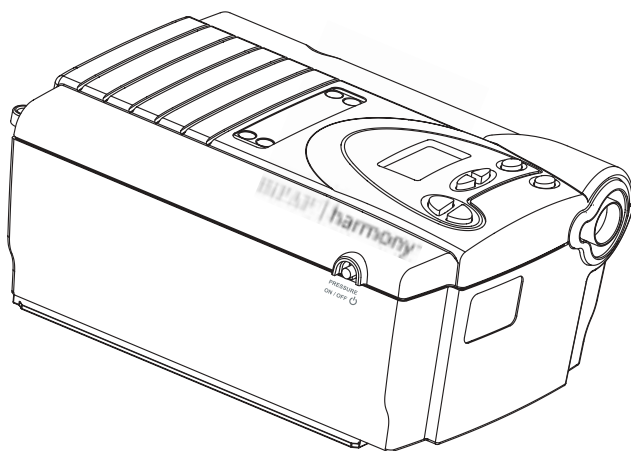


BiPAP® | harmony®



User Manual



BiPAP systems are the subject of one or more patents: U.S. Patents #5148802, #5239995, #531937, #5433193; Canadian Patent #2, 024,477; European Patent #EP0425092; German Patent #6902161681.5-08; and other pending U.S. and foreign patents. BiPAP, Harmony, Encore and SmartCard are registered trademarks of Respironics, Inc.

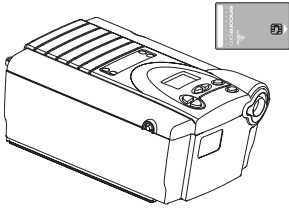
TABLE OF CONTENTS

CHAPTER 1: PACKAGE CONTENTS	4
CHAPTER 2: WARNINGS AND CAUTIONS	5
2.1 WARNINGS	5
2.2 CAUTIONS	6
2.3 INTENDED USE	6
2.4 CONTRAINDICATIONS	7
2.5 PRECAUTIONS	7
2.6 INDUSTRY CANADA NOTICE	8
CHAPTER 3: INTRODUCTION TO THE HARMONY	9
3.1 DEFINITIONS	9
3.2 WHAT IS THE HARMONY?	10
3.2 WHAT IS THE HARMONY?	11
3.3 SYMBOLS	12
3.4 HOW TO CONTACT RESPIRONICS	12
CHAPTER 4: HARMONY CONTROLS AND	
DISPLAY FEATURES	13
4.1 PRESSURE ON/OFF BUTTON	13
4.2 HARMONY CONTROL PANEL	13
4.2.1 CONTROL KEYS	14
4.2.2 ALARM AND POWER INDICATORS	15
4.2.3 DISPLAY SCREEN	15
4.2.4 BREATHING CIRCUIT CONNECTION	18
4.2.5 REAR PANEL	18
CHAPTER 5: SETTING UP THE HARMONY	20
5.1 INSTALLING THE AIR FILTERS	20
5.2 WHERE TO PLACE THE HARMONY	21
5.3 CONNECTING THE BREATHING CIRCUIT	21
5.4 COMPLETE HARMONY SETUP	23
5.5 PLUGGING THE HARMONY IN	24
5.5.1 USING AC POWER	24
5.5.2 USING DC POWER	24
CHAPTER 6: OPERATING THE HARMONY	26
6.1 STARTING THE HARMONY	26
6.2 CHANGING THE DEVICE SETTINGS	28
6.2.1 CHANGING THE HUMIDIFIER SETTING	29
6.2.2 NAVIGATING THE USER DISPLAY SCREENS	30
6.2.2.1 CHANGING THE FLEX SETTING	31
6.2.2.2 CHANGING THE RISE TIME SETTING	31
6.2.2.3 CHANGING THE RAMP STARTING PRESSURE	32
6.2.2.4 CHANGING THE LED BACKLIGHT SETTING	33

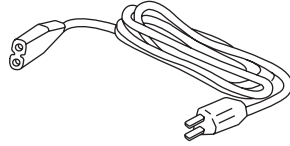
CHAPTER 7: HARMONY ALARMS	34
7.1 INTRODUCTION TO ALARMS	34
7.2 WHAT TO DO WHEN AN ALARM OCCURS	35
7.3 ALARM TABLES	37
7.3.2 MEDIUM PRIORITY ALARMS	38
7.3.3 LOW PRIORITY ALARMS	38
CHAPTER 8: TROUBLESHOOTING	39
CHAPTER 9: CLEANING AND MAINTENANCE	41
9.1 CLEANING THE HARMONY	41
9.2 CLEANING OR REPLACING THE INLET FILTERS	41
CHAPTER 10: ACCESSORIES	44
10.1 ADDING A HUMIDIFIER	44
10.2 ADDING OXYGEN TO THE HARMONY	44
CHAPTER 11: SPECIFICATIONS	45
ENVIRONMENTAL	45
PHYSICAL	45
ELECTRICAL	45
PRESSURE	46
CONTROL ACCURACY	46
INDEX	47

CHAPTER 1: PACKAGE CONTENTS

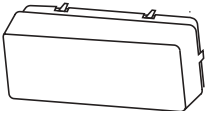
Your BiPAP Harmony should include the following items. If any of these items are missing, contact your home care provider.



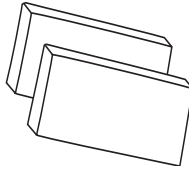
BiPAP Harmony with
Encore[®] Pro SmartCard[®]



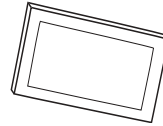
Power Cord



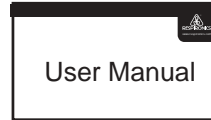
Filter Cap



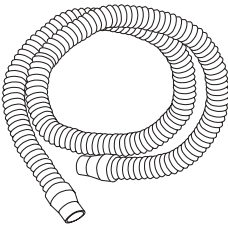
Pollen Filters



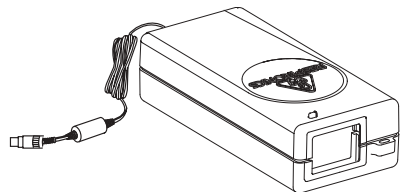
Ultrafine Filter



User Manual



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



External AC Power Supply

CHAPTER 2: WARNINGS AND CAUTIONS

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

CAUTION: Indicates the possibility of damage to the device.

