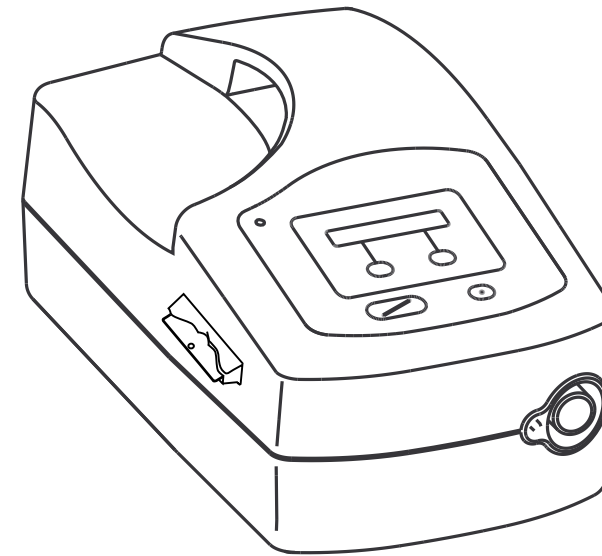


**PEOPLE
PRODUCTS
PROGRAMS**



BiPAP® Pro
Bi-level System

With Bi-Flex™

User Manual



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

RESPIRONICS®
Deutschland
Gewerbstrasse 17
82211 Herrsching Germany



1007234
LG 6/21/01



TABLE OF CONTENTS

Unpacking the System	3
Introduction	4
Warnings & Cautions	5
System Features	6
First Time Setup	8
Installing Filters	9
Power Cord	9
Device Settings	10
Comfort Control	11
Bi-Flex™ Level Setting	12
Ramp Pressure	12
Setting the Alert Tone	13
FOSQ Test	13
SmartCard™	14
Assembling the Circuit	15
Accessories	17
Adding a Humidifier	17
Using DC Power	17
Adding Oxygen	18
Carrying Case	18
Using an Ultra-fine Filter	18
Routine Use	19
Connecting the Circuit	19
Adjusting the Circuit	19
Starting Ramp	20
Turning the System Off	20
Helpful Hints	21
Screen Displays	21
Traveling With the System	23
Packing the System	23
Security Stations	23
Routine Maintenance	23
Power Cord	23
Filters	23
Cleaning	23
Reordering	24
Service	24
Total Operation Time	25
Troubleshooting	26
Specifications	29
Symbol Key	30
Warranty	31

The BiPAP Pro Bi-level device carries a two-year warranty. See the “Warranty” section of this manual for details.

For Information on Sleep Disorders, contact

**American Sleep Apnea Association
2025 Pennsylvania Ave. N.W., Suite 905
Washington, DC 20006
Telephone: 1-202-293-3650
Fax: 1-202-293-3656
<http://www.sleepapnea.org/links.html>**

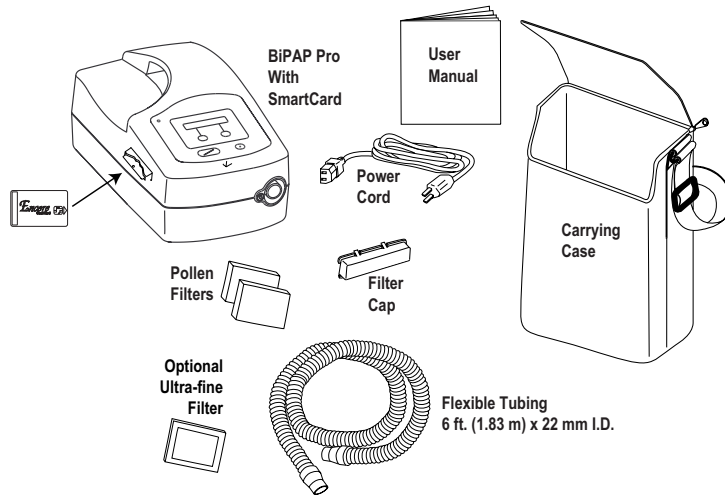
**National Sleep Foundation
729 Fifteenth Street N.W., Fourth Floor
Washington, DC 20005
<http://www.sleepfoundation.org/>**

BiPAP Pro Bi-level system is covered by one or more of the following patents: 5,148,802; 5,313,937; 5,433,193; 5,632,269; 5,803,065; 5,239,995; Re 35,295; 5,492,113; 5,551,418; 5,904,141; 5,313,937; 5,970,975; 6,029,664; 5,535,738; 5,794,615; 6,105,575; 638054 (Australia); 661575 (Australia); 698519 (Australia); 695046 (Australia); 2,024,447 (Canada); 0425092B1 (Europe); 2832812 (Japan); 2137336 (Japan); 660340 (Australia); 2,122,590 (Canada); other US and foreign patents pending. BiPAP, Bi-Flex, and Whisper Swivel are trademarks of Respiroics, Inc. BiPAP Pro With Bi-Flex is the latest edition of the Duet product line.

© Respiroics, Inc. 2001

UNPACKING THE SYSTEM

After unpacking the system, check to make sure you have everything shown here:



IMPORTANT!

If any of the above parts are missing, contact your home care provider.

Another feature is the Functional Outcomes of Sleep Questionnaire (FOSQ) "Quality of Life" test. Your doctor or home care provider may ask you to periodically complete this questionnaire and send in your answers (recorded on the Encore Data Management SmartCard). The FOSQ test is detailed in the enclosed "Sleep Apnea Solutions" brochure.

INTRODUCTION

Intended Use

The BiPAP Pro Bi-level system delivers positive airway pressure therapy for the treatment of adult Obstructive Sleep Apnea (OSA) only.

Introduction

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

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

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

IMPORTANT!

Read and understand the entire user's manual before operating this System. If you have any questions concerning the use of this system, contact your home care provider or health care professional.

