RESPIRONICS

REMstar**Pro**

REMstar**Auto**

M SERIES PROVIDER MANUAL

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CHAPTER 1: INTRODUCTION

This chapter provides information on:

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

1.1 SYSTEM CONTENTS

Your system includes the following items:

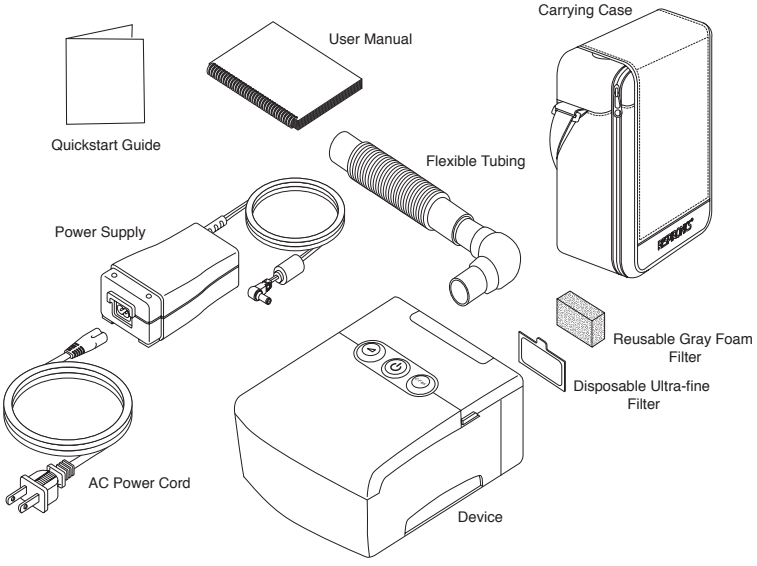


FIGURE 1–1 SYSTEM CONTENTS

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: *Always use these instructions along with the User Manual when assembling or adjusting this equipment.*

1.2 Intended Use

The Respironics REMstar Pro M Series and REMstar Auto M Series systems are CPAP (Continuous Positive Airway Pressure) devices designed for the treatment of Obstructive Sleep Apnea only in spontaneously breathing patients weighing >66 lbs (30 kg).

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

Several accessories are available to make the patient's OSA treatment with their system as convenient and comfortable as possible. To ensure that patients receive the safe, effective therapy prescribed for them, use only Respironics accessories.

1.3 Warnings, Cautions, and Contraindications

Caution: *U.S. 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. Rebreathing of exhaled air for longer than several minutes can in some circumstances lead to 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.

- 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 (Part Number 302418) must be placed in-line with the patient circuit. Failure to use the pressure valve could result in a fire hazard.
- Operation of the device may be adversely affected by:
    - Electromagnetic fields exceeding the level of 10 V/m in the test conditions of EN 60601-1-2
    - Operation of high frequency (diathermy) equipment
    - Defibrillators, or short wave therapy equipment
    - Radiation (e.g., x-ray, CT)
    - Magnetic fields (e.g., MRI)
- 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 the patient's airway.
- Do not operate the device in direct sunlight or near a heating appliance because these conditions can increase the temperature of the airflow delivered to the patient.
- To reduce the risk of contamination, you may place a bacteria filter (Part Number 342077) in-line between the device and the patient.
- The device does not have an alarm to detect occlusion of the exhalation port. Before each use, inspect the patient circuit to verify that the port is not occluded. Occlusion or partial occlusion can reduce airflow and result in rebreathing of exhaled air.

  Do not use antistatic or electrically conductive hoses or tubing with the device.
- 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, contact Respironics or an authorized service center for service.
- Repairs and adjustments must be performed by Respironics or an authorized service center. Service done by inexperienced or unqualified personnel, or installation of unauthorized parts 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.

- 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. Condensation may damage the device.
- Do not immerse the device or allow any liquid to enter the enclosure or the inlet filter.
- 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 H_20. In the event of certain fault conditions, a maximum pressure of 30 cm H_20 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 a patient exhibits signs of a sinus or middle ear infection. Not for use with patients whose upper airways are bypassed. Should your patient have any of these conditions, a physician will determine if CPAP therapy is appropriate.

1.4 System Overview

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

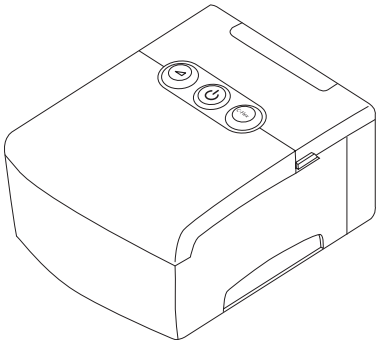


Figure 1–2 Device

1.4.1 C-Flex Comfort Feature

The device consists of a special comfort feature called C-Flex. When C-Flex is enabled, it enhances patient comfort by providing pressure relief during the expiratory phase of breathing. In the following diagram, the dashed lines represent normal CPAP therapy in comparison to the bold line representing C-Flex. C-Flex levels of 1, 2, or 3 progressively reflect increased pressure relief.

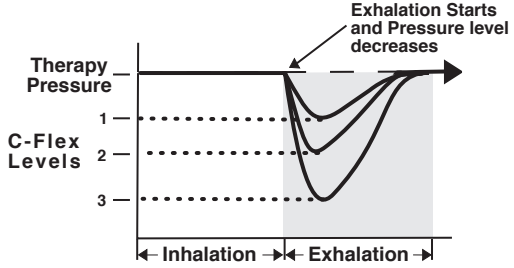


Figure 1–3 C-Flex Therapy

C-Flex pressure relief is determined by the C-Flex setting and the amount of patient flow. C-Flex returns to the set pressure by the end of exhalation, when the airway is most vulnerable to closure.

Note: *The patient also has access to this setting, if C-Flex is enabled.*

1.4.2 RAMP

The device is equipped with a linear ramp feature that allows patients to reduce the pressure and then gradually increase (ramp) the pressure to the prescription pressure setting so they can fall asleep more comfortably. Figure 1–4 illustrates how the ramp feature works.

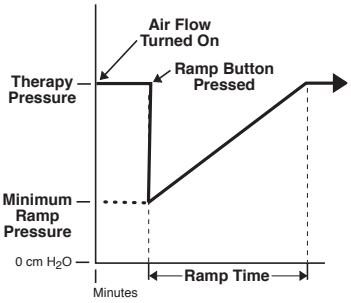


FIGURE 1–4 RAMP

When the device is in Auto-CPAP therapy, pressing the Ramp button lowers the pressure level to the minimum ramp pressure and then increases pressure in a linear fashion to the Auto minimum pressure setting over the set ramp time. If patient events are detected during the ramp, the Auto CPAP algorithm will treat the events, and then continue to ramp, as long as the device is not configured for split night therapy or the preset split night time period has expired during split night therapy.

1.4.3 Event Definitions

The REMstar Auto M Series monitors breathing and detects apneas and hypopneas.

Event	Definition
Apnea Detection	An apnea is indicated if there is an 80% reduction in airflow for 10 seconds compared to the average airflow over an extended period of several minutes or if there is no airflow detected for 10 seconds.
Flow Limitation Detection	The flow limitation algorithm analyzes the peak and shape of the inspiratory airflow waveform. The algorithm looks for relative changes in the peak, flatness, roundness, or skewness (shape) of the inspiratory portion of the airflow waveform. These changes are observed both over a short period of time (groups of 4 breaths) and over a long period of time (several minutes). Statistical measures are used to help minimize false event detection while allowing the device to be sensitive to even small changes. Also, these measures are disabled during unstable breathing conditions such as vibratory snore, apneas, hypopneas, high leak, and variable breathing.
Hypopnea Detection	A hypopnea is indicated if there is approximately a 40% reduction in airflow for a duration of between 10 and 60 seconds, compared to the average airflow over an extended period of several minutes. Following a reduction, the device must see two recovery breaths in order to label the event as a potential hypopnea. For the event to be determined to be a hypopnea, additional criteria are evaluated: • Are the pressures less than or equal to 8 cm H_2O? • Is flow limitation present in the valley of the hypopnea? • Is the hypopnea terminated with breaths having large tidal volumes? • Has a reduction in the energy content of the airflow signal been observed?
Snore Detection	Vibratory snore detection is disabled at pressure setpoints greater than 16 cm H_2O.

1.5 Access Levels

There are two levels of access for the device, provider mode and user mode.

1.5.1 Accessing Provider Mode

Prescribed therapy settings can only be set using the provider mode screens. To access provider mode, hold down the left and right arrow buttons (← →)simultaneously while applying power to the device. The device beeps twice to indicate that it is in provider mode.

To exit provider mode, press the **Start/Stop** (⏻) button.

Important! *Provider mode unlocks additional settings not available to the patient. To prevent patients from tampering with the settings, do not reveal the directions to access the provider mode screens.*

1.5.1.1 REMstar Pro M Series Provider Mode Settings

For the REMstar Pro M Series device, you can modify the following settings in provider mode:

- CPAP pressure setting
- C-Flex setting
- Ramp time setting
- Ramp starting pressure
- Mask disconnect alert (enable/disable)
- Auto-Off setting (enable/disable)
- Show AHI/System leak (enable/disable)
- Patient reminder

Additionally, you can view the following data from provider mode:

- Therapy usage hours
- Number of sessions (greater than four hours)
- System leak
- Apnea/Hypopnea index
- Blower hours

1.5.1.2 REMstar Auto M Series Provider Mode Settings

For the REMstar Auto M Series device, you can modify the following settings in provider mode:

- Therapy mode setting
- Auto maximum pressure setting (Auto-CPAP therapy only; not available in CPAP therapy)
- Auto minimum pressure setting (Auto-CPAP therapy only; not available in CPAP therapy)
- CPAP pressure setting
- C-Flex setting
- Ramp time setting
- Ramp starting pressure
- Mask disconnect alert (enable/disable)
- Auto-Off setting (enable/disable)
- Split Night Time setting (Auto-CPAP therapy only; not available in CPAP therapy)
- Show AHI/System leak (enable/disable)
- Patient reminder

Additionally, you can view the following data from provider mode:

- Therapy usage hours
- Number of sessions (greater than four hours)
- 90% therapy pressure averages (Auto-CPAP therapy only; not available in CPAP therapy)
- System leak
- Apnea/Hypopnea index
- Blower hours

1.5.2 Accessing User Mode

The device defaults to user mode when you apply power. If you are in provider mode and want to access the user mode screens, press the **Start/Stop** (⏻) button to change to user mode.