NOTE: Places emphasis on an operating characteristic.

2.1 WARNINGS

- This manual serves as a reference. The instructions in this manual are not intended to supersede the instructions of your health care provider.
- You should read and understand this entire manual before using the Harmony.
- The Harmony is not intended to provide your total ventilatory requirement.
- The prescription must only be adjusted by a trained home care provider.
- Use only the breathing circuit provided by your home care provider.
- When using a breathing circuit that contains a mask with an integrated exhalation port or a circuit with a separate exhalation device, do not tape, seal, or otherwise block the vent openings. Doing so could result in suffocation.
- If oxygen is used with the Harmony, the oxygen flow must be turned off when the Harmony is not in use.
- Oxygen supports combustion. Oxygen should not be used while smoking or in the presence of an open flame.
- Do not use the Harmony in the presence of flammable liquids or gases. Do not clean the Harmony with flammable fluids.
- Do not use the Harmony if the room temperature is above 95° F (35°C). If the device is used at room temperatures above 95° F, the temperature of the airflow may exceed 106° F (41°C), which could cause irritation to your airway.
- Do not operate the Harmony in direct sunlight or near a heating appliance because these conditions can increase the temperature of the air coming out of the Harmony.
- When the Harmony is used with a humidifier, position the humidifier so that the water level in the humidifier is lower than you and the humidifier is on the same level or lower than the Harmony.

-
- If you detect any unexplained changes in the performance of the Harmony, if the device is dropped or mishandled, or if the enclosure is broken, seek the assistance of your home care provider.
 - If water is spilled into the enclosure, discontinue use of the Harmony and remove the power cord. Pour out the excess liquid and allow the unit to dry out. If the device does not function properly, contact your home care provider.
 - Repairs and adjustments must be performed by Respironics - authorized service personnel only. Unauthorized service could cause injury, invalidate the warranty, or result in costly damage.
 - Periodically inspect electrical cords for damage or signs of wear.
 - To avoid electrical shock, unplug the Harmony before cleaning it.

2.2 CAUTIONS

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

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

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

2.3 INTENDED USE

The Harmony is intended to provide noninvasive ventilation in adult patients (>30 kg) for the treatment of respiratory insufficiency (a condition in which the patient can continue without ventilation for some period of time, such as overnight) or obstructive sleep apnea. This device may be used in the hospital or home.

The Harmony is intended for use with nasal masks and full-face masks as recommended by Respironics.

2.4 CONTRAINDICATIONS

The Harmony should not be used if you have severe respiratory failure without a spontaneous respiratory drive.

If any of the following conditions apply to you, consult your physician before using the Harmony:

- Inability to maintain a patent airway or adequately clear secretions
- At risk for aspiration of gastric contents
- Diagnosed with acute sinusitis or otitis media
- Allergy or hypersensitive to the mask materials where the risk from allergic reaction outweighs the benefit of ventilatory assistance
- Epistaxis, causing pulmonary aspiration of blood
- Hypotension

2.5 PRECAUTIONS

- Immediately report any unusual chest discomfort, shortness of breath, or severe headache.
- If skin irritation or breakdown develops from the use of the mask, refer to the mask instructions for appropriate action.
- The following are potential side effects of noninvasive positive pressure therapy:
 - Ear discomfort
 - Conjunctivitis
 - Skin abrasions due to noninvasive interfaces
 - Gastric distention (aerophagia)

2.6 INDUSTRY CANADA NOTICE

NOTICE: The Industry Canada Label identifies certified equipment. This certification means that the equipment meets telecommunications network protective, operational, and safety requirements as prescribed in the appropriate Terminal Equipment Technical Requirements documents. The Department does not guarantee the equipment will operate to the user's satisfaction.

Before installing this equipment, users should make sure that it is permissible to be connected to the facilities of the local telecommunications company. The equipment must also be installed using an acceptable method of connection. The customer should be aware that compliance with the above conditions may not prevent degradation of service in some situations.

Repairs to certified equipment should be coordinated by a representative designated by the supplier. Any repairs or alterations made by the user to this equipment, or equipment malfunctions, may give the telecommunications company cause to request the user to disconnect the equipment.

Users should ensure for their own protection that the electrical ground connections of the power utility, telephone lines and internal metallic water pipe system, if present, are connected together. The precaution may be particularly important in rural areas.

CAUTION: Users should not attempt to make such connections themselves, but should contact the appropriate electric inspection authority, or electrician, as appropriate.

Ringer Equivalence Number (REN): The REN assigned to each terminal device provides an indication of the maximum number of terminals allowed to be connected to a telephone interface. The termination on an interface may consist of any combination of devices subject only to the requirement that the sum of the Ringer Equivalence Numbers of all the devices does not exceed 5.

CHAPTER 3: INTRODUCTION TO THE HARMONY

This chapter contains the following information:

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

3.1 DEFINITIONS

The following terms appear throughout this manual:

Apnea	A condition marked by the cessation of spontaneous breathing.
CPAP	Continuous Positive Airway Pressure
EPAP	Expiratory Positive Airway Pressure
High Priority Alarm	Alarm signal indicating a condition that requires immediate attention
IPAP	Inspiratory Positive Airway Pressure
Low Priority Alarm	Signal indicating an information message
Medium Priority Alarm	Alarm signal indicating a condition that requires operator awareness
Operate State	The state of the Harmony device when the unit and the blower are both on.
Standby State	The state of the Harmony device when the unit is on, but the blower is off.
OSA	Obstructive Sleep Apnea
Patient Disconnect Alarm	This event occurs when the device detects a larger circuit leak. The event terminates when the circuit leak returns to normal limits or when initiated by the user.
Ramp	A feature that may increase patient comfort when therapy is started. The Harmony IPAP starts at the EPAP level and is increased gradually (breath by breath over several breaths) until the IPAP prescription pressure is reached.

Rise Time	The time it takes for the Harmony to change from EPAP to IPAP. You can adjust this time for your comfort.
RR	Respiratory Rate
Spontaneous (S)	A bi-level mode which responds to both your inhalation and exhalation by increasing pressure when you start to inhale and decreasing pressure when you start to exhale. There is no automatic delivery of a breath should you not inhale.
Spontaneous / Timed (S/T)	A bi-level mode which responds to both your inhalation and exhalation by increasing pressure when you start to inhale and decreasing pressure when you start to exhale. If you do not start inhaling within a set time, the Harmony automatically starts inhalation. When the Harmony starts inhalation, it controls the time of inhalation and automatically decreases the pressure for exhalation within a set time.