Contraindications

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

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

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

WARNINGS & CAUTIONS

CAUTION!

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

WARNING!

Indicates the possibility for injury to the user or the operator.

- The instructions in this manual are not intended to supersede established medical protocols.
- This device is intended for adult use only.
- This device is not intended for life support.
- All CPAP and bi-level devices have the potential to allow rebreathing of exhaled air. To reduce this potential, observe the following:
 - Use only Respirationics circuit accessories.
 - Do not wear the mask and headgear for more than a few minutes while the device is not operating.
 - Do not block or try to seal the vent holes in the exhalation port.

As with most CPAP and bi-level devices: At low CPAP pressures, some exhaled gas (CO₂) may remain in the mask and be rebreathed.

- Do not use this device if the room temperature is warmer than 95° F (35° C). If this 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 to your airway.
- This equipment is not suitable for use in the presence of a flammable anesthetic mixture in combination with oxygen or air, or in the presence of nitrous oxide (N₂O).
- To avoid electrical shock, disconnect the power cord before cleaning. **DO NOT** immerse the BiPAP Pro in any fluids.
- Contact your doctor if symptoms of sleep apnea recur.

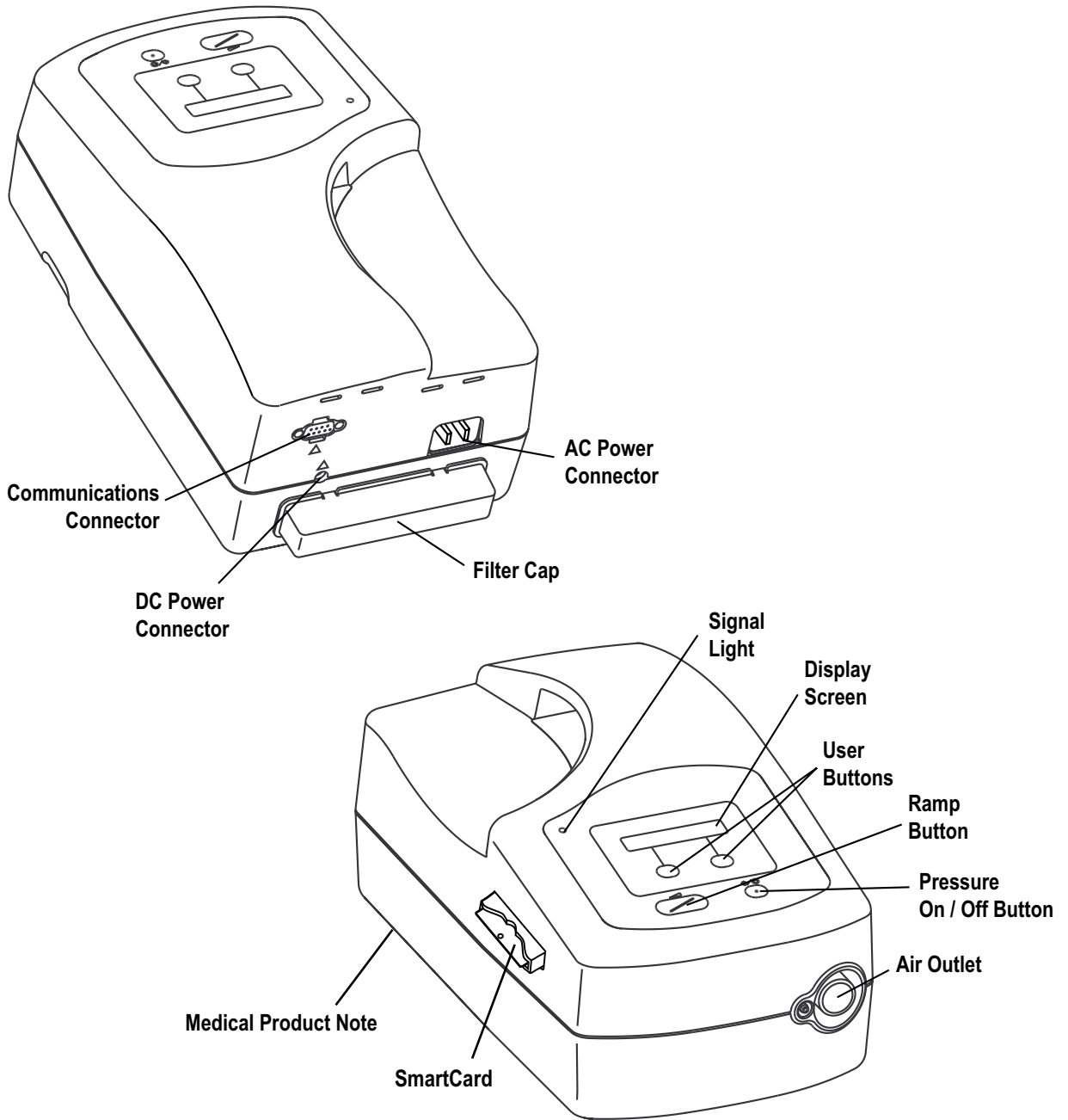
CAUTION!

Indicates the possibility of damage to the device.

- If you notice any unexplained changes in the performance of this device, if it makes unusual or harsh sounds, if it has been dropped or mishandled, if the enclosure is broken, or if water has entered the unit, discontinue use and contact your home care provider.
- Tobacco smoke may cause tar build-up that may result in the BiPAP Pro malfunctioning.
- The BiPAP Pro must be positioned on its base for proper operation.

Additional warnings and cautions are located throughout this manual as they apply.

