water chamber.</p> <p>If the device and humidifier fall and water gets into the device, drain all water out of the device and make sure it is completely dry before reapplying power.</p> <p>If the placement of the tubing causes the device to fall, make sure that you use proper hose management when setting up your device. Route the tubing behind the bed's headboard, as shown in Chapter 3, Setup.</p> <p>If the device falls or water gets into the device upon falling, let the device dry completely before restarting it. If the device does not operate correctly after falling, contact your home care provider.</p>
<p>The Ramp feature does not work when you press the Ramp button .</p>	<p>Your home care provider did not prescribe Ramp for you, or your CPAP pressure is already set to the minimum setting.</p>	<p>If Ramp has not been prescribed for you, discuss this feature with your home care provider to see if they will change your prescription.</p> <p>If your provider has enabled Ramp, but the feature still does not work, check the CPAP setting on your Active Display screen. If CPAP is set to the minimum setting (4.0 cm H₂O), the Ramp feature will not work.</p>

PROBLEM	WHY IT HAPPENED	WHAT TO DO
<p>You are having problems connecting the tubing to the device.</p>	<p>You have lost the air outlet port or are traveling and forgot to bring the port with you.</p>	<p>If you are not using a humidifier, you cannot connect your tubing to the device without the detachable air outlet port, shown below.</p>  <p>You must have the port attached properly before connecting your tubing.</p>
<p>You are experiencing excessive air leaks where the tubing connects to the device.</p>	<p>The air outlet port is not installed correctly and doesn't seal properly.</p>	<p>Remove the port and reattach it to make sure it's properly installed.</p> <p>To remove the port:</p> <ol style="list-style-type: none"> Put your thumb underneath the port and insert your index finger into the port opening. Pivoting from the bottom, unsnap the port and pull it away from the device. <p>To properly reattach the port:</p> <ol style="list-style-type: none"> Make sure it is correctly oriented (with the port opening at the top), and insert the two latches at the bottom of the port into the openings on the bottom of the device. Push the top of the port down to snap it into place. <p>Reattach your tubing, turn on the airflow, and check to make sure you do not still feel air coming out of the port area.</p>

PROBLEM	WHY IT HAPPENED	WHAT TO DO
The air out of the mask is much warmer than usual.	<p>The air filters may be dirty.</p> <p>The device may be operating in direct sunlight or near a heater.</p>	<p>Clean or replace the air filters as described in Chapter 7.</p> <p>The temperature of the air may vary somewhat based on your room temperature. Make sure that the device is properly ventilated. Keep the device away from bedding or curtains that could block the flow of air around the device. Make sure the device is away from direct sunlight and heating equipment.</p> <p>If the problem continues, contact your home care provider.</p>
The mask feels uncomfortable to wear, there is significant air leakage around the mask, or you experience other mask-related issues.	This could be due to improper headgear adjustment or improper mask fitting, etc.	If you experience any issues with your mask, refer to your mask instructions for information on proper fitting, etc. If the problem continues, contact your home care provider.
You have a runny nose.	This is caused by a nasal reaction to the airflow.	Call your health care professional.
You have throat or nose dryness.	The air is too dry.	Increase the room humidity. Consult with your health care professional about using a Respironics humidifier with the device. If you have a humidifier, refer to the instructions included with your humidifier to make sure it is working properly.
You experience nasal, sinus, or ear pain.	You may have a sinus or middle ear infection.	Stop using the device and contact your health care professional.

CHAPTER 6: ACCESSORIES

6.1 ADDING A HUMIDIFIER

You can use the M Series Heated humidifier or the M Series Pass-over humidifier with your device. They are available from your home care provider. A humidifier 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 breathing circuit connection at the mask. The humidifier must be level for proper operation.*

Refer to your humidifier's instructions for complete setup information.

6.2 ADDING SUPPLEMENTAL OXYGEN

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

WARNINGS

- When using oxygen with this system, the oxygen supply must comply with local regulations for medical oxygen.
- When using oxygen with this system, a Respirationics Pressure Valve must be placed in-line with the patient circuit. Failure to use the pressure valve could result in a fire hazard.
- Oxygen accelerates fires. Keep the device and the oxygen container away from heat, open flames, any oily substance, or other sources of ignition. Do not smoke in the area near the device or the oxygen.
- When using oxygen with this system, turn the device on before turning on the oxygen. Turn the oxygen off before turning the device off. This will prevent oxygen accumulation in the device.
- If administering fixed-flow supplemental oxygen, the oxygen concentration may not be constant. The inspired oxygen concentration will vary, depending on the CPAP setting, patient breathing pattern, and leak rate. Substantial leaks around the mask may reduce the inspired oxygen concentration to less than the expected concentrations. Appropriate patient monitoring should be implemented.