Users can modify the following settings in user mode:

- C-Flex (if enabled by the home care provider)
- Ramp starting pressure (if enabled by the home care provider)
- Mask alert (enable/disable)
- Auto off (enable/disable)
- FOSQ questionnaire

Additionally, users can view the following data in user mode:

- Therapy usage hours
- Number of sessions greater than 4 hours
- 90% therapy pressure averages – REMstar Auto only (in Auto-CPAP therapy)
- System leak (if enabled by the home care provider)
- Apnea/Hypopnea Index (if enabled by the home care provider)

1.6 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 providing therapy.
Apnea	A condition marked by the cessation of spontaneous breathing.
Auto-CPAP	Adjusts CPAP pressure automatically to improve patient comfort based on monitoring of apnea and snoring events.
Auto-Off	When this feature is enabled, the device automatically discontinues therapy whenever the mask is removed.
Auto-On	With this feature, the device automatically initiates therapy when the patient begins breathing on the device. This feature is always enabled.
BPM	Breaths Per Minute
C-Flex	A therapy feature that provides pressure relief during exhalation, if enabled by the home care provider.
CPAP	Continuous Positive Airway Pressure
FOSQ	Functional Outcomes of Sleep Questionnaire – A "quality of life" questionnaire designed specifically for people with sleep disorders. The results allow health care professionals to assess how CPAP therapy has improved the quality of their patients' lives.
LPM	Liters Per Minute
OSA	Obstructive Sleep Apnea
Patient Data Menu	The display mode in which the patient can view certain stored information, such as therapy usage hours.
Patient Setup Menu	The display mode in which the patient can change patient-adjustable settings, such as the ramp starting pressure.
Provider Data Menu	The display mode in which the provider can view certain stored information, such as therapy and blower hours.
Provider Setup Menu	The display mode in which the provider can change the prescription pressure and other device settings such as C-Flex and ramp time.
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 an error is detected.
Standby State	The state of the device when power is applied but the airflow is turned off.

1.7 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
	European Declaration of Conformity
	Canadian/US Certification
	Notified Body Approval for Standards Compliance
	TUV Safety Standard Compliance
	UL Recognized for Canada and the United States
	No User Serviceable Parts

1.8 How to Contact Respironics

If you need to contact Respironics directly, call the Respironics Customer Service department at 1-800-345-6443 or 1-724-387-4000. You can also use the following address:

RESPIRONICS®
1001 Murry Ridge Lane
Murrysville, Pennsylvania
15668-8550 USA

Visit Respironics web site at: www.respironics.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 three primary control buttons on the 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 patients 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.
C-Flex	C-Flex – This button adjusts the C-Flex comfort setting.

If patients do not want to modify their settings, they only need these three 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 menu.
▶	Allows you to access the Data screens. Also allows you to navigate to the next screen when in the Data or Setup menu.
−	When in user mode, allows patients to enter the FOSQ screens. Also allows users and providers to decrease the settings on the setup screens.
+	Allows you to enter the Setup screens. Also allows you to increase the settings on the setup screens.

The device's display screen shows the set pressure, patient data, instructions, and error messages. 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.

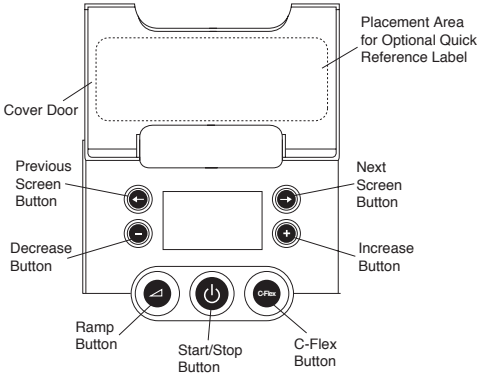


Figure 2–3 Device Control Panel

2.1.1 LED Backlight for Buttons

The Ramp, Start/Stop, and C-Flex buttons are lit by an LED backlight. There are three backlight intensities: off, bright, and dim. When the device is in Standby, the backlight is at the brightest intensity. Upon entering the Active state, the backlight is dim until activity is detected and then it changes to bright. If you remain in the Active state for 15 seconds or more but no activity is detected, the light will dim again.

2.1.2 Control Pad Inactivity

Some screens have timeout periods. The screens 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 device's rear panel (without a humidifier).

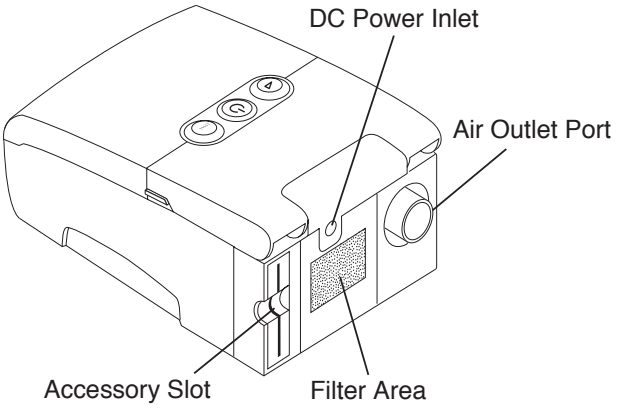


Figure 2–4 Device Rear Panel

The rear panel contains the following:

- An accessory slot for optional accessories such as the SmartCard or modem (see Chapter 6, *Accessories*, for more information).
- A filter area where the filter(s) 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 contains information on how to:

- Install the air filters
- Assemble the patient circuit
- Supply power to the device
- Start the device
- Verify the pressure

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 the filter(s):

1. If you are using the white disposable 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.*

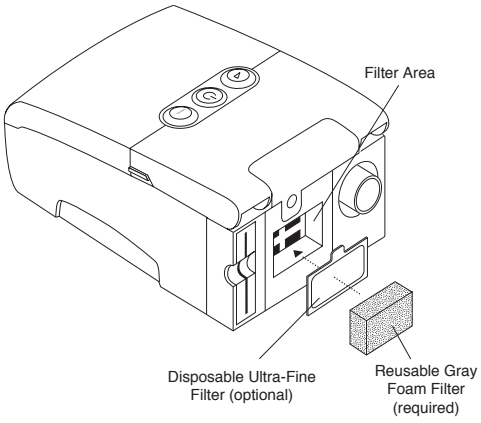


FIGURE 3–1 INSTALLING THE AIR FILTER

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

3.2 CONNECTING THE BREATHING CIRCUIT

Warning: *The exhalation device (e.g., the Whisper Swivel® II or exhalation port (on masks with an integrated exhalation port) is designed to exhaust CO_2 from the patient circuit. Do not block or seal the ports on the exhalation device.*

Warning: *The oxygen valve must be installed and used if oxygen is to be titrated to the patient circuit.*

You will need the following accessories in order to assemble the recommended circuit:

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

Follow the steps below to show the patient how to connect the breathing circuit to the device:

1. Connect the flexible tubing to the air outlet on the back of the device, as shown in Figure 3–2. You can use the optional, detachable swivel that is provided with the device and already attached to the tubing (shown in Figure 3–2), or you can remove the swivel and connect the tubing directly to the air outlet.

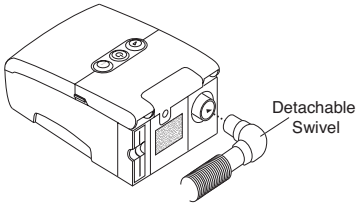


FIGURE 3–2 CONNECTING THE FLEXIBLE TUBING

Note: *If needed, connect a bacteria filter to the air outlet port, and then connect the patient tubing to the outlet of the bacteria filter.*

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.*

If you are using a humidifier, follow the instructions included with the humidifier to connect the tubing to the device.

Note: *On devices with a humidifier attached, the device's air outlet port, shown in Figure 3–3, is detached, and the tubing is attached directly to the air outlet port on the humidifier.*

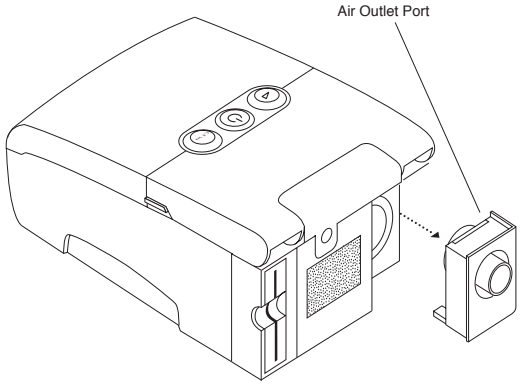


FIGURE 3–3 DETACHABLE AIR OUTLET PORT

2. Connect the tubing to the mask:

   a. If the patient is using a mask with a built-in exhalation port, connect the mask's connector to the flexible tubing, as shown in Figure 3–4.

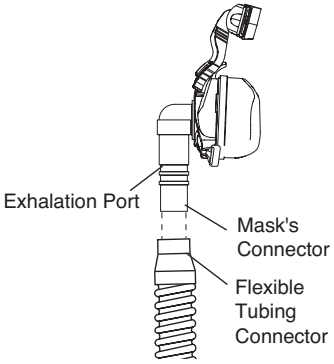


FIGURE 3–4 CONNECTING A MASK WITH BUILT-IN EXHALATION PORT

   b. If the patient is using a mask with a separate exhalation device, connect the open end of the flexible tubing to the exhalation device as shown in Figure 3–5. Position the exhalation device so that the vented air is blowing away from the patient's face. Connect the mask's connector to the exhalation device.