SYSTEM FEATURES



SYSTEM FEATURES

- AC Power Connector** Connect the power cord here.
- Air Outlet** Connect the flexible tubing here.
- Communications**
- Connector** For clinical use with applicable Respironics software and an IEC 950 approved device. Connect the communications cable here.
- DC Power Connector** Connect the optional DC power cord here.
- Display Screen** All System settings, total operating time, and therapy hours will be displayed here.
- Filter Cap & Filter** The pollen filter screens out normal household dust and pollens. The filter cap covers the filter, which must be in place at all times when the BiPAP Pro is operating.
- Medical Product Note** For convenience at airport security stations, a note on the bottom of the BiPAP Pro states that it is medical equipment. Taking this manual with you when you travel also may help you at security checkpoints.
- Pressure On / Off**
- Button** This button turns the airflow on or off.
- Ramp Button** This button decreases the pressure to the minimum ramp pressure setting.
- Signal Light** The green light signals when the BiPAP Pro is ready for use. The light will go out when the airflow is turned on. A flashing light signals that the BiPAP Pro needs to be serviced.
- SmartCard** The SmartCard records device usage information (e.g., a history of pressure settings and times the system was used for therapy). Contact your home care provider for further information about the SmartCard.
- User Buttons** These buttons can be used to change some of the System settings and to answer the FOSQ “Quality of Life” test.

FIRST TIME SETUP

WARNING!

DO NOT use the BiPAP Pro Bi-level system until an appropriate professional adjusts the settings!

Note to home care provider: Before beginning setup, be sure that you have available the BiPAP Pro Home Care Provider Setup Instructions. It contains instructions for setting up the BiPAP Pro.

WARNING!

DO NOT connect any equipment to the BiPAP Pro unless recommended by Respironics or your health care professional.

WARNING!

Respironics circuit accessories (e.g., nasal mask, exhalation port, flexible tubing) are for single patient use only and are not intended to be used on multiple patients.

CAUTION!

If the BiPAP Pro has been exposed to either very hot or very cold temperatures, allow the device to adjust to room temperature (approximately 2 hours) before beginning setup.

CAUTION!

When operating the BiPAP Pro system, make sure bedclothes, curtains, or other items are not blocking the filter cap openings or the vents on the BiPAP Pro. Make sure the BiPAP Pro is away from heating or cooling equipment (e.g., forced air vents, radiators, air conditioners).

ATTENTION!

The SmartCard does not need to be installed for the BiPAP Pro to work properly. The SmartCard records device usage information for use by your home care provider. Contact your home care provider if you have any questions about the SmartCard.

FIRST TIME SETUP

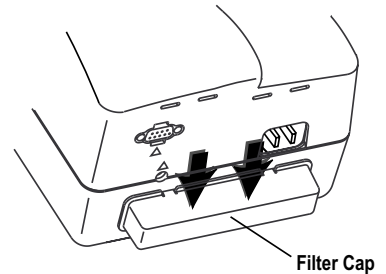
Installing Filters

1. **Install the filter and filter cap. For additional filter options, refer to the Accessories section.**

WARNING!

The filter must be in place at all times when the BiPAP Pro is operating.

- a. Place the pollen filter into the filter area on the back of the BiPAP Pro. An extra pollen filter is included for your convenience.
- b. **Attach the filter cap.** Insert the cap's bottom tabs into the openings below the filter area. Press down on the cap's top tabs and insert them into the openings above the filter area.



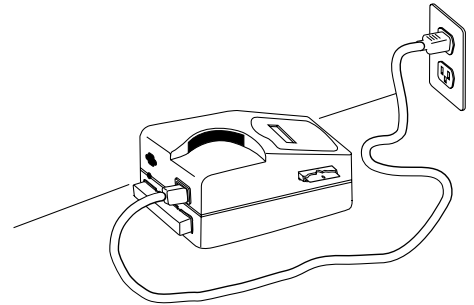
Power Cord

2. **Connect the power cord.**

Plug the socket end of the power cord into the AC inlet on the back of the BiPAP Pro. Plug the pronged end of the power cord into an electrical outlet.

IMPORTANT!

An international plug adapter may also be required to make your power cord compatible with the electrical outlet of the country you are in. If further assistance is required, contact Respironics International Customer Service at 1-724-387-4000 or US Customer Service at 1-800-345-6443.



CAUTION!

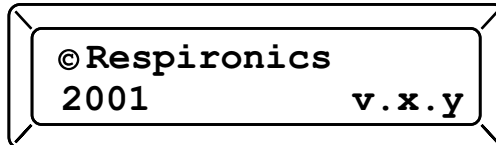
Inspect the power cord often for any signs of damage. Replace a damaged cord immediately.

CAUTION!

The BiPAP Pro is activated when the power cord is connected. The Pressure On / Off button only turns the blower on/off.

FIRST TIME SETUP

After the BiPAP Pro is plugged in, it will perform a brief self-diagnostic test. The following message will then appear on the display screen.



IMPORTANT!

DO NOT use the BiPAP Pro if the display is erratic. Contact your home care provider for further instructions.

IMPORTANT!

DO NOT turn the airflow on until the circuit tubing is connected.

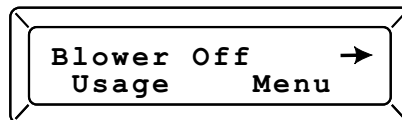
Device Settings

3. Follow the display screens to change the system settings.

IMPORTANT!

Make sure the airflow is turned OFF. You cannot change any settings while the BiPAP Pro's airflow is turned ON.

- a. The blower status will be displayed and the green signal light will be on. Press the button below "Menu."



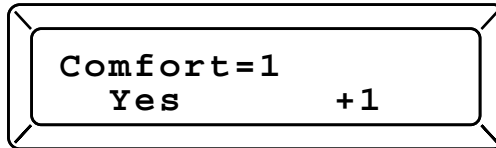
- b. A message will display asking if you want to change the settings. Press the button below "Yes."