3.2 WHAT IS THE HARMONY?

The Harmony, shown in Figure 3–1, supplies air pressure through a breathing circuit.

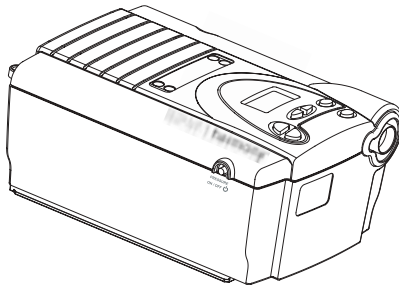


Figure 3–1 The Harmony

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

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

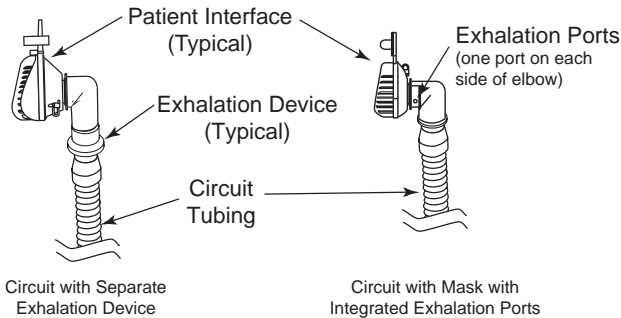


Figure 3–2 Typical Breathing Circuits








NOTE: The exhalation port may be part of the mask or may be part of a separate exhalation device.

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

The Harmony can operate on AC or DC power. The DC power option is not intended as a battery backup. When DC power is obtained from a vehicle battery, the Harmony should not be used while the vehicle's engine is running.

3.3 SYMBOLS

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

Symbol	Meaning
	Attention, consult accompanying documents
	DC Power
	Type BF Applied Part
	Class II (Double Insulated)
	European CE Declaration of Conformity
	Notified Body Approval for Standards Compliance
	Canadian/US Certification

3.4 HOW TO CONTACT RESPIRONICS

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



CHAPTER 4: HARMONY CONTROLS AND DISPLAY FEATURES

Figure 4–1 shows the location of the Harmony’s control panel, Pressure On/Off button, and breathing circuit connection.

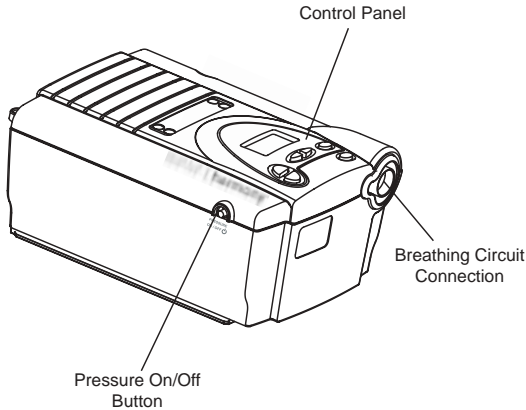


Figure 4–1 Harmony Front and Top

4.1 PRESSURE ON/OFF BUTTON

The Harmony’s **Pressure On/Off** button, located on the side of the unit, starts and stops the unit’s airflow. Press the button in to turn the airflow on. This puts the Harmony in the **Operate** state. Depress the button to turn the airflow off and put the Harmony in the **Standby** state.

When the Harmony is in Standby, any ramp in progress is terminated, the alarms are reset (except for the System Errors alarm), and the humidifier is turned off.

The **Pressure On/Off** button is independent of the display screen.

4.2 HARMONY CONTROL PANEL

The control panel contains the following control keys and indicators.

4.2.1 CONTROL KEYS

The control keys on the control panel are shown in Figure 4–2.

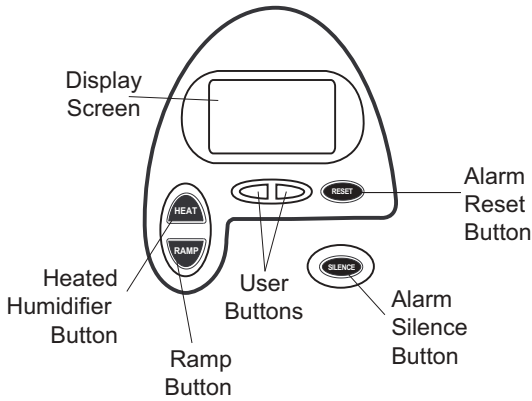


Figure 4–2 Harmony Control Panel

HEAT

When the optional REMstar or H2 heated humidifier is prescribed, this button controls the humidifier's output. Follow the instructions provided with the humidifier. When a humidifier is not in use, this button can be used to adjust the parameters shown in the user menu screens.

RAMP

When the airflow is turned on, this button lowers the airflow pressure, allowing you to fall asleep more easily. When the airflow is turned off, this button can be used to adjust the parameters shown in the user menu screens.

USER

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

SILENCE

This button silences the audible portion of an alarm for one minute.

RESET

This button allows you to clear an alarm and reset the device for alarm detection.

NOTE: If the display backlight is off, the first press of a control key turns the backlight on and does nothing else. The normal key action is suppressed until you press the key a second time. The instructions in this manual assume that the backlight is already on.

4.2.2 ALARM AND POWER INDICATORS

Figure 4–3 shows the Harmony’s alarm and power indicators.

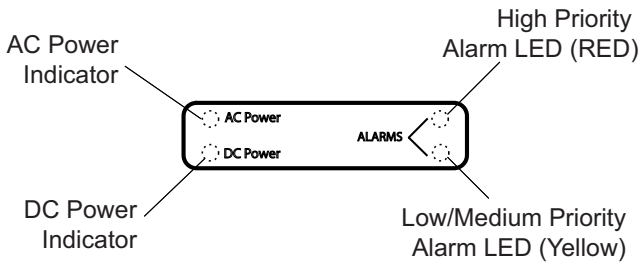


Figure 4–3 Harmony Alarm and Power Indicators

AC Power Indicator	This green LED lights up when the Harmony is connected to AC Power.
DC Power Indicator	This green LED lights up when the Harmony is connected to DC power.
Red Alarm Indicator	The red LED lights up when a high priority alarm occurs.
Yellow Alarm Indicator	This yellow LED lights up when a medium or low priority alarm occurs.