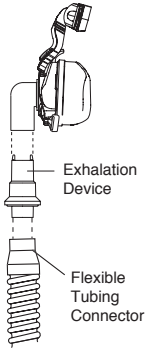


FIGURE 3–5 CONNECTING A MASK WITH A SEPARATE EXHALATION DEVICE

Warning: *The exhalation device (e.g., Whisper Swivel II) or exhalation port (on masks with an integrated exhalation port) is designed to exhaust CO_2 from the patient circuit. Do not block or seal the ports on the exhalation device.*

Warning: *If the patient is using a full face mask, the mask must be equipped with a safety (entrainment) valve.*

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

3.3 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 the device with a humidifier, refer to the Quickstart Guide included with the device or the instructions included with the humidifier for details on how to power the device and humidifier.*

3.3.1 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 3–6.

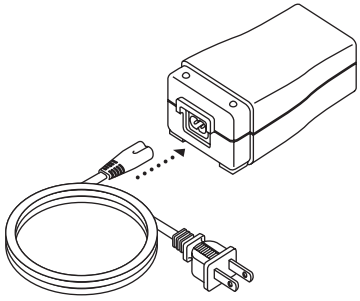


Figure 3–6 Connecting the Power Cord to the Power Supply

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 3–7.

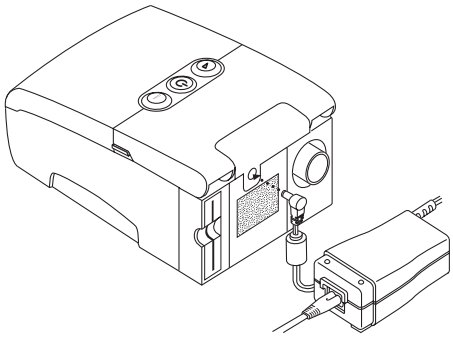


FIGURE 3–7 CONNECTING THE POWER SUPPLY CORD TO THE DEVICE

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.*

3.3.2 USING DC POWER

The Respironics DC Power Cord or Respironics Portable Battery Pack 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, Portable Battery Pack, 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, Portable Battery Pack, and adapter cable for information on how to operate the device using DC power.

3.4 Complete Assembly Example

Figure 3–8 shows an example of how a complete assembly will look, with breathing circuit connected and power applied to the device.

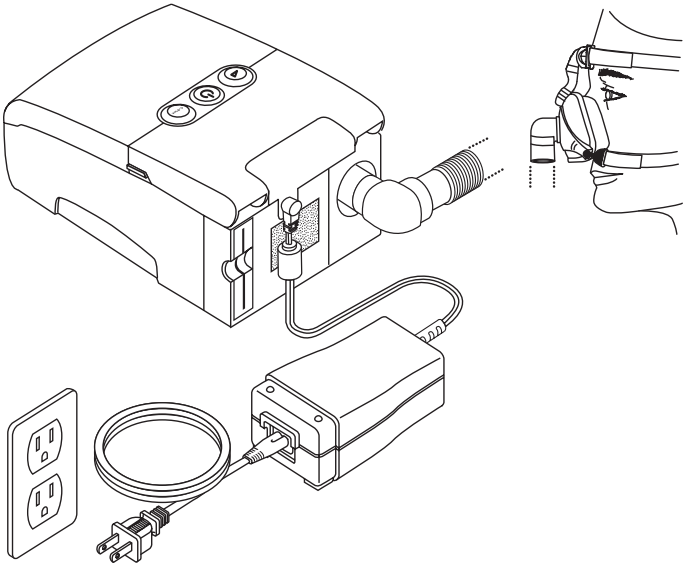


Figure 3–8 Final Assembly Example (Shown with Optional Accessory Module)

3.5 VERIFYING THE PRESSURE

WARNING: *If the device fails to perform within the stated specifications, have the system serviced by a qualified Respironics-approved service facility.*

If part of your patient setup procedure is to verify actual pressure with a manometer, please use the following instructions to ensure that the device is functioning properly. You will need the following equipment to calibrate the pressure:

- Respironics Pressure Calibration Kit includes:
  - Respironics Whisper Swivel II (PN 332113)
  - Respironics O_2 Enrichment Final Assembly (PN 312710)
  - Closed end cap, (PN 501121)
- Respironics 6ft (1.83m) x 22 mm I.D. flexible tubing (PN 621032)
- Pressure Tubing – Tubing Type: PVC Tubing, 1/8" I.D. x 1/4" O.D. 6-12" length (PN 304018)
- Respironics Digital Manometer or equivalent (PN 302227)

  Minimum Specifications:
  - 0 – 25 cm H_2O (or better)
  - ±0.3 cm H_2O accuracy
  - ±0.1cm H_2O resolution
- Foam filter

To calibrate the pressure, complete the following steps:

1. Install a foam filter into the device.
2. With the device unplugged, connect the system as illustrated in Figure 3–9.

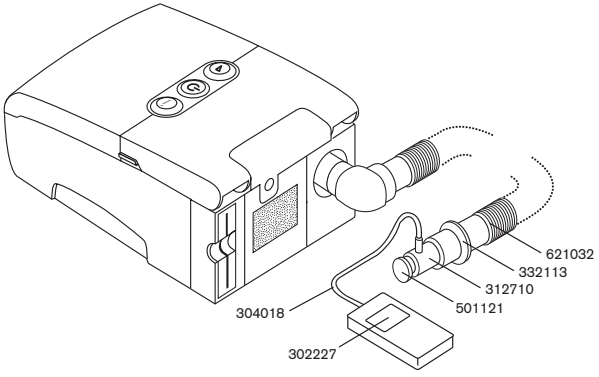


FIGURE 3–9 CONNECTING THE PRESSURE VERIFICATION EQUIPMENT

3. Turn the manometer on. If it does not display a reading of zero, adjust the manometer to calibrate it. If the manometer has variable settings for devices, set it to cm/H_20.
4. Plug in the device while simultaneously holding in the ← → buttons to place the device in provider mode.
5. Set the therapy parameters according to the patient specific data.
6. Set the device to the specific pressure value for the patient.
7. Verify that the pressure setting matches the pressure displayed on the manometer.

   If the pressure setting does not match the measured value for the device, contact Respironics or an authorized service center to have the device serviced.

Note: *Output pressures may vary at local altitude and barometric pressure. Because of these factors, devices may slightly vary in output pressure over the range of the altitude settings.*

8. Set up the remaining parameters and exit provider mode. The unit is ready for patient use.

Chapter 4: Operating the Device

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 three primary buttons light up and the Software Version screen momentarily appears, shown in Figure 4–1.

Figure 4–1 Software Version Screen

Note: *Version 1.0 shown in Figure 4–1 is an example. Your device may have a different software version installed.*

2. The next screen to appear is the Standby screen. If you are in provider mode, the Provider Mode Standby screen appears, while if you are in user mode, the User Mode Standby screen displays. Figures 4–2 and 4–3 show these screens.

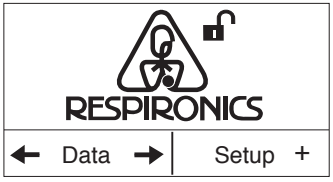


Figure 4–2 Provider Mode Standby Screen

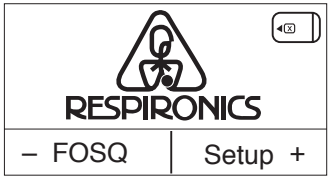


Figure 4–3 User Mode Standby Screen

Note: *The FOSQ option only appears if a SmartCard is inserted or a modem is connected to the device.*

3. Finally, from user mode, once you press the ⏻ button to turn on the airflow, the Active Display screen displays, shown in Figure 4–4.

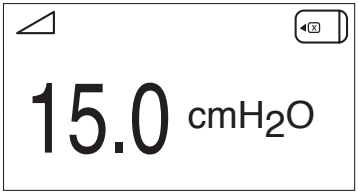


FIGURE 4–4 ACTIVE DISPLAY

The Active Display screen shows the set pressure.

Some symbols indicating when certain conditions are turned on or detected will also appear on the Active Display screen or on the Standby screen. These symbols are described below:

SYMBOL	DESCRIPTION
	Ramp – Patients can initiate the ramp feature by pressing the Ramp button. The ramp symbol displays on the Active Display screen when the ramp function is active.
Mask Leak	Mask Leak Alert – This flashing text displays on the Active Display screen if the Mask Alert setting is enabled and the device detects an excessive mask leak.
Auto Off	Auto-Off – This flashing text displays on the Standby screen if the Auto-Off setting is enabled and the device detects a mask disconnect.
	SmartCard – A SmartCard symbol displays if a SmartCard is inserted in the device. If the card is inserted incorrectly, the symbol will flash intermittently.
	SleepLink Card – This symbol displays if a SleepLink card is inserted in the device.
	Modem – This symbol displays if a modem is connected to the device. (Note: This symbol will vary in appearance depending on the type of modem being used.)

4. If oxygen is being used, turn on the oxygen flow. Make sure you place the Respironics pressure valve (PN 302418) in-line with the patient circuit.

Warning: *Always turn the airflow on before turning on the oxygen, and always turn the oxygen off before turning off the airflow.*

5. Place the mask on the patient.

4.2 Changing and Viewing Settings in Provider Mode

Accessing provider mode unlocks additional settings that cannot be modified while in user mode. To access provider mode:

1. Plug the AC power cord into the power supply and an electrical outlet, as described in Chapter 3.
2. Hold down both the left and right ← → buttons while simultaneously plugging the power supply into the device. Once the device beeps twice, it is in provider mode and you can release the buttons.

You can view and modify prescription settings using the Provider Setup screens and view data about device usage on the Provider Data screens.

To navigate the display screens:

- Use the → button to navigate to the next screen and the ← button to navigate to the previous screen.
- Use the + and — buttons to adjust the settings on the Setup screens.

4.2.1 REMstar Pro M Series Provider Setup Screens

Figure 4–5 shows how to navigate the REMstar Pro M Series Provider Setup screens using the left and right ← → buttons.