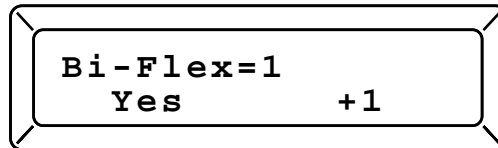
If you press "No," go to page 13 for instructions.

FIRST TIME SETUP

When you choose “Yes” at the “Change Settings?” screen, either the Comfort Control or Bi-Flex level setting will appear. (The display at this screen is set by your home care provider.) If Comfort Control appears, follow the instructions in step c.



If the Bi-Flex feature appears, follow the instructions in step d.



Comfort Control

- c. Comfort Control establishes the time that the BiPAP Pro takes to change from EPAP to IPAP when you begin inhaling. A Comfort Control setting of “Off” will result in the fastest transition from EPAP to IPAP. Settings of “1”, “2”, or “3” will progressively result in a longer transition to IPAP. You can adjust this setting for your comfort.

To adjust the Comfort control, press the front panel button that appears under “+1” at the Comfort Control screen. When the desired setting appears next to “Comfort=”, press the front panel button that appears under “Yes” at the Comfort Control screen.

FIRST TIME SETUP

The Bi-Flex Level Setting

- d. The Bi-Flex level setting screen displays the Bi-Flex level prescribed by your home care provider. This setting establishes a level of pressure relief that takes place at the end of inhalation and at the start of exhalation. Settings of “1”, “2,” or “3” will progressively provide increased pressure relief. You can adjust this setting to suit your comfort level.

To adjust the Bi-Flex setting, press the front panel button that appears under “+1” at the Bi-Flex feature screen. When the desired setting appears next to “Bi-Flex=”, press the front panel button that appears under “Yes” at the Bi-Flex feature screen.

NOTE: If the Bi-Flex setting chosen does not correspond to your breathing rate, adjust the setting for a more natural breathing rate.

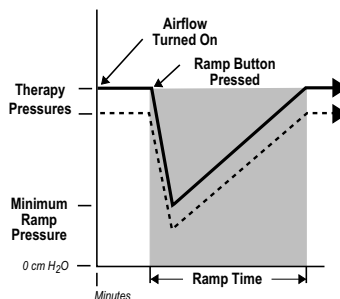
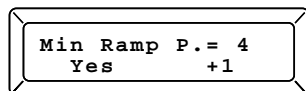
Setting the Minimum Ramp Pressure

- e. The Ramp feature will reduce the pressures and then gradually increase (ramp) the pressures to the prescription pressure settings so that you can fall asleep more comfortably. If your health care professional has prescribed ramp for you, the minimum ramp pressure setting will appear next. If ramp has not been prescribed for you, go to step f.

The minimum ramp pressure will be displayed. Your home care provider will have already set a minimum ramp pressure. If you feel the minimum ramp pressure is set too low or too high, you can change the setting. (Range: 3 cm H₂O to EPAP pressure setting)

If the minimum ramp pressure is correct, press the button below “Yes.”

To change the pressure in 1 cm H₂O increments, press the button below “+1” until the desired pressure is displayed. Press the button below “Yes” to confirm the setting.



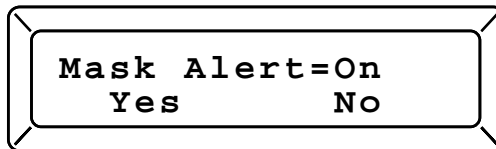
Turning the Alert Tone On or Off

- f. The audible mask alert is a beeping sound that the BiPAP Pro makes when a large, continuous air leak has been detected in the circuit. You have the option of turning the alert tone On or Off.

If the setting is correct, press the button below “Yes.”

To change the setting, press the button below “No.”

Press the button below “Yes” to confirm the setting.



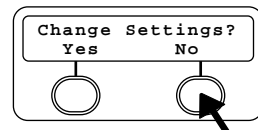
IMPORTANT!

The Mask Alert is a convenience feature that may not work at extreme altitudes or with some mask types or circuit configurations (e.g., pass-over humidifier, full face mask). *This will not adversely affect the therapy you receive from the system.*

FOSQ Test

When “Change Settings” is displayed, if you press the button below “No,” a screen will appear that says “FOSQ Test?” .

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



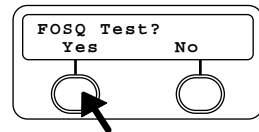
FIRST TIME SETUP

IMPORTANT!

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

A message will display asking if you want to take the FOSQ test. If you want to take the test, Press the button below “Yes.”

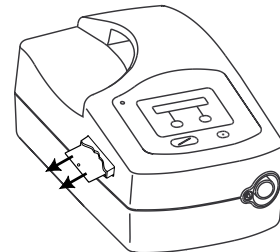
(NOTE: This screen will not display if the SmartCard is not installed.)



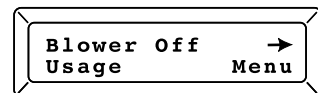
If you do not want to take the test, press the button below “No” and the display will go back to the main screen.

SmartCard

A SmartCard is installed in the side of the BiPAP Pro to record information for the home care provider. Your home care provider may ask you to periodically remove the SmartCard and send it to him or her for evaluation.



The arrow in the upper right corner of the display screen signifies that the SmartCard is installed properly.



FIRST TIME SETUP

Assembling the Circuit

4. **Assemble the circuit.** You will need the following accessories in order to assemble the recommended circuit.