NOTE: All LED indicators turn on during the System Self Test screen.

4.2.3 DISPLAY SCREEN

The display shows you the current pressure control settings and displays alarm messages. A backlight activates when the **User** buttons are pressed and remains on until there are no keystrokes for one minute.

Figure 4–4 shows the Harmony display screen.

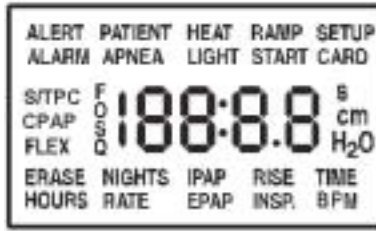


Figure 4–4 Harmony Display Screen

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

ALARM	Indicates that the device requires user attention as indicated on the screen.
ALERT	Indicates that the device requires user attention as indicated on the screen. Not used for Harmony devices.
APNEA	Indicates that an apnea alarm has occurred or its setting is being displayed.
BPM	Indicates that a breath rate setting is being displayed.
CARD	Indicates that a SmartCard is inserted and detected.
CPAP	Indicates that the Harmony is in the Continuous Positive Airway Pressure (CPAP) mode.
cm H₂O	Indicates that the alphanumeric digits are displaying a pressure valve.
EPAP	Indicates that an EPAP pressure setting is being displayed.
ERASE	Indicates that the user may clear the compliance data.
FLEX	Indicates that a C-Flex or Bi-Flex comfort setting is being displayed.
FOSQ	Indicates that the FOSQ test is active. Not used for Harmony devices.

HEAT	Indicates that the humidifier is turned on and/or its setting is displayed.
HOURS	Indicates that the Therapy Hour Meter is being displayed.
INSP. TIME	Indicates that the inspiratory time setting is being displayed.
IPAP	Indicates that an IPAP pressure setting is being displayed.
LIGHT	Indicates that the keypad LED backlight setting is being displayed or is active.
NIGHTS	Indicates that the session counter is being displayed. Not used for Harmony devices.
PATIENT	Indicates that a Patient Disconnect alarm is active or its setting is being displayed.
PC	Indicates the Pressure Control mode. Not used for Harmony devices.
RAMP	Indicates that the Ramp function is in progress, or during Provider mode, that the Ramp length is being displayed.
RAMP START	Indicates that the Ramp Starting Pressure is being displayed.
RATE	Used in conjunction with the BPM.
RISE TIME	Indicates that a rise time setting is being displayed.
S	Indicates that the alphanumeric digits are displaying a time value.
SETUP	Indicates that the device is in Provider mode and not in User or Diagnostic mode.
S/T	Indicates that the Harmony is in the Spontaneous mode if only the S appears, or the Spontaneous/Timed mode if the S/T appears.

4.2.4 BREATHING CIRCUIT CONNECTION

Figure 4-5 shows where the circuit tubing connects to the Harmony.

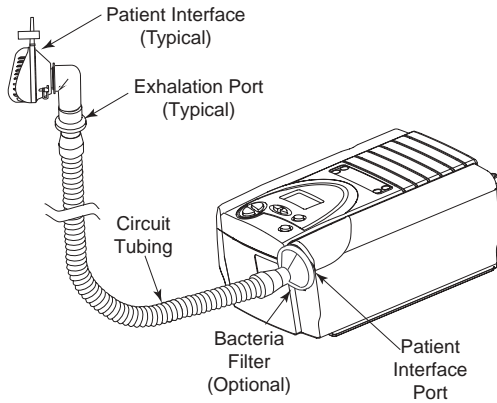


Figure 4-5 Breathing Circuit Connection

4.2.5 REAR PANEL

Figure 4-6 shows the Harmony's rear panel.

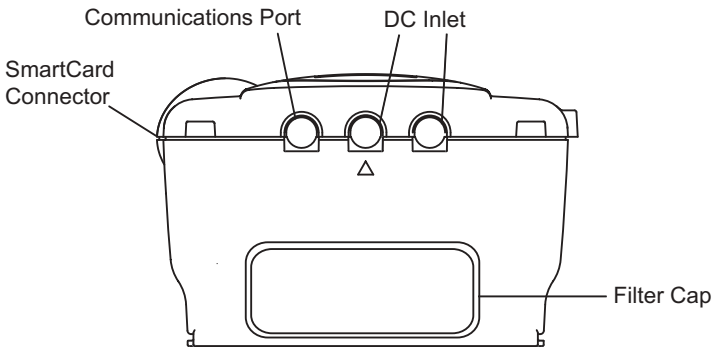


Figure 4-6 Rear Panel

NOTE: The SmartCard Connector is located on the side of the Harmony.

The rear panel contains the following:

RS-232 Communications Connector	This connector accepts the Respirationics Communications cable for computer and external modem communication.
DC Inlets	There are two DC inlets on the rear panel, one for connecting the external AC power supply and another for battery operation using an external DC power supply.
Filter Cap	The filter cap can be removed to inspect the inlet air filters.

CHAPTER 5: SETTING UP THE HARMONY

This chapter provides instructions on how to:

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

5.1 INSTALLING THE AIR FILTERS

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

The Harmony uses a gray foam filter that is washable and reusable, and an optional white, ultra-fine filter that is disposable. One filter of each kind is supplied with the Harmony.

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

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

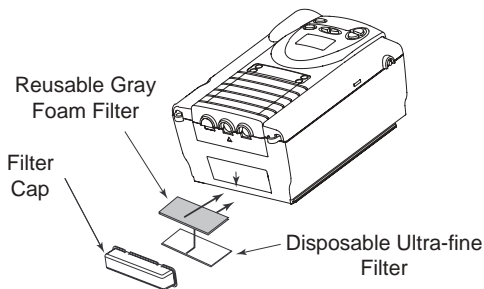


Figure 5–1 Installing the Filters

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

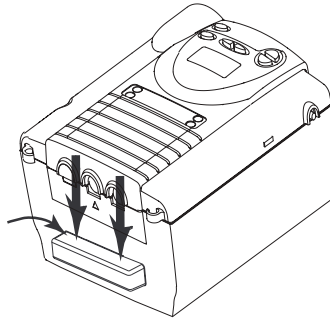


Figure 5–2 Attaching the Filter Cap

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

See Chapter 8 to clean or replace the filters.