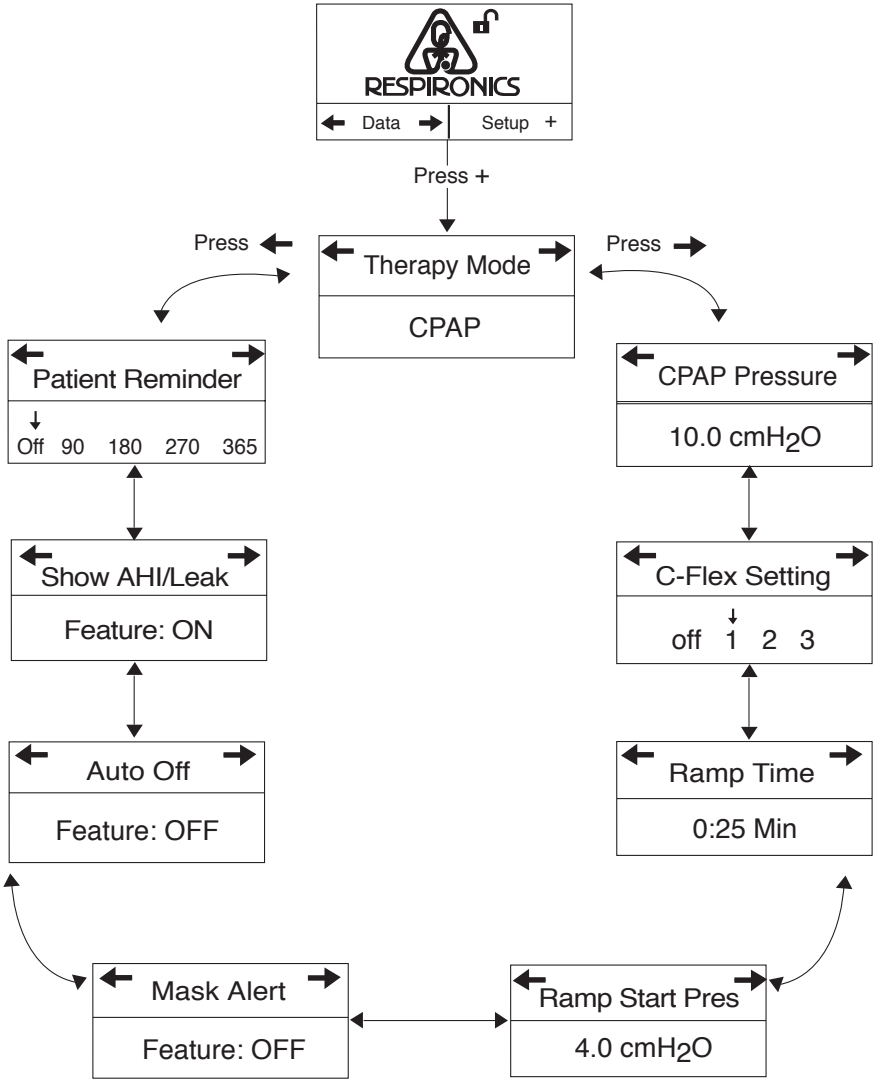
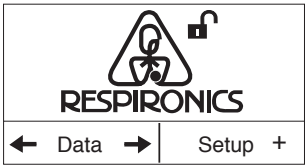
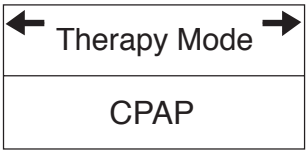


Figure 4–5 REMstar Pro M Series Provider Setup Screens

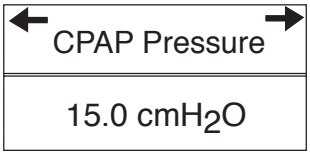
The REMstar Pro M Series Provider Setup screens are described below.



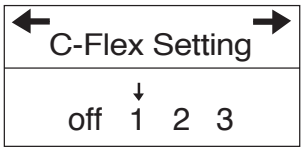
1. **Provider Mode Standby Screen**
   The Standby screen appears when you first enter provider mode. You can access both the Setup screens and the Data screens from this menu.
   To access the Provider Setup screens, press the + button.
   Note: *You can access the Data screens (described later in this chapter), by pressing the ← → buttons.*
   Note: *The 🔓 symbol at the top of the screen indicates that you are in provider mode.*
   Once inside the Setup menu, press the → or ← buttons to cycle through the screens.



2. **Therapy Mode Screen**
   This screen displays the therapy mode setting, which will always be CPAP for the Remstar Pro M Series device. With CPAP therapy, there is one level of output pressure for both the inspiratory and expiratory breathing phases.

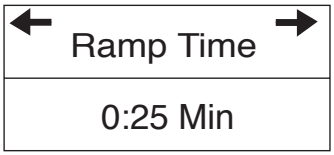


3. **Therapy Pressure Setting Screen**
   This screen displays the current CPAP pressure setting. The initial default setting is 10 cm H_2O. Use the + button to increase the setting and use the – button to decrease the setting by 0.5 cm H_2O increments. You can adjust the setting from 4 cm H_2O to 20 cm H_2O.



4. **C-Flex Setting Screen**
   You can modify the C-Flex setting on this screen. Use the + and – buttons to increase or decrease the setting by 1. An arrow appears above the selected setting.
   - Off disables (locks) the C-Flex setting and prevents the patient from using C-Flex.
   - 1 sets C-Flex to a default of 1.
   - 2 sets C-Flex to a default of 2.
   - 3 sets C-Flex to a default of 3.

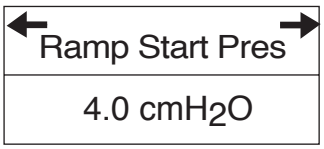
   Note: *The patient also has access to this setting, if C-Flex is enabled.*



5. **Ramp Time Screen**
When you set the ramp time, the device increases the CPAP pressure from the value set on the Ramp Starting Pressure screen to the CPAP pressure setting over the length of time specified here. You can modify the ramp time by pressing the + or – buttons to increase or decrease the setting in 5-minute increments. The range for this setting is 0 to 45 minutes.

Note: *If the CPAP pressure is set to 4 (the minimum setting), this screen will not display.*

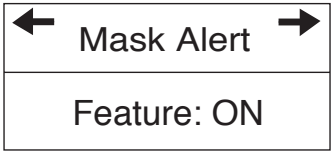
Note: *If the Ramp Time is set to 0, the Ramp Starting Pressure screen will not display.*



6. **Ramp Starting Pressure Screen**
You can increase or decrease the ramp starting pressure in 0.5 cm H_2O increments by pressing the + or – buttons. The default setting is 4 cm H_2O. You can adjust the setting from 4 cm H_2O to the CPAP pressure setting.

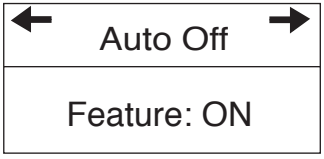
Note: *This screen will not display if the CPAP pressure is set to 4 cm H_2O or if the ramp time is set to zero. Additionally, if the ramp starting pressure is set higher than the CPAP pressure setting, the ramp starting pressure will be decreased automatically by the device to match the CPAP pressure.*

Note: *The patient also has access to this setting, unless the ramp time is set to 0.*



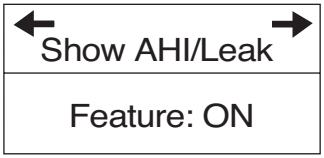
7. **Mask Alert Screen**
You can enable or disable the mask alert setting by pressing the + or – buttons to select Off or On. The default setting is OFF. If this feature is enabled, then the words **Mask Leak** flash on the Active display screen if a significant mask leak is detected, and an audible alert sounds.

Note: *The patient also has access to this setting.*

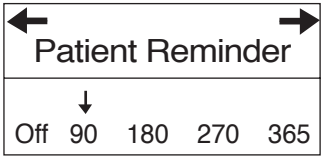


8. **Auto-Off Screen**
You can enable this feature if you want the device to automatically discontinue therapy whenever the patient removes the interface (e.g., mask) from their airway.
Press the + or – buttons to select OFF or ON. If this feature is enabled, then the words **Auto Off** flash on the Standby screen whenever a mask disconnect is detected. The airflow shuts off, and the **Auto Off** message continues to appear on the Standby screen until the condition is corrected.

Note: *The patient also has access to this setting.*



9. **Show AHI/System Leak Screen**
You can select whether or not the Apnea/Hypopnea index and System Leak averages are displayed on the Patient Data screens. Press the + or – buttons to select OFF or ON. The default setting is ON.



10. **Patient Reminder**
You can set a reminder on this screen that will let patients know when it's time to perform a certain task, such as replacing the mask. Use the + or – buttons to select one of the following settings:
    - Off – No reminder is set.
    - 90 – A reminder appears on the device display after 3 months.
    - 180 – A reminder appears on the device display after 6 months.
    - 270 – A reminder appears on the device display after 9 months.
    - 365 – A reminder appears on the device display after one year.

    The default setting is Off.

    Note: *You can set a specific patient reminder message using the Encore Pro software, and put this message on a SmartCard or send it to the patient's device via a modem.*

After you finish modifying the REMstar Pro M Series Provider Setup screens, press the ⏻ button to exit provider mode.

4.2.2 REMstar Pro M Series Provider Data Screens

Figure 4–6 shows how to navigate the REMstar Pro M Series Provider Data screens.