CHAPTER 7: CLEANING AND MAINTENANCE

This chapter describes how to clean the device and its filters and provides tips on traveling with your REMstar M Series system.

7.1 CLEANING THE DEVICE

Warning: *To avoid electrical shock, always unplug the power cord from the wall outlet or DC power source before cleaning the device.*

Caution: *Do not immerse the device in liquid or allow any liquid to enter the enclosure, inlet filter, or any opening.*

1. Unplug the device, and wipe the outside of the device with a cloth slightly dampened with water and a mild detergent. Let the device dry completely before plugging in the power cord.
2. Inspect the device and all circuit parts for damage after cleaning. Replace any damaged parts.

7.2 CLEANING OR REPLACING THE FILTERS

Caution: *Operating the device with a dirty filter may keep the system from working properly and may damage the device.*

Under normal usage, you should clean the gray foam filter at least once every two weeks and replace it 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 clean the ultra-fine filter.

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

1. If the device is operating, stop the airflow by pressing the  button. Disconnect the device from the power source.
2. Remove each filter from the enclosure by gently squeezing the filter in the center and pulling it away from the device, as shown in Figure 7-1.

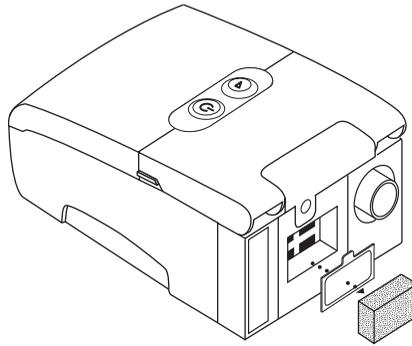


FIGURE 7-1 REMOVING THE FILTERS

3. Examine each filter for cleanliness and integrity.
4. Wash the gray foam filter in warm water with a mild detergent. Rinse thoroughly to remove all detergent residue. Allow the filter to air dry completely before reinstalling it. If the foam filter is torn, replace it. (Only Respironics-supplied filters should be used as replacement filters.)
5. If the optional white ultra-fine filter is dirty or torn, replace it.
6. Reinstall the filters, inserting the white ultra-fine filter first if applicable, as shown in Figure 7-2.

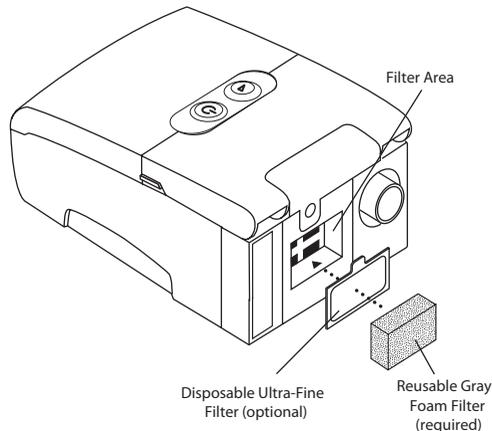


FIGURE 7-2 REINSTALLING THE FILTERS

Caution: *Never install a wet filter into the device. It is recommended that you clean the filter in the morning and alternate using the two foam filters provided with the system to ensure sufficient drying time for the cleaned filter.*

7.3 CLEANING THE TUBING

Clean the tubing daily. Disconnect the flexible tubing from the device. Gently wash the tubing in a solution of warm water and a mild detergent. Rinse thoroughly. Air dry.

7.4 SERVICE

The REMstar M Series device does not require routine servicing.

Warning: *If you notice unexplained changes in the performance of this device, if it is making unusual or harsh sounds, if the device or power supply have been dropped or mishandled, if the enclosure is broken, or if water has entered the device, discontinue use, and contact your home care provider.*

7.5 TRAVELING WITH THE SYSTEM

When traveling, the carrying case is for carry-on luggage only. The carrying case will not protect the system if it is put through checked baggage.