5.2 WHERE TO PLACE THE HARMONY

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

If you are using a humidifier, place the humidifier and unit on a placemat or other waterproof material to protect your furniture from moisture. Position the humidifier so the water level is lower than you and the humidifier is on the same level or lower than the Harmony. See the humidifier instructions for complete setup information.

5.3 CONNECTING THE BREATHING CIRCUIT

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

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

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

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

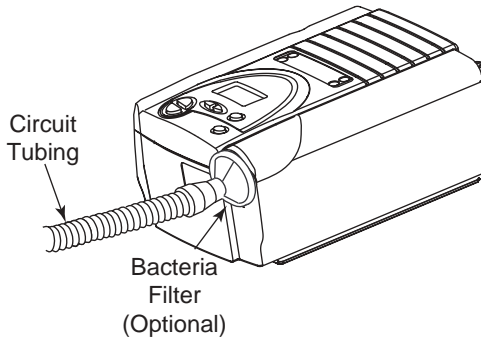


Figure 5–3 Connecting the Tubing to the Outlet

2. Connect the open end of the circuit tubing to the exhalation port as shown in Figure 5–4. If you are using a mask that has the exhalation port built into the mask, connect the tubing directly to the mask and skip to Step 4.



Figure 5–4 Connecting the Tubing to the Exhalation Port

WARNING: The exhalation device or exhalation port is designed to exhaust CO₂ from the patient circuit. Do not block or seal the ports on the exhalation device.

3. Connect the exhalation port to the mask connector as shown in Figure 5–5.

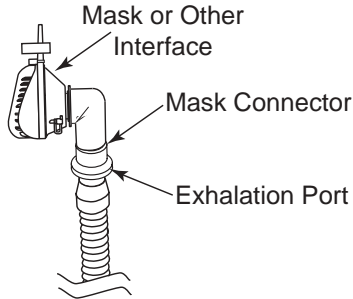


Figure 5–5 Connecting the Mask

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

5.4 COMPLETE HARMONY SETUP

Figure 5–6 shows the completed breathing circuit setup for the Harmony.

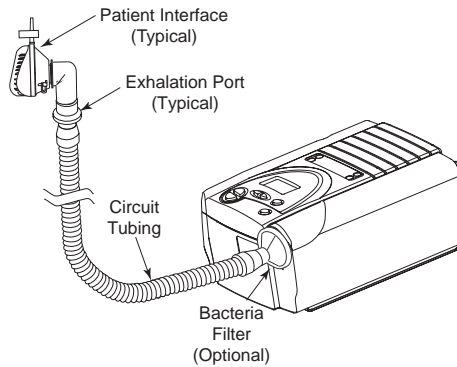


Figure 5–6 Complete Harmony Breathing Circuit

5.5 PLUGGING THE HARMONY IN

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

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

5.5.1 USING AC POWER

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

1. Plug the pronged end of the AC power supply's cord into an electrical outlet.

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

2. Leaving a small amount of slack in the cord, connect the cord on the other side of the power supply to the AC inlet on the Harmony, as shown in Figure 5–7.

NOTE: The external AC power supply features an AC cord retainer to provide strain relief for the AC power cord.

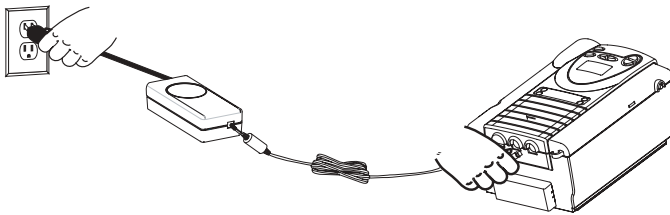


Figure 5–7 Plugging in the AC Power Supply

5.5.2 USING DC POWER

Complete the following steps to operate the Harmony using DC power:

CAUTION: Only use a Respironics-supplied DC boost converter.

1. Plug the DC boost converter into the rear of the Harmony, as shown in Figure 5–8.
2. Leaving a small amount of slack in the cord, press the cord into the DC cord retainer.
3. Connect the DC cord to the appropriate DC source. See the instructions that came with the DC boost converter for proper DC connections.

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

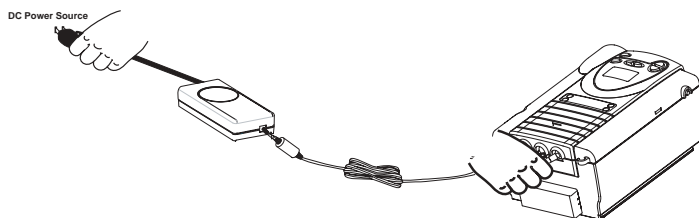


Figure 5–8 Plugging in the DC Boost Converter

CHAPTER 6: OPERATING THE HARMONY

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

6.1 STARTING THE HARMONY

1. Plug the Harmony in to power up the unit. The Harmony sounds a confirmation alarm and the keypad buttons light up.

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

Several screens appear initially during this step:

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



Figure 6–1 Self Test Screen

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

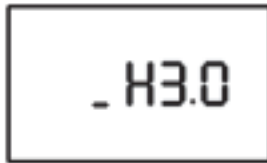


Figure 6–2 Software Version Screen

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



Figure 6-3 Blower Hours Screen

NOTE: With the exception of the **Pressure On/Off** button, the keypad is inactive during these first three screens. Each of these first three screens appears for approximately 1-3 seconds.

- d. The next screen that appears is the Standby screen, shown in Figure 6-4. This indicates that the Harmony is in the Standby state.

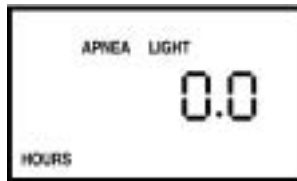


Figure 6-4 Standby Screen

2. Press the **Pressure On/Off** button to put the unit into the Operate state. The Monitoring screen, shown in Figure 6-5, appears.

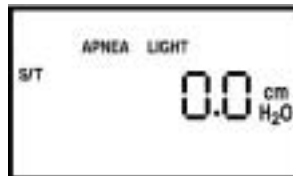


Figure 6-5 Monitoring Screen

The Monitoring screen displays the actual measured pressure along with the appropriate icons.