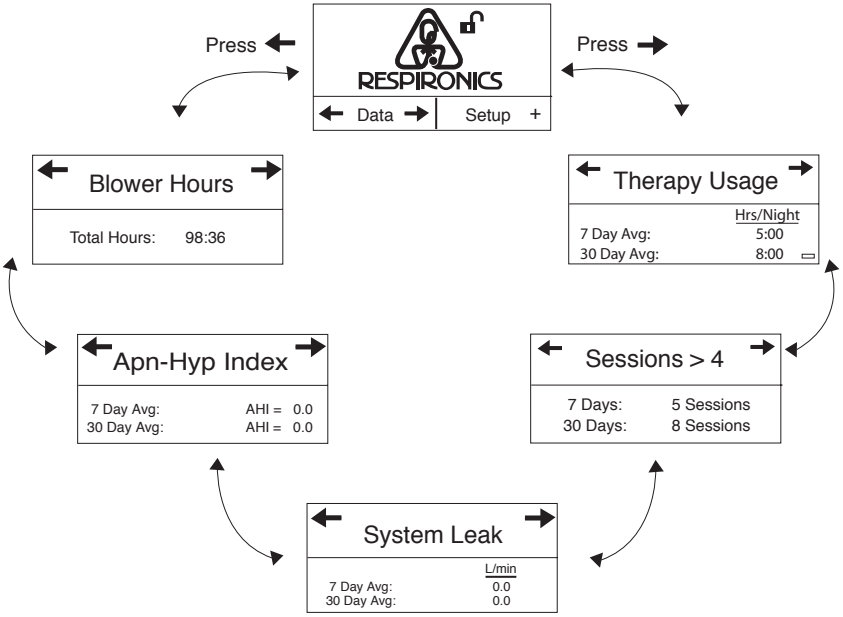
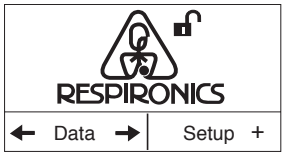
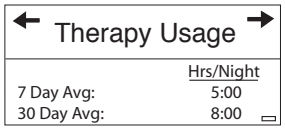


Figure 4–6 REMstar Pro M Series Provider Data Screens

The REMstar Pro M Series Provider Data screens are described below.



1. **Provider Mode Standby Screen**
   From the Standby screen, press the → button to enter the Data menu. The Therapy usage screen appears. Once inside the Data menu, press the → or ← buttons to cycle through the screens.

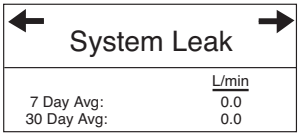


2. **Therapy Usage Screen**
   This screen displays the amount of time that the patient has received therapy (with the blower on and the patient connected).
   The screen displays both a 7 and 30-day average. The maximum value that can be displayed for both averages is 24 hours.
   You can reset these values and **all** of the other Data screens to zero by pressing the – button for approximately 5 seconds. This data may be useful in tracking patient compliance. Resetting the values will not erase the total operation time or other patient data.

   Note: *The patient can view this information but cannot reset it.*

3. **Sessions Greater than 4 Hours Screen**
   This screen displays the number of device therapy sessions that exceeded 4 hours in 7-day and 30-day periods. You can reset these values to zero from the Therapy Usage screen by pressing the – button for approximately 5 seconds. The maximum value that can be displayed for the 7-day period is 35 sessions, and the maximum value for the 30-day period is 150 sessions.

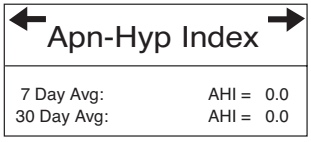
   Note: *The patient can view this information but cannot reset it.*



4. **System Leak Screen**
This screen displays a 7-day and 30-day average of the leak history for the unit in liters per minute (LPM). System leak is a combination of intentional and unintentional air leak. Intentional leak is the expected leak at the exhalation port. Some leak is required to minimize CO_2 rebreathing. Unintentional leak occurs around the patient interface. If there is a large increase in the amount of leak indicated on this screen, the patient may need a mask refitting. Leaks that should be fixed include leaks into the eyes, leaks that bother the patient, or leaks that affect pressure stability.

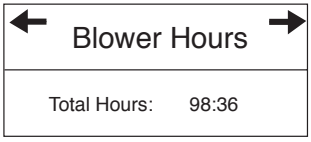
   You can reset the values to zero from the Therapy Usage screen by pressing the – button for approximately 5 seconds. The maximum value that can be displayed for both averages is 127 LPMs.

   Note: *The patient can view this information but cannot reset it.*



5. **Apnea/Hypopnea Index Screen**
This screen displays the patient's Apnea/Hypopnea index (AHI) for the last 7 and 30 days. You can reset these values to zero from the Therapy Usage screen by pressing the – button for approximately 5 seconds. The maximum value that can be displayed for both averages is 255.

   Note: *The patient can view this information but cannot reset it.*



6. **Blower Hours Screen**
This screen displays the total number of hours that the blower has been active over the life of the device. The maximum value that can be displayed is 24999:54 hours. If this maximum value is reached, the number will reset to zero.

4.2.3 REMstar Auto M Series Provider Screens

Figure 4–7 shows how to navigate the REMstar Auto M Series Provider Setup screens using the left and right ← → buttons.

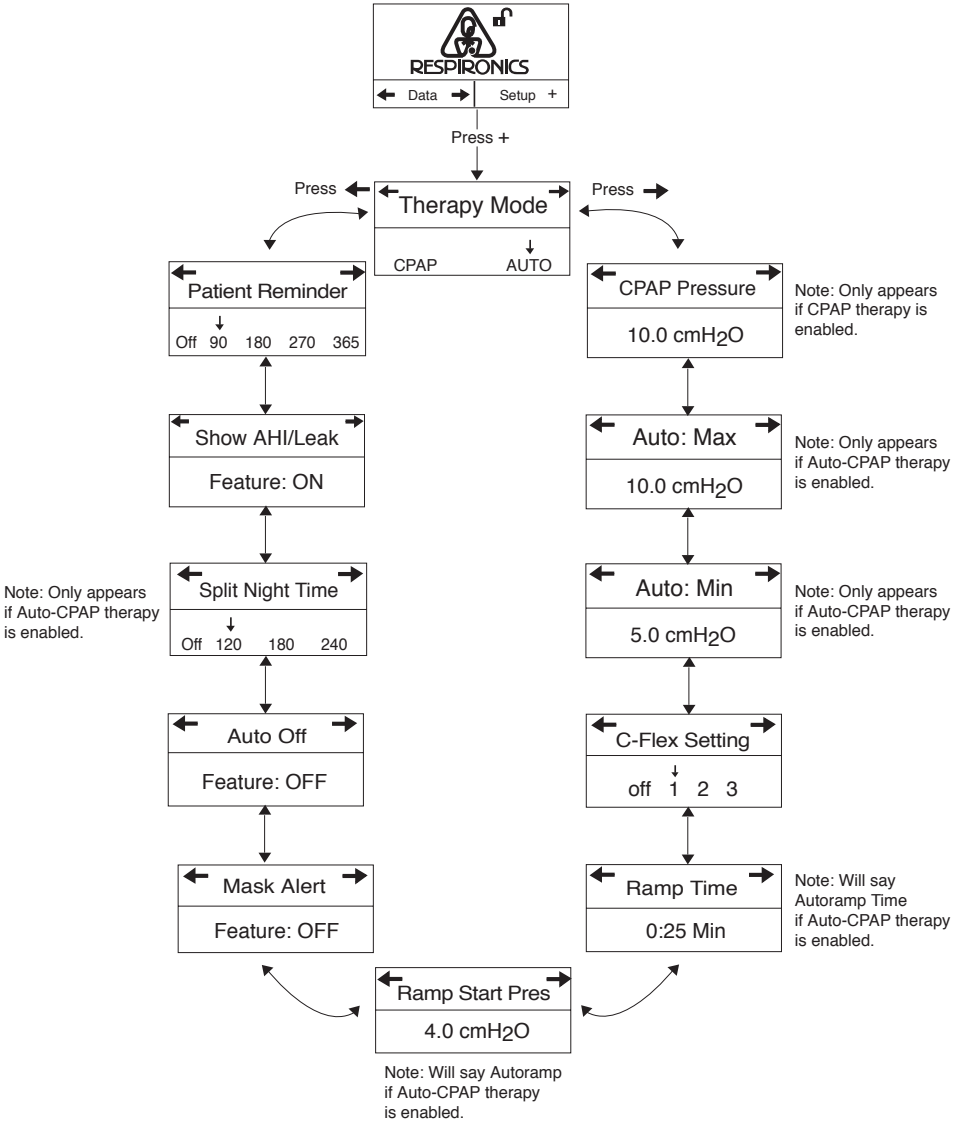
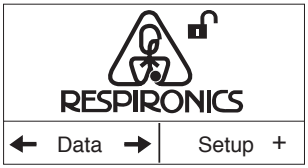


Figure 4–7 REMstar Auto M Series Provider Setup Screens

The REMstar Auto M Series Provider Setup screens are described below.

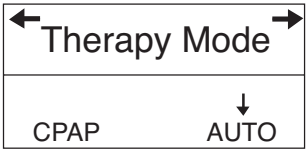


1. **Provider Mode Standby Screen**
The Standby screen appears when you first enter provider mode. You can access both the Setup screens and the Data screens from this menu.
To access the Provider Setup screens, press the + button.

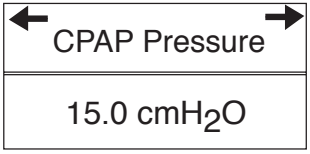
   Note: *You can access the Data screens (described later in this chapter), by pressing the ← → buttons.*

   Note: *The 🔓 symbol at the top of the screen indicates that you are in provider mode.*

   Once inside the Setup menu, press the → or ← buttons to cycle through the screens.

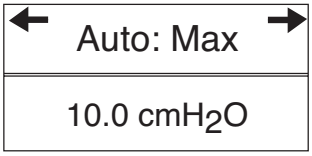


2. **Therapy Mode Screen**
This screen displays the therapy mode setting. You can select CPAP therapy or Auto-CPAP therapy. CPAP therapy provides one level of output pressure for both the inspiratory and expiratory breathing phases. Auto-CPAP therapy provides CPAP therapy while automatically adjusting the pressure level when apnea, hypopnea, flow limitation, or snoring events are detected.



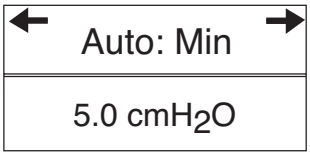
3. **Therapy Pressure Setting Screen**
This screen displays the current CPAP pressure setting. The initial default setting is 10 cm H_2O. Use the + button to increase the setting and use the – button to decrease the setting by 0.5 cm H_2O increments. You can adjust the setting from 4 cm H_2O to 20 cm H_2O.

