t r a n q u i l i t y bilevel

Compact Bilevel System
Model 1700
Patient Operating Instructions

The Respironics Tranquility Bilevel is a medical device. It has been prescribed by a physician to assist breathing.

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Glossary of Symbols

Symbol Description



Attention, consult accompanying documents (such as, manuals). Read and understand this entire manual before using this bilevel system.

- O Power switch Off (Disconnection from the mains)
- Power switch On (Connection to the mains)
- ∼ Alternating current



Class II equipment (Double insulated)

IPX1 Protected against vertically falling water



Type BF applied part

User/Owner Responsibility

This Respironics Bilevel system and accessories are designed to work as described in this manual. You should not use parts that are damaged, broken, worn out, dirty or otherwise ineffective. Read this entire manual before using this Bilevel system.

The user/owner of this system shall have the sole responsibility and liability for any injury to persons or damage to property (including this equipment) resulting from:

- 1. Operation not in accordance with supplied operating instructions;
- 2. Maintenance not in accordance with authorized maintenance instructions;
- 3. Maintenance by anyone other than a factory-authorized service representative;
- 4. Modification of the system or accessories; or
- 5. Use of damaged or unauthorized components or accessories.

The Scope of this Manual

This manual will show you how to use the Respironics Tranquility Bilevel PAP system. This system provides positive pressure to the breathing passages to assist breathing. **Read and understand this entire manual before trying to use this system.**

Introduction

Nasal Bilevel PAP devices produce small amounts of air pressure at different levels. You will use a nasal mask to apply these pressures. This pressure opens the breathing passages to prevent blockages and to assist breathing. The Bilevel system is different from Continuous Positive Airway Pressure (CPAP). CPAP provides one level of pressure. Bilevel provides two levels of pressure, one during *inspiration* and a second lower pressure during *expiration*.

The Tranquility Bilevel (Model 1700) system from Respironics, is a medical device that uses a blower. The blower is controlled to provide two levels of pressure. The controller allows for the adjustment of the way the pressure changes from one level to the other. The *ComfortControl*TM on the front of the unit will allow you to adjust the way pressure is delivered. You can select the setting that you feel is the most comfortable. Also, this compact unit features a linear ramp, a useful handle, and a filter. You can easily wash or replace the filter.

Warnings and Cautions

WARNING-indicates a potentially harmful situation

- 1. This is a non-continuous ventilatory assist device. It is intended to assist you with your breathing. It must not be used as a *ventilator* that supports or sustains life. This device is not intended to provide you with total support of your breathing. In all cases you should expect to have no more than short term effects if the device fails to provide pressure during long periods of time (for example, over night).
- 2. Do not use this Bilevel unit in the presence of flammable *anesthetics*.
- 3. Do not use the Bilevel unit around water in any way. You may use Bilevel with a Respironics supplied *Humidifier*:
- 4. If this unit should come in contact with water, unplug the unit.
- 5. This unit should never be turned on and left unattended.
- 6. Never operate this unit if the power cord or plug is damaged
- 7. If this unit has been dropped or damaged, contact your dealer or Respironics at once.
- 8. Adjusting the pressure without a physician's instruction could be harmful.
- 9. Use only a nasal mask and patient circuit supplied by Respironics. The Tranquility Bilevel must be on and operating properly before you attempt to use the nasal mask and patient circuit.
- 10. Do not block or obstruct the vent hole located on the front of the nasal mask.
- 11. Make sure that all breathing connections are properly secured.

- 12. For 12VDC operation, do not use any DC to AC inverter other than that supplied or recommended by Respironics.
- 13. Check and verify fuse rating before replacement.
- 14. When using oxygen with this system, make sure that this Bilevel is on before you turn the oxygen source. When you wish to stop using this Bilevel system, turn off the oxygen flow first before turning this Bilevel unit off.
- 15. Oxygen quickly accelerates fire. If you are using oxygen, keep this Bilevel system as well as the oxygen source away from heat or open flame. There must be no smoking in the area near the Bilevel.
- 16. As with any electrical device, do not use this Bilevel unit during an electrical storm.
- 17. Do not use this Bilevel unit with a portable electrical generator.
- 18. At low pressures, the flow through the exhalation port may not be enough to clear all of the exhaled gases from the hose. As a result, you may breathe in some of the air that you have breathed out or exhaled.
- 19. Be aware that *interference* with the operation of this device can occur from external sources. While this device contains methods and techniques that can provide protection from external sources of interference, you should take the steps listed here to avoid interference. Keep the device at least three feet away from all electrical appliances such as TV sets, electric blankets, air conditioners, cordless phones and cellular phones.
- 20. The air flow for breathing produced by the Bilevel can be as much as 1.8°F (1.0°C) higher than the temperature of the room. Use caution if the room temperature is warmer than 90°F (32°C).

CAUTION: FEDERAL USA LAW RESTRICTS THIS DEVICE TO SALE BY, OR ON THE ORDER OF, A LICENSED PHYSICIAN. THIS BILEVEL UNIT SHOULD BE USED ONLY UNDER THE SUPERVISION OF A LICENSED PHYSICIAN.

CAUTION-indicates a condition that may lead to equipment damage, malfunction, or inaccurate operation.

- 1. Do not use a room humidifier within six feet of this unit. Dampness may affect device parts.
- 2. Do not use attachments that are not recommended by Respironics.

- 3. This Bilevel system is to be used in the manner described in this manual.
- 4. Never drop or insert any objects into the connecting hose or air outlets or inlets.
- 5. Operating the unit with a dirty filter may keep the Bilevel from working properly.
- 6. Do not use extension cords or electrical adapters.
- 7. Do not sterilize this unit.