- **Respironics Flexible Tubing (6 ft. [1.83 m] x 22 mm I.D.)**
- **Respironics Nasal Mask With Exhalation Port**
- **Respironics Headgear**

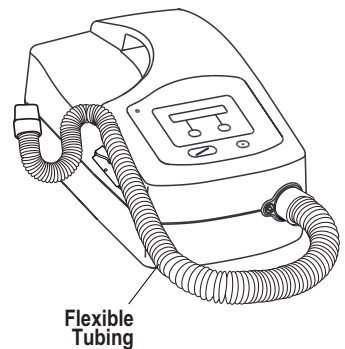
WARNING!

Do not connect any equipment to the BiPAP Pro unless recommended by Respironics or the health care professional. If circuit accessories other than those recommended by Respironics are connected to the BiPAP Pro, then pressures must be verified. Use of these accessories may alter the pressure received, reducing the effectiveness of treatment.

WARNING!

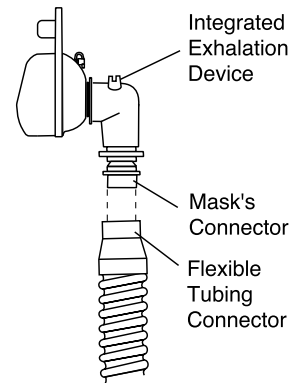
If the BiPAP Pro is used for multiple persons (e.g., rental devices) a low-resistance, main flow bacteria filter should be installed in-line between the BiPAP Pro and the circuit tubing. Appropriate diagnostic pressures must be determined when a bacteria filter is in place.

- a. Connect the flexible tubing to the air outlet on the front of the BiPAP Pro.



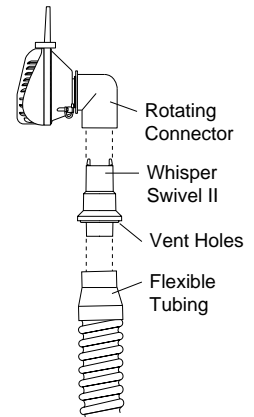
FIRST TIME SETUP

b. If you are using a mask with a built-in exhalation port: Connect the mask's connector to the flexible tubing.



If you are using a mask with a separate exhalation port: Connect the exhalation port to the end of the flexible tubing.

Position the exhalation port so that the vented air is blowing away from your face. Connect the mask's connector to the exhalation port.



WARNING!

The exhalation port is designed to exhaust CO₂ from the circuit. Continuous flow is required for safe operation. Do not block or otherwise try to seal the air openings on the exhalation port.

WARNING!

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

Contact your home care provider for additional information on the optional accessories.

IMPORTANT!

When using optional accessories, always follow the instructions enclosed with the accessories.

Adding a Humidifier

Humidifiers are available from your home care provider. The humidifiers may reduce nasal dryness and irritation by adding moisture 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 BiPAP Pro device. The humidifier must be level for proper operation.

CAUTION!

Condensation may damage the BiPAP Pro. Always allow the unit to reach room temperature before use.

IMPORTANT!

“Mask Alert,” “Auto-On,” and “Auto-Off” are convenience features that may not work at extreme altitude levels or with some mask types or circuit configurations (e.g., pass-over humidifier, full-face mask). If this occurs, press the Pressure On/Off button on the BiPAP Pro to turn the airflow on or off. This will not adversely affect the therapy you receive from the system.

Using a DC Power System

You can also use the BiPAP Pro in a stationary recreational vehicle, boat or motor home with a 12 volt DC power source. The BiPAP Pro should not be operated while the vehicle is in motion. Contact your home care provider for additional information.

CAUTION!

Use only the Respironics DC Power System available from your home care provider. Use of any other system may cause damage to the BiPAP Pro or your vehicle.

CAUTION!

DC Power is not intended to be used as battery back-up. DO NOT connect the DC Power System while the BiPAP Pro is operating on AC power. System damage may occur.

ACCESSORIES

Adding Oxygen to the System

Please note the warnings listed below when using oxygen with the BiPAP Pro system.

WARNING!

When you are using oxygen with the BiPAP Pro, the oxygen supply must comply with the local regulations for medical oxygen.

WARNING!

When you are using oxygen with this system, a Respironics Pressure Valve (part number 302418) must be placed in-line with the patient circuit.

WARNING!

Oxygen should be administered only on the order of a health care professional. Consult with your home care provider if your health care professional has prescribed oxygen for you.

WARNING!

When using oxygen with the BiPAP Pro system, turn the BiPAP Pro on before turning the oxygen on. Turn the oxygen off before turning the BiPAP Pro off. This will prevent oxygen accumulation in the BiPAP Pro.

WARNING!

Oxygen accelerates fires. Keep the BiPAP Pro and the oxygen container away from heat, open flames, any oily substances, or other sources of ignition. DO NOT smoke in the area near the BiPAP Pro or the oxygen.

Carrying Case

The carrying case holds the BiPAP Pro and accessories. When traveling by airplane, the carrying case is for carry-on luggage only. Never check the BiPAP Pro through the baggage department.

Using an Ultra-fine Filter

You can use an optional ultra-fine filter in addition to the pollen filter for more complete filtration of very fine particles. The ultra-fine filter is most beneficial to those who are sensitive to tobacco smoke or to other substances with small particles.

Connecting the Circuit

IMPORTANT!

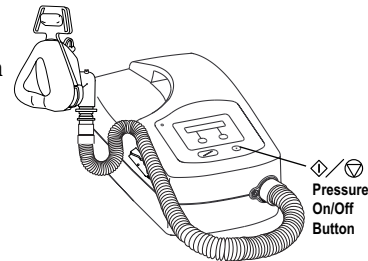
1. Connect the circuit.

Before each use, examine the flexible tubing for any damage or debris. Replace any damaged tubing.

- a. Connect the mask to the headgear, following the instructions included with the mask and headgear.
- b. **If your home care provider has selected the Auto-On feature for you**, put on the mask and headgear, and breathe normally through your nose. The airflow should automatically turn ON when you begin breathing through the circuit. If the airflow does not turn on within four breaths, turn it ON by pressing the Pressure On/Off button on the top of the BiPAP Pro. When operating the System with some mask types, some circuit configurations, or at higher altitudes, the airflow may NOT automatically turn on.