3. Put on your mask assembly when the air starts to flow.
4. Make sure that no air is leaking from your mask into your eyes. If it is, adjust the mask and headgear until air stops leaking into your eyes. See the instructions that came with your mask for more information.
5. If you are using the Harmony while sleeping, try placing the tubing from the Harmony over your headboard. This may reduce tension on the mask.

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

6. Relax. Take normal, relaxed breaths through your nose.

NOTE: If you are having trouble with your mask, see Chapter 7, *Troubleshooting*, for some suggestions.

6.2 CHANGING THE DEVICE SETTINGS

You can view the following settings on the Harmony display screen:

- Measured pressure
- Mode
- SmartCard
- Breath Rate
- Patient alarms

Additionally, you can view and modify the following settings using the display screens:

- Humidifier
- Flex
- Rise Time
- Ramp start pressure
- LED backlight

NOTE: If the display backlight is off, the first press of any key turns the backlight on. Normal key function is suppressed until the key is pressed a second time.

NOTE: When changing any setting (except for the Ramp Start Pressure setting), once a maximum setting is reached, the setting rolls back over to the minimum setting, and likewise, once a minimum setting is reached, it rolls back over to the maximum setting provided.

For example, the minimum Flex setting is **1** and the maximum is **3**. Once the Flex setting is increased to **3**, if you press the **Heat** key again, the setting will go back at **1**. Or, once the Flex setting is decreased to **1**, if you press the **Ramp** key again, the setting will go back to **3**.

6.2.1 CHANGING THE HUMIDIFIER SETTING

If you are using an optional REMstar or H2 heated humidifier with your Harmony, you can adjust the humidifier heat setting by completing the following steps:

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

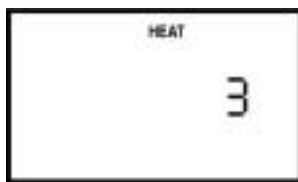


Figure 6–6 Humidifier Setting Screen

2. Press the **Heat** key to increase the humidifier setting, or press the **Ramp** key to decrease the setting. You can adjust the setting from **1** to **5**. The change takes effect immediately as you adjust the setting.

For additional information on using a humidifier with the Harmony, see Chapter 9.

6.2.2 NAVIGATING THE USER DISPLAY SCREENS

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

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

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

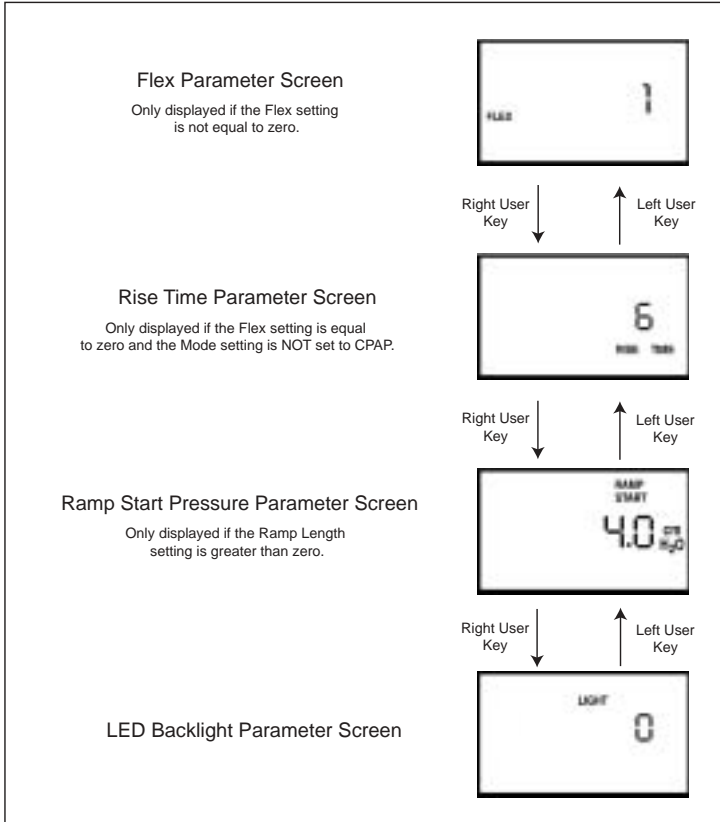


Figure 6–7 Navigating the User Display Screens

6.2.2.1 CHANGING THE FLEX SETTING

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

NOTE: The Flex feature is not prescribed for all users. If the screen shown in Figure 6–8 does not appear on your display, you cannot adjust this setting.

To change the Flex setting, complete the following steps:

1. From the Monitoring screen, press the **Right User** key. The Flex Setting screen appears, as shown in Figure 6–8.

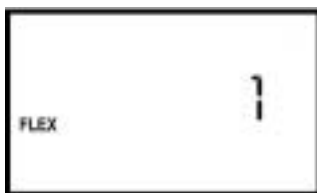


Figure 6–8 Flex Setting Screen

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

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

6.2.2.2 CHANGING THE RISE TIME SETTING

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

NOTE: The rise time feature is not prescribed for all users. If the screen shown in Figure 6–9 does not display, you cannot adjust this setting.

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

1. From the Monitoring screen, press the **Right User** key. The Rise Time Setting screen appears, as shown in Figure 6–9.



Figure 6–9 Rise Time Setting Screen

2. Increase or decrease the rise time setting from **1** to **6** by pressing the **Heat** or **Ramp** key until you find the right setting. A setting of **1** is the fastest rise time, while **6** is the slowest.

NOTE: When the Harmony is in Bi-Flex mode, it will use a rise time of 3 regardless of the chosen setting.

6.2.2.3 CHANGING THE RAMP STARTING PRESSURE

The Harmony is equipped with an optional ramp feature that your home care provider can turn on or off. This feature will reduce the pressure and then gradually increase (ramp) the pressure to the prescription pressure setting so you can fall asleep more comfortably.

NOTE: The ramp feature is not prescribed for all users. If the screen shown in Figure 6–10 does not appear on your display, you cannot adjust this setting.

If your physician prescribed ramp for you, complete the following steps:

1. From the Monitoring screen, press the **Right User** key until the Ramp Start Setting screen appears, as shown in Figure 6–10.