For your convenience at security stations, there is a note on the bottom of the device stating that it is medical equipment. It may be helpful to bring this manual along with you to help security personnel understand the REMstar M Series device.

If you typically use a humidifier with your device, but leave the humidifier home when traveling, make sure you attach the **air outlet port** to your device when you remove the humidifier from the device. You need the port to connect the tubing directly to your device. Figure 7–3 illustrates how to attach the air outlet port.

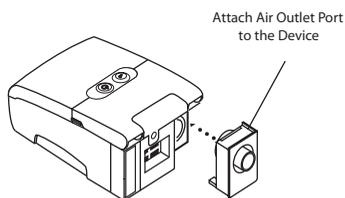


FIGURE 7–3 ATTACHING THE AIR OUTLET PORT TO THE DEVICE

7.5.1 INTERNATIONAL TRAVEL

If you are traveling to a country with a line voltage different than the one you are currently using, a different power cord or an international plug adaptor may be required to make your power cord compatible with the power outlets of the country to which you are traveling. Contact your home care provider for additional information.

CHAPTER 8: SPECIFICATIONS

ENVIRONMENTAL

	OPERATING	STORAGE
TEMPERATURE	41° F to 95° F (5° C to 35° C)	-4° F to 140° F (-20° C to 60° C)
RELATIVE HUMIDITY	15 to 95% (non-condensing)	15 to 95% (non-condensing)
ATMOSPHERIC PRESSURE	77 to 101 kPa (0 - 7500 ft.)	N/A

PHYSICAL

Dimensions: 7.5 in. L x 5.0 in. W x 3.125 in. H (19 x 12.7 x 7.9 cm)

Weight: Approximately 2.2 lbs. (1 kg) without a humidifier

STANDARDS COMPLIANCE

This device is designed to conform to the following standards:

- IEC 60601-1 General Requirements for Safety of Medical Electrical Equipment
- EN ISO 17510-1 Sleep Apnea Breathing Therapy Devices

ELECTRICAL

AC Power Consumption: 100 – 240 VAC, 50/60 Hz, 1.0 A max.

DC Power Consumption: 12 VDC, 3.0 A max.

Type of Protection Against Electric Shock: Class II Equipment

Degree of Protection Against Electric Shock: Type BF Applied Part

Degree of Protection Against Ingress of Water: Device: Drip Proof, IPX1

AC Power Supply: Drip Proof, IPX1

Mode of Operation: Continuous

Electromagnetic Compatibility: The device meets the requirements of EN 60601-1-2, 2nd edition.

Fuses: There are no user-replaceable fuses.

PRESSURE

Pressure Increments: 4.0 to 20.0 cm H₂O (in 0.5 cm H₂O increments)

Pressure Stability:

4.0 to 20.0 cm H₂O (±1.0 cm H₂O)

Measured in accordance with EN ISO 17510-1 @ 1/3, 2/3, and Pmax with BPM set to 10, 15, and 20 BPM @ 68° F (±9° F) (20° C ±5° C), 50% RH (±5%).

Maximum Flow:

35 LPM

Measured in accordance with EN ISO 17510-1 @ 1/3, 2/3, and Pmax with BPM set to 10, 15, and 20 BPM @ 73° F (±3.6° F) (23° C ±2° C), 50% RH (±5%).

DISPOSAL

Dispose of the device 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 emissions CISPR 11	Group 1	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network.
RF emissions CISPR 11	Class B	
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) IEC 61000-4-2	±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 (50% 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.
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 location in a typical hospital or home environment.

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
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	<p>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.</p> <p>Recommended separation distance: $d = 1.2 \sqrt{P}$ 150 kHz to 80 MHz</p> <p>$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz</p> <p>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).</p> <p>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.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol: </p>
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	
<p>NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</p> <p>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.</p> <p>b: Over the frequency range 150 kHz to 80 MHz, the field strengths should be less than 3 V/m.</p>			

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND THIS DEVICE:

The 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	23
<p>For transmitters rated at a maximum output power not listed above, the recommended separation distance <i>d</i> 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.</p> <p>Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</p> <p>Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</p>			

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:

1001 Murry Ridge Lane

Murrysville, Pennsylvania 15668-8550

1-800-345-6443

1-724-387-4000