   Note: *This screen only displays if CPAP therapy is enabled. It will not appear if Auto-CPAP therapy is enabled.*



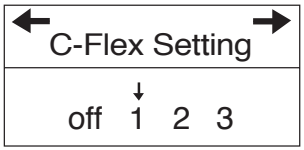
4. **Auto Maximum Pressure Screen**
This screen allows you to modify the Auto Maximum pressure setting. The setting you specify here will be the maximum pressure for the device. Auto therapy will adjust the CPAP pressure between the Auto Maximum and the Auto Minimum pressure settings. Use the + button to increase the setting and use the – button to decrease the setting by 0.5 cm H_2O increments. The default setting is 20 cm H_2O.

   Note: *This screen only displays if Auto-CPAP therapy is enabled.*



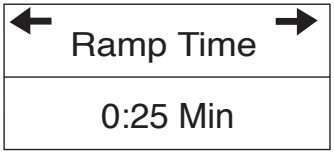
5. **Auto Minimum Pressure Screen**
This screen allows you to modify the Auto Minimum pressure setting. The setting specified here will be the minimum pressure for the device. Auto therapy will adjust the CPAP pressure between the Auto Maximum and the Auto Minimum pressure. Use the + button to increase the setting and use the – button to decrease the setting by 0.5 cm H_2O increments.
The default setting is 4 cm H_2O.

Note: *This screen only displays if Auto-CPAP therapy is enabled.*

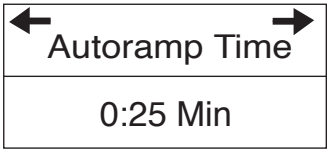


6. **C-Flex Setting Screen**
You can modify the C-Flex setting on this screen. Use the + and – buttons to increase or decrease the setting by 1. An arrow appears above the selected setting.
- Off disables (locks) the C-Flex setting and prevents the patient from using C-Flex.
- 1 sets C-Flex to a default of 1.
- 2 sets C-Flex to a default of 2.
- 3 sets C-Flex to a default of 3.

Note: *The patient also has access to this setting, if C-Flex is enabled.*



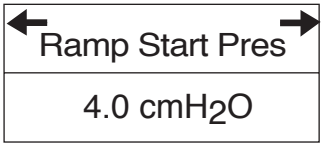
7. **Ramp Time Screen**
When you set the ramp time, the device increases the CPAP pressure from the value set on the Ramp Starting Pressure screen to either the CPAP pressure setting (if in CPAP mode) or the Auto Minimum pressure setting (if in Auto-CPAP mode) over the length of time specified here. You can modify the ramp time by pressing the + or – buttons to increase or decrease the setting in 5-minute increments. The range for this setting is 0 to 45 minutes.



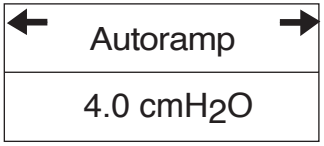
If you are in CPAP mode, the screen says Ramp Time. However, if you are in Auto-CPAP mode, the screen says Autoramp Time, as shown at left.

Note: *If the CPAP pressure (if in CPAP mode) or Auto Minimum pressure (if in Auto-CPAP mode) is set to 4 (the minimum setting), this screen will not display.*

Note: *If the Ramp Time is set to 0, the Ramp Starting Pressure screen will not display.*



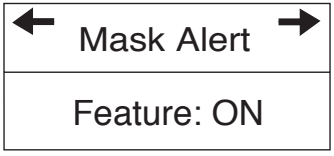
8. **Ramp Starting Pressure Screen**
You can increase or decrease the ramp starting pressure in 0.5 cm H_2O increments by pressing the + or – buttons. The default setting is 4 cm H_2O. You can adjust the setting from 4 cm H_2O to the CPAP pressure setting (if in CPAP mode) or the Auto Minimum pressure setting (if in Auto-CPAP mode).



If you are in CPAP mode, the screen says Ramp Start Pres. However, if you are in Auto-CPAP mode, the screen says Autoramp, as shown at left.

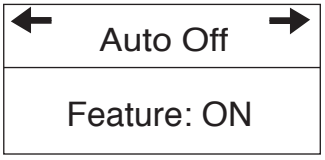
Note: *This screen will not display if the CPAP pressure (if in CPAP mode) or Auto Minimum pressure (if in Auto-CPAP mode) is set to 4 cm H_2O or if the ramp time is set to zero. Additionally, if the ramp starting pressure is set higher than the CPAP pressure (if in CPAP mode) or Auto Minimum pressure (if in Auto-CPAP mode), the ramp starting pressure will be decreased automatically by the device to match the CPAP or Auto Minimum pressure.*

Note: *The patient also has access to this setting, unless the ramp time is set to 0.*



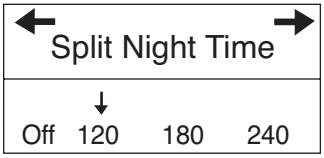
9. **Mask Alert Screen**
You can enable or disable the mask alert setting by pressing the + or – buttons to select OFF or ON. The default setting is Off.
If this feature is enabled, then the words **Mask Leak** flash on the Active display screen if a significant mask leak is detected, and an audible alert sounds.

Note: *The patient also has access to this setting.*



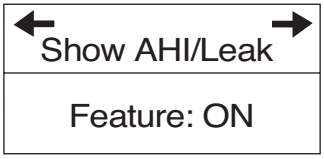
10. **Auto-Off Screen**
You can enable this feature if you want the device to automatically discontinue therapy whenever the patient removes the interface (e.g., mask) from their airway.
Press the + or – buttons to select OFF or ON. If this feature is enabled, then the words **Auto Off** flash on the Standby screen whenever a mask disconnect is detected. The airflow shuts off, and the **Auto Off** message continues to appear on the Standby screen until the condition is corrected.

Note: *The patient also has access to this setting.*

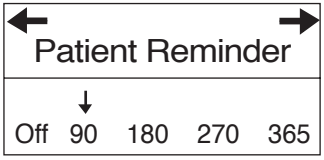


11. **Split Night Time Screen**
You can modify the Split Night Time setting on this screen, which indicates the amount of time spent in CPAP therapy before transitioning to Auto-CPAP therapy. The default setting is Off. You can also set it to 120, 180, or 240 minutes.

Note: *This screen only displays if Auto-CPAP therapy is enabled.*



12. **Show AHI/System Leak Screen**
You can select whether or not the Apnea/Hypopnea index and System Leak averages are displayed on the Patient Data screens. Press the + or – buttons to select OFF or ON. The default setting is ON.



13. **Patient Reminder**
You can set a reminder on this screen that will let patients know when it's time to perform a certain task, such as replacing the mask. Use the + or – buttons to select one of the following settings:
    - Off – No reminder is set.
    - 90 – A reminder appears on the device display after 3 months.
    - 180 – A reminder appears on the device display after 6 months.
    - 270 – A reminder appears on the device display after 9 months.
    - 365 – A reminder appears on the device display after one year.

    The default setting is Off.

Note: *You can set a specific patient reminder message using the Encore Pro software, and put this message on a SmartCard or send it to the patient's device via a modem.*

After you finish modifying the REMstar Auto M Series Provider Setup screens, press the ⏻ button to exit provider mode.

4.2.4 REMstar Auto M Series Provider Data Screens

Figure 4–8 shows how to navigate the REMstar Auto M Series Provider Data screens.

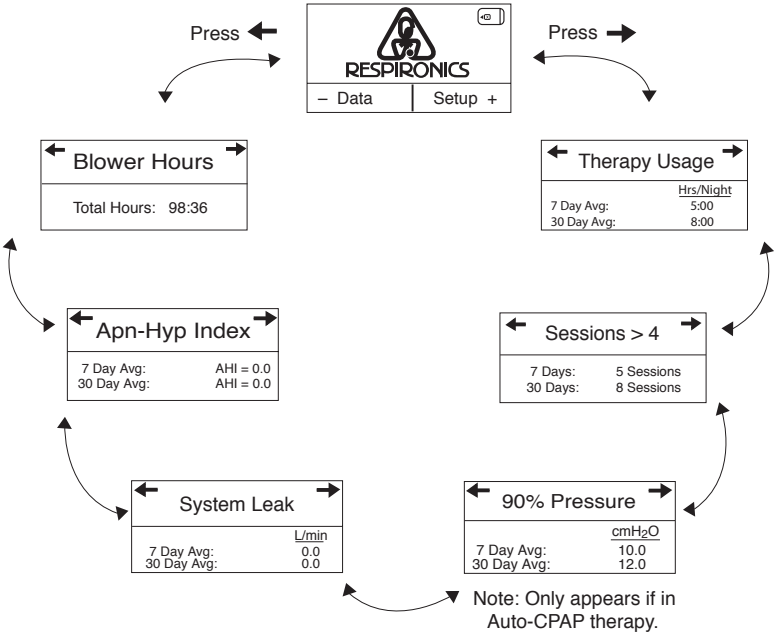
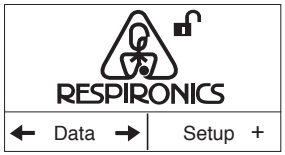
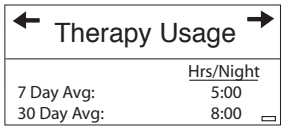


Figure 4–8 REMstar Auto M Series Provider Data Screens

The REMstar Auto M Series Provider Data screens are described below.



1. **Provider Mode Standby Screen**
   From the Standby screen, press the → button to enter the Data menu. The Therapy usage screen appears. Once inside the Data menu, press the → or ← buttons to cycle through the screens.

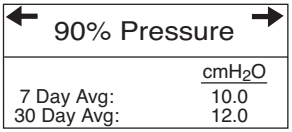


2. **Therapy Usage Screen**
   This screen displays the amount of time that the patient has received therapy (with the blower on and the patient connected).
   The screen displays both a 7 and 30-day average. The maximum value that can be displayed for both averages is 24 hours.
   You can reset these values and **all** of the other Data screens to zero by pressing the – button for approximately 5 seconds. This data may be useful in tracking patient compliance. Resetting the values will not erase the total operation time or other patient data.