Figure 6-10 Ramp Start Setting Screen

2. Press the **Heat** or **Ramp** key to increase or decrease the ramp starting pressure as needed. You can adjust the setting from 4.0 cm H₂O to the EPAP or CPAP setting.

6.2.2.4 CHANGING THE LED BACKLIGHT SETTING

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

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

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

1. From the Monitoring screen, press the **Right User** button until the LED Backlight Setting screen appears, as shown in Figure 6-11.

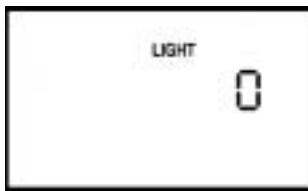


Figure 6-11 LED Backlight Setting Screen

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

CHAPTER 7: HARMONY ALARMS

This chapter describes the Harmony alarms and what you should do if an alarm occurs.

7.1 INTRODUCTION TO ALARMS

The Harmony provides three alarm levels: high, medium, and low priority.

- High Priority** These alarms require immediate response. The alarm signal consists of a red LED indicator and a sound that is either continuous or a pattern of three beeps, a pause, and then two more beeps. The display has the message **ALARM** at the top of the screen.
- Medium Priority** These alarms require prompt response. The alarm signal consists of a yellow LED and a sound that repeats a pattern of three beeps. The display has the message **ALARM** at the top of the screen.
- Low Priority** These alarms require your awareness. The alarm signal consists of a yellow LED and a sound that repeats a pattern of two beeps. The display has the message **ALARM** at the top of the screen.

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

The alarm LED indicators are located on the right side of the keypad, as shown in Figure 7–1.

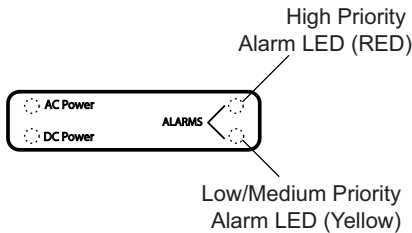


Figure 7–1 Alarm LED Indicators

In addition to the alarm LED indicators, the keypad also contains alarm **Reset** and **Silence** buttons, as shown in Figure 7-2.

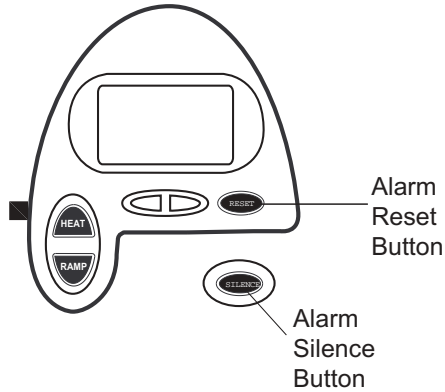


Figure 7-2 Alarm Buttons

7.2 WHAT TO DO WHEN AN ALARM OCCURS

The following example applies to most alarm conditions. Follow these steps unless otherwise directed by the alarm tables that follow.

1. Look at the alarm indicators and listen to the alarm sound.

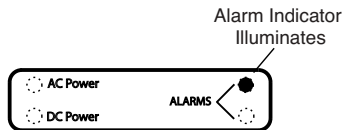


Figure 7-3 Alarm Indicator Illuminates

Note the color of the LED and whether the LED is solid or flashing.

2. Look at the display for text.



Figure 7–4 Sample Alarm Display

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

3. Press the **Silence** key to temporarily silence the alarm (for one minute).
4. Look up the alarm in the alarm tables in Section 7.3 and perform the action specified.
5. Press the **Reset** key to clear the alarm.

The alarm is cleared and the display returns to the screen that was showing at the time of the alarm.

7.3 ALARM TABLES

The following tables summarize the high priority, medium priority, and low priority alarms.

Alarm LED	Alarm Sound	Display Message	Harmony Action	Possible Cause	Your Action
Red Flash	● ● ● ● ●	ALARM and PATIENT words flash	Operates	Breathing circuit is disconnected or has a large leak.	Reconnect the circuit or fix the leak.
Red Flash	● ● ● ● ●	ALARM and APNEA words flash	Operates	An apnea event occurred during therapy.	Report the alarm to your home care provider.
Red Flash	● ● ● ● ● or [REDACTED]	ALARM flashes and an error code displays	Shuts down. Blower cannot be restarted.	Harmony failure	Cannot be silenced. Remove power from the unit and contact your home care provider.
Red Flash	● ● ● ● ●	ALARM and cmH ₂ O flash	Operates	Excessive leak or blockage; malfunctioning unit.	Check for the following: dirty inlet filters, blocked air intake, excessive leak in the circuit. If the alarm continues, call your home care provider.
Red Solid	[REDACTED]	Blank screen	Shuts down	Battery is discharged. -or- Power was lost while the unit was providing therapy.	Remove DC power source from the unit, replace the battery, restore power to the unit; or seek a reliable AC power source. Press the Pressure On/Off button to silence the alarm, turn off the red LED, and restore power.

7.3.2 MEDIUM PRIORITY ALARMS

Alarm LED	Alarm Sound	Display Message	Harmony Action	Possible Cause	Your Action
Yellow Flash	● ● ●	DC Power LED Flashes	Operates	Battery nearly discharged.	Replace the battery.

7.3.3 LOW PRIORITY ALARMS

Alarm LED	Alarm Sound	Display Message	Harmony Action	Possible Cause	Your Action
Yellow Solid	● ●	CARD flashes and card error code (Cxx) displays	Operates	There is a problem with the SmartCard inserted in the SmartCard connectivity slot.	Remove the SmartCard from the device and contact your home care provider.
Yellow Solid	● ●	ALARM, CARD, and cmH ₂ O flash and LCD light is on	Operates	The SmartCard storage capacity is reached.	Remove the SmartCard from the device and contact your home care provider.
Yellow Solid	● ●	DC power LED flashes Blank screen	Operates	Harmony lost AC power and is now operating on DC power. At start-up only, alarm notifies you that a battery is being used to provide power.	Check AC power and seek reliable power source. Provide AC power if you do not want to use a battery; otherwise, no action needed.