- or -

If your home care provider has not selected the Auto-On feature for you, put on the mask and headgear, and immediately turn the airflow ON by pressing the Pressure On/Off button on the top of the BiPAP Pro. Breathe normally through your nose.



Adjusting the Circuit

2. Adjust the circuit.

- a. Lie down on your bed and adjust the flexible tubing so it is free to move if you turn in your sleep.
- b. Adjust the mask and headgear until you have a comfortable fit and there are no airflow leaks into your eyes.

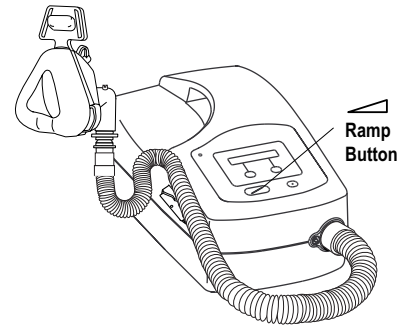
ROUTINE USE

When the airflow is on, the green signal light will go out. The word “Menu” will no longer be displayed, and the pressure setting will be shown.

Starting Ramp

The Ramp feature will reduce the pressure and then gradually increase (ramp) the pressure to the therapeutic pressure setting so that you can fall asleep more comfortably. If your health care professional prescribed ramp for you, pressing the Ramp button will reduce the air pressure when you are trying to fall asleep. NOTE: The ramp feature is not prescribed for all users.

3. Press the Ramp button on the top of the BiPAP Pro. You can use the Ramp button as often as you wish during the night.



Turning the System OFF

4. Remove the mask and headgear.

If your home care provider has selected the Auto-Off feature for you, the airflow will automatically turn off (in less than 1 minute). If the audible mask alert is turned on, the alert tone will sound (in less than 45 seconds after you remove the mask.)

-or-

If your home care provider has not selected the Auto-Off feature for you, immediately turn the airflow OFF by pressing the Pressure On/Off button on the top of the BiPAP Pro. If the audible mask alert is turned on, the alert tone will sound (in less than 45 seconds after you remove the mask).

IMPORTANT!

The Auto-Off feature may have been disabled by your home care provider. Press the Pressure On/Off button on the top of the BiPAP Pro to turn the airflow OFF.

Helpful Hints

- If the alert tone sounds, press any button on the BiPAP Pro to silence the alert tone. Refer to the “Screen Displays” section of the manual for further instructions.
- If you want to talk after putting on the mask, and ramp has been prescribed for you, use the Ramp button to reduce the pressure. This will make talking easier.
- Make sure that bedding, curtains, or other items are not blocking the filter or vents of the BiPAP Pro. Air must flow freely around the BiPAP Pro for the system to work properly.

Screen Displays

During use, any of the following displays may appear on the screen.

1. “Mask Alert” - A large circuit leak, such as mask removal, has been detected.

What will happen:

- The alert tone will sound in less than 45 seconds (if the mask alert feature has been turned on).
- The airflow will turn off in less than 1 minute (if the Auto-Off feature has been turned on).

What to do:

- Press any button on the BiPAP Pro to silence the alert tone and clear the display screen.
- Check the circuit (flexible tubing, mask) for any leaks and adjust the mask and headgear.
- Press the Pressure On / Off button to restart the airflow.

IMPORTANT!

The audible mask alert setting can be turned on or off. See the “First Time Use” section for instructions.

ROUTINE USE

2. **“System Error ###” - The BiPAP Pro is not functioning correctly and may need servicing.**

What will happen:

- The airflow will turn off immediately.
- The alert tone will sound.
- The signal light will flash on and off.

What to do:

- Reset the BiPAP Pro by unplugging the power cord from the electrical outlet and then plugging it in again.
- If the message appears again, contact your home care provider or Respironics for directions on having the BiPAP Pro serviced. Please have the serial number of the BiPAP Pro and the error code ready when you call.

IMPORTANT!

This alert setting cannot be turned on or off.

3. **“Remote Connected” - This message will appear during clinical use only.**
4. **“Remove Card” - The Encore SmartCard has been inserted improperly.**

What to do:

- Remove the SmartCard. Reinsert the SmartCard, making sure that the printed side of the card is facing up and the end with the arrow goes into the device first.
- If the message appears again, remove the card and contact your home care provider to have the SmartCard replaced. You can continue to use the BiPAP Pro. Removing the SmartCard will not affect the performance of the BiPAP Pro.
- If the SmartCard is not installed, the device usage will not be recorded. When a SmartCard is installed, an arrow will appear in the upper right corner of the screen.

5. **“  ” - The SmartCard is in place.**

TRAVELING WITH THE SYSTEM/ROUTINE MAINTENANCE

Packing the System

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

Security Stations

For ease at security stations, there is a note on the bottom of the BiPAP Pro stating that it is medical equipment. It may be helpful to bring this manual along with you to help security personnel understand the BiPAP Pro.

Checking the Power Cord

If you are traveling to another country, an international plug adapter may be required to make your power cord compatible with the power outlets of the country to which you are traveling.

IMPORTANT!

For more information, contact Respiroics International Customer Service at 1-724-387-4000 or US Customer Service at 1-800-345-6443.

Cleaning and Replacing the Filter

The pollen filter should be cleaned at least once every two weeks under normal usage and replaced with a new one every six months.

CAUTION!

Operating the BiPAP Pro with a dirty filter may keep the system from working properly and damage the BiPAP Pro.