   Note: *The patient can view this information but cannot reset it.*

3. **Sessions Greater than 4 Hours Screen**
   This screen displays the number of device therapy sessions that exceeded 4 hours in 7-day and 30-day periods. You can reset these values to zero from the Therapy Usage screen by pressing the – button for approximately 5 seconds. The maximum value that can be displayed for the 7-day period is 35 sessions, and the maximum value for the 30-day period is 150 sessions.

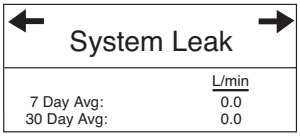
   Note: *The patient can view this information but cannot reset it.*



4. **90% Therapy Pressure Screen**
This screen displays a 7-day and 30-day average of the 90% pressure calculated for the session. The 90% pressure is the pressure at which the patient spent 90% of the session time at or below. For example, if a patient has the device (with airflow) on for 10 hours, and spends 9 hours at or below 11 cm H_2O, and 1 hour above 11 cm H_2O, then the 90% pressure is 11 cm H_2O. The maximum value for both averages is 20.0 cmH_2O.

Note: *This screen is only for reference. Your home care provider may periodically ask you for this information.*

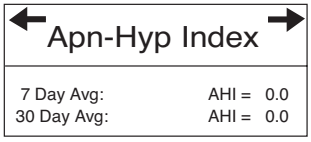
Note: *This screen only displays if you are in Auto-CPAP therapy.*



5. **System Leak Screen**
This screen displays a 7-day and 30-day average of the leak history for the unit in liters per minute (LPM). System leak is a combination of intentional and unintentional air leak. Intentional leak is the expected leak at the exhalation port. Some leak is required to minimize CO_2 rebreathing. Unintentional leak occurs around the patient interface. If there is a large increase in the amount of leak indicated on this screen, the patient may need a mask refitting. Leaks that should be fixed include leaks into the eyes, leaks that bother the patient, or leaks that affect pressure stability.

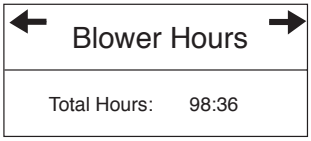
You can reset the values to zero from the Therapy Usage screen by pressing the – button for approximately 5 seconds. The maximum value that can be displayed for both averages is 127 LPMs.

Note: *The patient can view this information but cannot reset it.*



6. **Apnea/Hypopnea Index Screen**
This screen displays the patient's Apnea/Hypopnea index (AHI) for the last 7 and 30 days. You can reset these values to zero from the Therapy Usage screen by pressing the – button for approximately 5 seconds. The maximum value that can be displayed for both averages is 255.

Note: *The patient can view this information but cannot reset it.*



7. **Blower Hours Screen**
This screen displays the total number of hours that the blower has been active over the life of the device. The maximum value that can be displayed is 24999:54 hours. If this maximum value is reached, the number will reset to zero.

4.3 Changing and Viewing Settings in User Mode

When the device is in the Active state and the airflow is turned on, the patient can view the set pressure on the Active display screen.

Additionally, the patient can view the following settings from the Patient Data screens:

- Therapy usage hours
- Number of sessions greater than 4 hours
- 90% therapy pressure averages – (REMstar Auto only, in Auto-CPAP therapy)
- System leak (if enabled by the home care provider)
- Apnea/Hypopnea Index (if enabled by the home care provider)

The patient can also view and modify the following settings on the Patient Setup screens:

- C-Flex (if enabled by the home care provider)
- Ramp starting pressure (if enabled by the home care provider)
- Mask alert (enable/disable)
- Auto off (enable/disable)

Note: *Patients can access the C-Flex setting (if enabled) by either pressing the C-Flex button on the device or by navigating the Patient Setup screens.*

See the device user manual for more information.

Chapter 5: Device Alerts and Troubleshooting

This chapter describes the device alerts and provides troubleshooting information.

5.1 Device Alerts

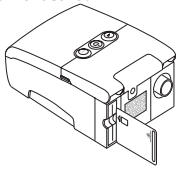
The device provides two alert levels, high and medium priority.

- **High Priority** – These alerts require immediate operator response. The alert signal consists of a high priority sound, which is a continuous two-beep pattern (indicated in the following table as: • • • •). Additionally, the backlights on the buttons provide a high priority flashing pattern consisting of a continuous, bright-to-off, two-flash pattern (indicated in the following table as: ◊◊ ◊◊ ◊◊).
- **Medium Priority** – These alerts require prompt operator response. The alert signal consists of a medium priority sound, which is a continuous one-beep pattern (indicated in the following table as: • •). Additionally, the backlights on the buttons provide a medium priority flashing pattern consisting of a continuous, bright-to-dim, one-flash pattern (indicated in the following table as: ◊ ◊ ◊).

5.1.1 Alert Summary Table

The following table summarizes the high and medium priority alerts.

Alert	Audible Indicator	Visual Indicator	Device Action	Possible Cause	Patient Action	Provider Action
System Error	• • • •	Backlights: ◊◊ ◊◊ ◊◊ Screen displays the following message: Service Required ⚠	The device enters the "Safe state" in which the device power remains on, but the airflow is disabled.	Device failure	Press any of the display screen buttons to silence the alert. Remove the power supply cord from the device to remove power. Plug the cord back into the device's power inlet to restore power. If the alert continues to occur, contact your home care provider.	If you have another power supply available, try changing the power supply and reapplying power to the device. If this resolves the problem, send the defective power supply to an authorized service representative or Respironics for service. If trying another power supply does not correct the problem, or if you do not have a spare power supply, send the device and power supply to Respironics or an authorized service center for service. Please have the serial number ready when you call.

Alert	Audible Indicator	Visual Indicator	Device Action	Possible Cause	Patient Action	Provider Action
SmartCard Error	• •	Backlights: ◊ ◊ ◊ Screen displays the following flashing error symbol: 	The device continues to operate and provide therapy, but data logging is unavailable and FOSQ is deactivated.	A problem exists with the SmartCard inserted in the accessory slot. The card may be improperly inserted or the data may be corrupt.	Remove the SmartCard to clear the alert. Confirm that the card is properly oriented, with the arrow pointing towards the device, as shown below, and reinsert the SmartCard.  If the alert continues to occur, remove the SmartCard from the device and contact your home care provider. The card may be corrupt and need replaced.	Confirm that the card is properly inserted. If the alert continues, the card may be corrupt. Replace the SmartCard.
Mask Leak	• •	Backlights: ◊ ◊ ◊ The words **Mask Leak** flash on the Active Display screen.	The device continues to operate.	The breathing circuit is disconnected or there is a large air leak.	Check your breathing circuit connections and reconnect the tubing if it has come loose. Press any of the display buttons to clear the alarm. Make sure your mask is on properly before you press the ⏻ button to restart the airflow. If the alert continues to occur, disable the mask alert setting following the instructions in Chapter 4, and continue your therapy overnight. Contact your home care provider the next morning to have your mask checked. You may need a mask refitting.	Make sure the breathing circuit is properly connected. If there is an air leak, correct the leak. If the alert still continues, contact an authorized service representative or Respironics to have the device serviced. Please have the serial number ready when you call.

Alert	Audible Indicator	Visual Indicator	Device Action	Possible Cause	Patient Action	Provider Action
Auto Off	None	The words **Auto Off** flash on the Standby screen, indicating that a mask disconnect has occurred.	The airflow shuts off and the device enters the Standby state 45-60 seconds after the mask disconnect is detected.	The mask has been removed.	Put your mask back on and press the ⏻ button to turn the airflow on and resume therapy.	No action needed.
Patient Reminder	None	Backlights: ◊ ◊ ◊ Screen displays a customized reminder message whenever the device transitions from the Active state to the Standby state.	The device continues to operate.	You can set a patient reminder scheduled to pop up at a particular time to remind the patient to replace the mask, change the filters, etc.	Press any of the display buttons to acknowledge the message and clear it. If you do not acknowledge the reminder, it will disappear after 6 minutes, and then reappear for three consecutive days whenever the device transitions from the Active state to the Standby state. If you still do not acknowledge the message, the reminder period will reset and the message will not reappear until the next time the Patient Reminder setting expires.	Make sure that the patient is performing whatever action you indicated on the reminder (e.g., to inspect the mask for damage, etc.).

5.2 Troubleshooting

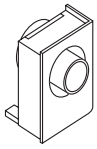
The table below lists common problems you or the patient may experience with the device or mask and possible solutions to those problems.

Problem	Why It Happened	What to Do
Nothing happens when you apply power to the device. The audible indicator does not sound and the backlights on the buttons do not light.	There's no power at the outlet or the device is unplugged.	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, have the device serviced by Respironics or an authorized service representative. If you are using DC power, make sure the DC power cord and battery adaptor cable connections are secure. Check the battery. It may need recharged or replaced. If the problem persists, check the DC cord's fuse following the instructions supplied with the DC cord. The fuse may need replaced. If the problem still occurs, have the device serviced. If you are using a humidifier, make sure you follow the instructions for applying power that are provided with the humidifier.

Problem	Why It Happened	What to Do
The device does not operate when you press the ⏻ button. The airflow does not turn on.	There may be a problem with the blower.	Make sure the device is powered correctly, following the instructions on the previous page. If the audible indicator sounds and the button backlights turn on when you apply power, but the airflow does not turn on, there may be a problem with the device. Contact Respironics or an authorized service center to have the device serviced. Please have the serial number ready when you call. ***Note:*** *When the device is functioning correctly, after you press the ⏻ button, the device beeps and the airflow turns on after a slight delay. This brief delay is normal.*
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 Electromagnetic Interference (EMI) emissions.	Unplug the device and the power supply. Reapply power to the device. If the problem continues, tell the patient to 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.). If the problem still occurs, contact Respironics or an authorized service center to have the device serviced.
Device Resets/Reboots: The device shuts down and restarts automatically during therapy. (This is unlikely to occur.)	The device comes installed with troubleshooting software that automatically monitors performance.	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 error alert to indicate that the device be returned to the home care provider for service: Service Required ⚠

Problem	Why It Happened	What to Do
The Ramp feature does not work when you press the Ramp button (⧄).	The Ramp Time is set to 0. Or, the CPAP pressure is set to the ramp start pressure (CPAP mode). Or, the Auto Minimum pressure is set to the ramp start pressure (Auto-CPAP mode).	Change the Ramp Time setting as described in Chapter 4. Or, if in CPAP mode, set the CPAP pressure setting above the ramp start pressure. If in Auto-CPAP mode, set the Auto Minimum pressure setting above the ramp start pressure. If the problem still continues, contact Respironics or an authorized service center to have the device serviced.