CHAPTER 8: TROUBLESHOOTING

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

Problem	Why It Happened	What To Do
Does not operate when you press the Pressure On/Off button.	<p>If the power LED is off, no power at the outlet or the Harmony is unplugged.</p> <p>If the power LED is on, problems in the Harmony.</p>	Check the outlet power and verify that the Harmony is plugged in.
The air out of the mask is much warmer than usual.	<p>The inlet filters may be dirty.</p> <p>The Harmony may be operating in direct sunlight or near a heater.</p>	Clean or replace the inlet air filters as described in Chapter 9. If the Harmony is in direct sunlight or near a heater, move it. If the problem persists, contact your home care provider.
The mask feels uncomfortable to wear.	This could be due to improper headgear adjustment or improper mask fitting.	Check the headgear adjustment as described in the headgear instructions. Contact your home care provider for a refitting or a different size mask.
There is significant air leakage around the mask.	This could be due to improper headgear adjustment or improper mask fitting.	Check the headgear adjustment as described in the headgear instructions. Contact your home care provider for a refitting or a different size mask.

Problem	Why It Happened	What To Do
Redness occurs when the mask cushion comes in contact with the skin.	This could be due to improper mask fitting or improper mask cleaning.	<p>Contact your home care provider for a refitting or a different size mask.</p> <p>Be sure to rinse the mask thoroughly after cleaning to remove residue. See the mask cleaning instructions.</p>
Redness occurs when the mask cushion accessory comes in contact with the skin.	Irritation or allergic reaction to the mask material.	Use a barrier between your skin and the mask, such as 3M's Microfoam® or Squibb's Duoderm®.
Sore or dry eyes.	The mask may not be positioned correctly, or the mask is not properly fitted.	<p>Check the headgear adjustment as described in the headgear instructions.</p> <p>Contact your home care provider for a refitting or a different size mask.</p>
Runny nose.	Nasal reaction to the air flow.	Call your doctor.

CHAPTER 9: CLEANING AND MAINTENANCE

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

9.1 CLEANING THE HARMONY

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

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

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

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

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

9.2 CLEANING OR REPLACING THE INLET FILTERS

The Harmony has two removable filters at the air inlet. The gray foam filter is washable and reusable. The optional white, ultra-fine filter is disposable.

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

1. Make sure the Harmony is not operating, and disconnect the power cord from the wall outlet.
2. As shown in Figure 9–1, remove the filter cap by gently pressing down on the top panel and pulling the cap out from Harmony's body.

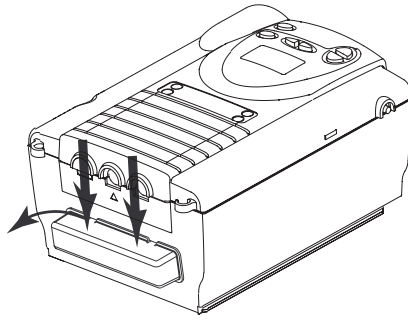


Figure 9–1 Removing the Filter

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

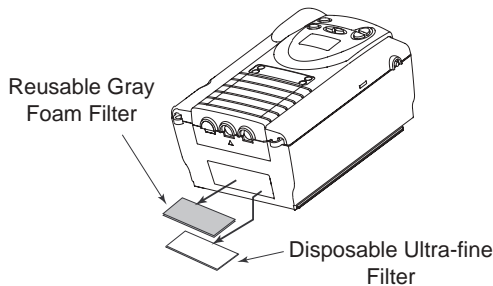


Figure 9–2 Removing the Air Filters

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

8. Replace the filter cap.

Contact your home care provider to order filters.

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

CHAPTER 10: ACCESSORIES

There are several accessories you can use with the Harmony.

10.1 ADDING A HUMIDIFIER

The REMstar Heated Humidifier, REMstar Pass-over Humidifier, and H2 Heated Humidifier are available from your home care provider. The humidifiers may reduce nasal dryness and irritation by adding moisture (and heat, if applicable) to the airflow.

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

Refer to the humidifier instructions for complete information on how to set up your humidifier.

10.2 ADDING OXYGEN TO THE HARMONY

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

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

WARNING: Oxygen supports combustion. Oxygen should not be used while smoking or in the presence of an open flame.

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

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

CHAPTER 11: SPECIFICATIONS

ENVIRONMENTAL

	Operating	Storage
Temperature	5°C to 35 °C	-20°C to 60°C
Relative Humidity	15 to 95% (non-condensing)	15 to 95% (non-condensing)
Atmospheric Pressure (5600 feet to sea level)	83 to 102kPa	

PHYSICAL

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

Weight: Approximately 4.1 lb

ELECTRICAL

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

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

AC Current: 1.25 A maximum

DC Current: 3.0 A maximum

Protection against electric shock: Class II

Degree of protection against electric shock: Type BF Applied Part

Degree of protection against harmful ingress of water:

Harmony unit:
Ordinary Equipment,
IPX0

AC Power Supply:
Ordinary Equipment,
IPX1

DC Boost Converter:
Ordinary Equipment,
IPX1

Modes of Operation:	Continuous
Electromagnetic Compatibility:	The Harmony meets the requirements of EN 60601-1-2.
Fuses:	There are no user-replaceable fuses.

PRESSURE

Output:	4 to 30 cm H ₂ O
----------------	-----------------------------

CONTROL ACCURACY

Parameter	Range	Accuracy
IPAP	4 to 30 cm H ₂ O	± 2.5 cm H ₂ O*
EPAP	4 to 25 cm H ₂ O	± 2.5 cm H ₂ O*
CPAP	4 to 20 cm H ₂ O	± 2.5 cm H ₂ O*
Breath Rate	0 to 30 BPM	Greater of ± 1 BPM or ± 10% of the setting
Timed Inspiration	0.5 to 3.0 seconds	± 10% of the setting
Ramp Duration	0 to 45 minutes	± 10% of the setting
Rise Time	1 to 6**	± 25%*

* Measured at the patient end of circuit with a Whisper Swivel II exhalation port and no patient flow. Dynamic pressure accuracy is ± 5 cm H₂O measured at the patient end of the circuit with a Whisper Swivel II and varying flow conditions.

** The range of values correspond to hundreds of milliseconds (e.g., a setting of 4 indicates a Rise Time of .4 seconds).

LIMITED WARRANTY

Respironics, Inc. warrants that the BiPAP Harmony 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 one year. 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
1-412-387-4000

Index

[P E O P L E]
[P R O D U C T S]
[P R O G R A M S]



RESPIRONICS®

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

1012892
JH 3/14/03