1. Remove the filter cap by gently pressing down on the two latches on the top of the filter cap.
2. Change the filter.
 - a. Remove the pollen filter by gently pulling around the edges of the filter. Rinse the filter in a steady stream of running water. Squeeze out the water and repeat. Air-dry on a rack for 8 to 12 hours or in a clothes dryer for 15 to 20 minutes.
 - b. Insert the filter into the filter area on the back of the BiPAP Pro.

CAUTION!

Never install a wet filter into the BiPAP Pro. We recommend that you clean the filter in the morning and alternate using the two pollen filters provided with the system to ensure enough drying time for the cleaned filter.

3. Replace the filter cap.

ROUTINE MAINTENANCE

Cleaning the System

WARNING!

To avoid electrical shock, unplug the BiPAP Pro before cleaning. DO NOT immerse the BiPAP Pro into any fluids.

1. Disconnect the flexible tubing from the BiPAP Pro. Gently wash the flexible tubing daily in a solution of warm water and a mild detergent. Rinse thoroughly. Air-dry.
2. Wipe the outside of the BiPAP Pro with a cloth slightly dampened with water and mild detergent. Let the BiPAP Pro dry before plugging in the power cord.
3. Inspect the BiPAP Pro and all circuit parts for any damage after cleaning. Replace any damaged parts.
4. For details on cleaning your mask and accessories, refer to the instructions packaged with the accessories.

Reordering

Contact your home care provider to order all accessories or replacement filters (e.g., humidifier, mask).

Service

The BiPAP Pro does not require routine servicing.

CAUTION!

If you notice any unexplained changes in the performance of this device, if it is making unusual or harsh sounds, if it has been dropped or mishandled, if the enclosure is broken, or if water has entered the unit, discontinue use. Contact your home care provider.

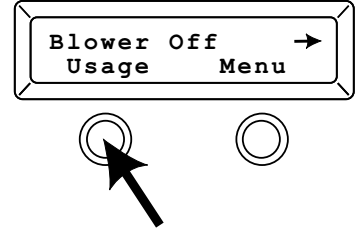
WARNING!

If the BiPAP Pro malfunctions, contact your home care provider immediately. Never attempt to open the BiPAP Pro's enclosure. Only Respironics authorized service personnel may perform repairs and adjustments. Unauthorized service could cause injury, could invalidate the warranty, or could result in costly damage.

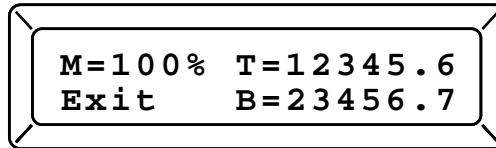
ROUTINE MAINTENANCE

Total Operation Time

To display the total operation time, press the button below “Usage.” The usage hours will appear for 10 seconds. The BiPAP Pro will then return to the main screen.



Total Operation Time Display



- M** = The amount of memory space available. The BiPAP Pro records patient usage information (e.g., a history of pressure settings; number of times the system was used for therapy). Some physicians and home care providers record this information. When “M=000%” appears, contact your home care provider if he/she has asked you to monitor the BiPAP Pro’s memory level. When “M=---%” appears, then the SmartCard is not installed in your BiPAP Pro.
- T** = The therapy hours are the total number of hours that the BiPAP Pro has operated with the airflow turned on. Like a trip meter in a car, the therapy hours can be reset to zero by the home care provider.
- B** = The total blower time is the total number of hours that the BiPAP Pro has been in use. This total includes factory testing time.
- Exit** = Returns the display to the main screen.

TROUBLESHOOTING

The table below lists common problems you may have with the BiPAP Pro system and possible solutions to those problems. If none of the corrective actions solve the problem, contact your home care provider.

Problem	Solution(s)
Sore or dry eyes.	Readjust the headgear. Contact your home care provider to be fitted for a different mask style or size.
Redness on your face where the mask contacts your skin.	Loosen the headgear. Check the mask's spacer to see that it is in good condition. Use a barrier between your skin and the mask, such as 3M's Microfoam tape, Squibb's Duoderm tape, or Hollister's Restore tape. Contact your home care provider to be fitted for a different mask style or size. Contact your health care professional if the problem persists.
Dryness or burning sensation in your throat or nose.	Consult with your health care professional or home care provider about using a humidifier with the BiPAP Pro. If you are using a nasal mask, you may want to also use a chin strap to help keep your mouth closed during the night.
Nasal, sinus, or ear pain.	You may have a sinus infection or middle ear infection. Stop using the BiPAP Pro, and contact your health care professional.
The pressure being delivered feels different.	Contact your home care provider or Respironics for directions on having the BiPAP Pro serviced. Please have the BiPAP Pro's serial number ready when you call.
The airflow from the BiPAP Pro seems warm.	Replace or clean the filter. Make sure the BiPAP Pro is away from bedding or curtains that could block the flow of air around the BiPAP Pro. Make sure the BiPAP Pro is away from heating equipment (e.g., forced air vents, radiators).

TROUBLESHOOTING

Problem	Solution(s)
The noise level of the BiPAP Pro has changed to include unusual or harsh sounds during operation.	Discontinue use. Contact your home care provider or Respirationics for directions on having the BiPAP Pro serviced. Please have the BiPAP Pro's serial number ready when you call.
The BiPAP Pro has been dropped or mishandled.	Discontinue use. Contact your home care provider or Respirationics for directions on having the BiPAP Pro serviced. Please have the BiPAP Pro's serial number ready when you call.
The enclosure of the BiPAP Pro is broken.	Discontinue use. Contact your home care provider or Respirationics for directions on having the BiPAP Pro serviced. Please have the BiPAP Pro's serial number ready when you call.
Water has entered the BiPAP Pro.	Discontinue use. Contact your home care provider or Respirationics for directions on having the BiPAP Pro serviced. Please have the BiPAP Pro's serial number ready when you call.
The BiPAP Pro will not turn on.	Make sure that the BiPAP Pro is plugged into a working outlet. If you are using a DC battery, the battery may need to be recharged or replaced or the fuses may need to be replaced. Contact your home care provider or Respirationics for directions on having the BiPAP Pro serviced. Please have the BiPAP Pro's serial number ready when you call.
The BiPAP Pro has hours recorded on the time meter when it is delivered.	The BiPAP Pro is tested at the factory prior to shipment. It may be possible for several hours of testing time to be recorded on the BiPAP Pro.
The "Mask Alert" message appears on the display screen and the alert tone is sounding.	Press any button on the BiPAP Pro to silence the alert tone and clear the display screen. The system has detected a large leak in the circuit or you have taken the mask off without turning the airflow off. Check the circuit connections for leaks.