Problem	Why It Happened	What to Do
The device has fallen off the table or nightstand.	The device may not have been properly seated on the nightstand, or the placement of the tubing may have caused the device to fall.	Tell the patient to always make sure the 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. Also, tell the patient to place the device away from the edge of the nightstand or table, so it doesn't accidentally get knocked off the table. If using a humidifier, make sure that the device and humidifier are placed below the patient's head and mask, so that any condensation in the tubing drains back into the water chamber. 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. If the placement of the tubing causes the device to fall, make sure the patient uses proper hose management when setting up the device. If the device falls or water gets into the device upon falling, let the device dry completely and then restart it. If it does not operate correctly after falling, contact Respironics or an authorized service center.

Problem	Why It Happened	What to Do
The patient is having problems connecting the tubing to the device.	They have lost the air outlet port or are traveling and forgot to bring the port with them.	If the patient is not using a humidifier, they cannot connect the tubing to the device without the detachable air outlet port, shown below.  Remind the patient that the port must be attached properly before connecting the tubing.
The patient is experiencing excessive air leaks where the tubing connects to the device.	The air outlet port is not installed correctly and doesn't seal properly.	Remove the port and reattach it to make sure it's properly installed. To remove the port: a. Put your thumb underneath the port and insert your index finger into the port opening. b. Pivoting from the bottom, unsnap the port, and pull it away from the device. To properly reattach the port: a. 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. b. Push the top of the port down to snap it into place. Reattach the tubing, turn on the airflow, and check to make sure you do not still feel air coming out of the port area.

Problem	Why It Happened	What to Do
The air out of the mask is much warmer than usual.	The air filters may be dirty. The device may be operating in direct sunlight or near a heater.	Remind the patient to regularly clean or replace the air filters as described in the user's manual. The temperature of the air may vary somewhat based on the room temperature. Tell the patient to make sure that the device is properly ventilated and to 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. If the problem continues, contact Respironics or an authorized service center for assistance.
The mask feels uncomfortable to wear, there is significant air leakage around the mask, or the patient experiences other mask-related issues.	This could be due to improper headgear adjustment or improper mask fitting, etc.	Refer to the mask instructions for information on proper fitting, etc. You may need to try a different mask or refit the patient's existing mask.
The patient has a runny nose.	This is caused by a nasal reaction to the airflow.	Tell the patient to call their health care professional.
The patient has throat or nose dryness.	The air is too dry.	Have the patient increase the room humidity or use a humidifier with the device.
The patient experiences nasal, sinus, or ear pain.	The patient may have a sinus or middle ear infection.	Tell the patient to stop using the device and contact their health care professional.

Chapter 6: Circuits and Accessories

This chapter describes the Respironics-approved breathing circuit and accessories available for the device.

Warning: *Refer to each accessory's instruction sheet for the applicable warnings, cautions, and notes.*

6.1 Circuit Configurations

Warning: *Do not connect any equipment to the device unless recommended by Respironics or the health care professional. Verify that an exhalation port is present to exhaust CO_2 from the circuit. If circuit accessories other than those recommended by Respironics are connected to the device, then pressures must be verified. Use of these accessories may alter the pressure received, reducing the effectiveness of treatment.*

This device is intended for use with Respironics-approved patient circuits. Typical components include:

- Bacteria Filter (optional)
- Respironics 6 ft. (1.83 m) x 22 mm reusable flexible tubing
- Respironics patient interface (e.g., mask) with integrated exhalation port (or Respironics mask with separate exhalation port such as the Whisper Swivel II)
- Respironics headgear
- Respironics Pressure Valve (Part Number 302418), if adding supplemental oxygen
- Humidifier (optional)

Additional accessories may be added to the circuit to meet specific needs.

6.2 DC Power

The Respironics DC Power Cord or Respironics Portable Battery Pack 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 Respironics DC Power Cord) enables the device to be operated from a 12 VDC free-standing battery.

6.3 SmartCard

The device is delivered with an Encore Pro SmartCard. The SmartCard is a plastic card similar in size and shape to a normal credit card. However, instead of holding information on a magnetic strip, it holds it in a small silicon chip embedded in the card. When installed into the device, the SmartCard records the date, time, and duration of each use (storage capacity: at least 6 months). When capacity is reached, the oldest data is overwritten. Using the Respironics SmartCard reader/writer and the Encore® Pro software, you can download and view the usage data. Follow the instructions included with the software to download the data.

Note: *If the card is not installed, the device usage will not be recorded. When a SmartCard is installed, a SmartCard symbol appears in the upper right corner of the Active Display screen.*

The SmartCard can also be programmed with the patient's prescription by using applicable Respironics software and the SmartCard reader/writer (available from Respironics). When the programmed SmartCard is inserted into the device, the prescription settings are automatically transferred into the device and erased from the SmartCard. The SmartCard will then start to collect patient data.

6.4 Software

Respironics Encore® Pro Data Management software for reading compliance data and setting up a prescription via a SmartCard.

6.5 Humidifiers

The device works with the following humidifiers:

- M Series Heated Humidifier
- M Series Pass-over Humidifier

The humidifiers may reduce nasal dryness and irritation by adding moisture (and heat, if applicable) to the airflow. Always refer to the instructions enclosed with the humidifier being used.

6.6 Adding Supplemental Oxygen

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

6.6.1 Warnings

- The oxygen supply must comply with local regulations for oxygen use.
- When using oxygen with this system, a Respironics Pressure Valve (Part number 302418) must be placed in-line with the patient circuit.
- Oxygen should be administered only on the order of a physician.
- Supplemental oxygen should not be added to the breathing circuit by placing the source where the gas will be entrained through the inlet filter on the rear of the device.
- Continuous patient monitoring is recommended while administering oxygen. Patient monitoring should consist of, at a minimum, patient observation and pulse oximetry. Arterial blood gas measurements should be used when necessary.
- 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.
- 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.
- 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.

6.6.2 Adding Supplemental Oxygen

The delivered oxygen concentration varies with changes in flow in the circuit. The following may have an impact on oxygen concentration:

- Pressure settings
- Respiratory rate
- Circuit leak rate
- Oxygen flow rate

To add oxygen to the circuit, the oxygen supply must comply with the local regulations for medical oxygen. The oxygen flow into the oxygen valve cannot exceed 15 LPM and the pressure cannot exceed 50 psi.

Chapter 7: Cleaning and Maintenance

This chapter describes how to clean the device and its filters.

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.

7.1.1 Cleaning and Disinfection for Multiple Users

Warning: *If you are using the device on multiple users, discard and replace the bacteria filter each time the device is used on a different person.*

If you are using the device on multiple users, complete the following steps to clean and disinfect the device before each new user.

a. Unplug the device before disinfecting.

b. Disinfect the outside of the device only. Use a cloth with one of the following cleaning agents to clean the exterior of the device:
   - Hydrogen Peroxide, 3%
   - 100% Isopropyl Alchohol
   - Vinegar, 5% acidity
   - Water
   - Chlorine bleach, household, 5.25% Sodium Hypochloride, 1 to 5 part reduction with water.

c. Allow the device to dry completely before plugging in the power cord.

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 the filter(s) from the enclosure by gently squeezing the filter in the center and pulling it away from the device, as shown in Figure 7–1.

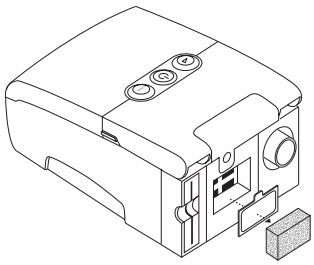


Figure 7–1 Removing the Filters

3. Examine the filter(s) 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 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.

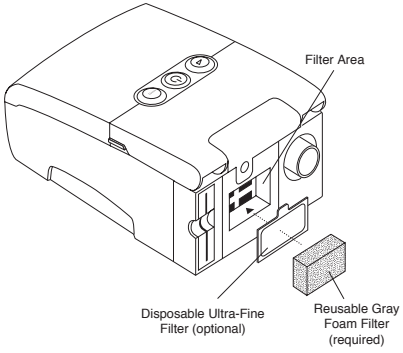


FIGURE 7–2 REINSTALLING THE FILTERS

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 MAINTENANCE

Warning: *Periodically inspect electrical cords and cables for damage or signs of wear.*

See the device's service manual for recommended periodic maintenance.

Chapter 8: Specifications

Environmental

	Operating	Storage
Temperature	41° F (5° C) to 95° F (35° C)	-4° F (-20° C) to 140° F (60° C)
Relative Humidity	15 to 95% (non-condensing)	15 to 95% (non-condensing)
Atmospheric Pressure	77 to 101kPa (0 - 7500 ft)	N/A

Physical

Dimensions:	7.5” L x 5.0” W x 3.125” H (19 x 12.7 x 7.9 cm)
Weight:	Approximately 2.2 lbs (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: (Reorder number 1015642): 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 H_2O (in 0.5 cm H_2O increments)

Pressure Stability:
<10.0 cm H_2O (±0.5 cm H_2O)
≥10.0 to 20.0 cm H_2O (±1.0 cm H_2O)
Measured in accordance with EN ISO 17510-1 @ 1/3, 2/3, and Pmax with BPM set to 10, 15, and 20 BPM @ 20° C (±5° C), 50% RH (±5%), and an atmospheric pressure of 101.54 kPascals.

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 @ 23° C (±2° C), 50% RH (±5%), and an atmospheric pressure of 101.54 kPascals.

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 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 emissions CISPR 11	Class B	The 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) 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 (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	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical hospital or home environment.
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

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

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:

1001 Murry Ridge Lane

Murrysville, Pennsylvania 15668-8550

1-724-387-4000