TROUBLESHOOTING

Problem	Solution(s)
The Mask Alert is not working.	Auto-On, Auto-Off, and Mask Alert are convenience features that may not work with some mask types, circuit configurations, or at extreme altitudes. This will not adversely affect the therapy received from the System. In the settings menu, make sure the display reads “Mask Alert=On.”
Pressing the Ramp button does not reduce the air pressure.	Contact your home care provider. Ramp may not have been prescribed for you. Make sure the ramp pressure setting is lower than your EPAP pressure setting.
The airflow will not automatically turn ON or OFF.	Auto-On, Auto-Off, and Mask Alert are convenience features that may not work with some mask types or circuit configurations or at extreme altitudes. This will not adversely affect the therapy received from the System. The Auto-On and Auto-Off settings may have been disabled by your home care provider.
The memory display reads “M=000%.”	The BiPAP Pro records patient usage information (e.g., a history of pressure settings, times the system was used for therapy). Some physicians and home care providers record this information to assist in your bi-level treatment. When “000%” is displayed, contact your home care provider if he/she has asked you to monitor the memory level. Information will still be recorded once “000%” is displayed.
The memory display reads “M=---.”	The SmartCard is not installed in the side of the BiPAP Pro. Your home care provider or health care professional may have decided that recording the BiPAP Pro’s usage is not important for your therapy.
The memory display reads “M=!!!.”	The BiPAP Pro may not be operating correctly. Contact your home care provider or Respirationics for directions on having the BiPAP Pro serviced. Please have the serial number of the BiPAP Pro ready when you call.

TROUBLESHOOTING/SPECIFICATIONS

Problem	Solution(s)
The “System Error” message appears on the display screen.	The BiPAP Pro may not be operating correctly. Reset the BiPAP Pro by unplugging the power cord from the electrical outlet and then plugging it in again. If the message appears again, contact your home care provider or Respironics for directions on having the BiPAP Pro serviced. Have the serial number of the BiPAP Pro and the error code ready when you call.

The “Remove Card” message appears on the display screen.	The SmartCard has been inserted improperly. Remove the SmartCard. Reinsert the SmartCard making sure that the printed side of the card is facing up and the end with the arrow goes into the device first. If the message appears again, contact your home care provider or Respironics for directions on having the BiPAP Pro serviced. Have the serial number of the BiPAP Pro and the error code ready when you call.
--	--

Device Size
Dimensions: 11.42” x 7.09” x 5.51” (29 x 18 x 14 cm)
Weight: 5.8 lbs. (2.6 kg)

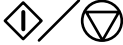






Product Use, Transport, and Storage	Operation	Transport & Storage
Temperature:	41 to 95° F (5 to 35° C)	-4 to 140° F (-20 to 60° C)
Humidity:	15 to 95% Relative (non-condensing)	15 to 95% (non-condensing)
Atmospheric Pressure:	82.8 to 102 kPascals	50 to 102 kPascals

Standards Compliance
 This device is designed to conform to the following standards:
 IEC 60601-1 Medical Electrical Equipment -
 General Requirements for Safety
 IEC 60601-1-2 Electromagnetic Compatibility
 US Deviations (UL 2601-1:1997)
 Canada Deviations (CAN/CSAC22.2 No. 601.1-M90)

Power Requirements
The electrical installation of the room must comply with local requirements.
 100 to 240 VAC, 50/60 Hz, 1.0 A max.
 12 VDC, 4.0 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: Ordinary Equipment (IPX0).
 Mode of Operation: Continuous.
 Pressure Range: 3 to 20 cm H₂O (in 1 cm H₂O increments).

SYMBOLS

Symbol Key

	Pressure ON / OFF
	Ramp
	DC Power
	Type BF Applied Part
	Class II (Double Insulated)
IPX0	Ordinary Equipment
	Attention, consult accompanying documents
	European CE Marking

LIMITED WARRANTY

Respironics, Inc. warrants that the BiPAP Pro device 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 Respironics, Inc. at 1001 Murry Ridge Lane, Murrysville, Pennsylvania 15668, USA, 1-724-387-4000 (International Customer Service) or 1-800-345-6443 (US Customer Service).

IMPORTANT!

Fill in the information below when you receive the BiPAP Pro system.

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

System Prescribed for: _____

Date of Purchase or Rental: _____

Pressure Settings: IPAP ____ cm H₂O EPAP ____ cm H₂O

Mask Type: _____

Mask Size: _____

Comfort Flap Nasal Mask Accessory: yes no

If you have any questions concerning the system, contact

• Home Care Company: _____

Telephone Number: _____

• Doctor: _____

Telephone Number: _____

• Respironics, Inc.

1001 Murry Ridge Lane

Murrysville, Pennsylvania

15668-8550 USA

Customer Service

Telephone Number: 1-724-387-4000 (International Customer Service)

or 1-800-345-6443 (US Customer Service)

Respironics

Deutschland

Gewerbestr. 17

82211 Herrsching Germany