Note: At a fixed flow rate of oxygen flow, the inhaled oxygen concentration will vary, depending on the pressure settings, your breathing pattern, mask selection, and leak rate. This warning applies to most types of CPAP or Bilevel devices.

Set-up and Use

Unpacking and Inspection

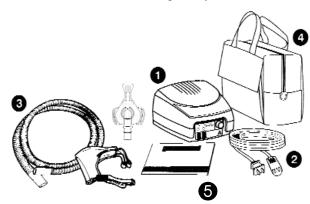
When you get your Bilevel system, carefully open the box and unpack the system. Make sure that you have all the parts listed below and that nothing looks damaged. This basic package does not include accessories. Accessories can be ordered separately.

Included with this system are the following:

- 1. Tranquility Bilevel (Model 1700) nasal PAP unit
- 2. AC Power Cord
- 3. Six-foot Hose and Tubing Adapter
- 4. Carry Case
- 5. User Instruction Manual

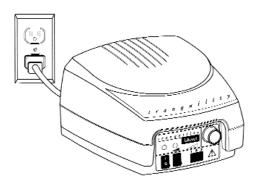
You will need a Nasal Mask and Headgear in order to use this system.

IF ANY OF THESE COMPONENTS ARE FOUND TO BE MISSING OR DAMAGED CONTACT RESPIRONICS AT ONCE.

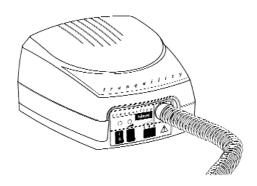


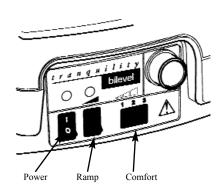
Initial Use

- Prior to each use, inspect this unit for any signs of damage, failure or worn parts. Call Respironics or your Home Care Dealer immediately to replace these parts. Check to see if there is any moisture in the area of this Bilevel unit. Also check the air inlets and outlets for any blockage or the presence of any dust or dirt. If you notice any moisture, dry the area completely before use. Remove any blockage and/or dust or dirt from the air inlets or outlets before each use. Do not use a room humidifier within six feet of this Bilevel unit.
- 2. Place the Bilevel unit in a clean, dry place. Place the Bilevel near an electrical outlet not controlled by a wall switch. Do not use extension cords or electrical adapters. Place this unit in an upright position on a night stand or other suitable surface. Make sure that the front facing you and that nothing is blocking the vents. Never place the Bilevel on a table or night stand that cannot safely support the Bilevel unit.
- 3. Connect the power cord to the AC power inlet on the rear of the unit. Check to be sure that the Power switch is in the OFF position. Plug the other end of the power cord into the unswitched outlet.



- 4. Attach the Bilevel Hose to the Air Outlet Port on the front of the Bilevel unit.
- 5. Attach the Nasal Mask to the other end of the Hose.
- 6. Refer to the Nasal Mask Instructions for information on using the mask and headgear and on adjusting the fit. Do not block the hole (bias flow port) located at the base of the Mask.
- 7. Turn the Bilevel unit on using the Power switch located on the front of the unit. The unit will deliver the set pressure once the mask is in place. Air flow will begin to move through the hose.





- 8. Place the Nasal Mask on. Adjust the straps to get rid of any leaks. Do not overtighten the straps. The mask and headgear should fit comfortably.
- 9. As you breathe in, you will find that the pressure rises slightly. As you exhale, it will fall. This will make your therapy more comfortable.
- 10. The *ComfortControl*™ can be used to make the change in pressure even more comfortable. This control can be set to 1, 2 or 3 based on your preference. This control will alter the rate of change between the two pressures. You may change this setting at any time.



- 11. The Ramp button may be used to decrease the pressure to a lower level. The pressure will then increase to the set pressure over a set period of time. Your Home Care Dealer has already set the ramp time. The ramp indicator will remain lit during the ramp period. The ramp makes the Bilevel more comfortable as you fall asleep.
- 12. In the morning or whenever you wish to stop using the unit, you can switch the unit off. Switch the Power Switch to the OFF position and remove the Nasal Mask.

Routine Use

Regular use of the Tranquility Bilevel System involves a simple brief, routine that is detailed here.

- 1. Switch the Power switch to the ON position. The Power indicator light will come on. You will feel air coming out of the hose. The pressure will rise to the level set by the Home Care Dealer once the mask is in place.
- 2. Place the Nasal Mask, with the Headgear and Hose attached, on and adjust the Headgear straps as needed. Check the mask for any leaks and adjust as needed.
- 3. Press the ramp button to begin the ramp period. The ramp light will come on and the pressure will be reduced.
- 4. If the Hose becomes disconnected at either the Nasal Mask or the Bilevel unit, the unit may go into a Flow Limit mode. In this mode the pressure will be reduced to prevent any damage to the unit. When there is no longer a leak, the pressure will return to the proper level.

- 5. If you need to get up during the night, turn the Power switch to the OFF position and remove the Mask. When you wish to start using the Bilevel unit again, turn the unit ON and replace the Nasal Mask and Headgear. Make sure to check for leaks.
- 6. In the morning or when you are through using the unit, turn the Power switch OFF and remove the mask.
- 7. The Nasal Mask, Headgear, and Hose should be removed from the system for cleaning.

Humidifier Use

An optional *Humidifier* is available through Respironics for use with the system. The Humidifier is a reservoir that fits under your unit. When properly filled with distilled water, it adds moisture to the airflow. This moisture can reduce nasal dryness and irritation. Do not leave water in the Humidifier when the Bilevel is not in use. If the blower accidentally comes on, small amounts of water may be blown out of the Humidifier. Follow the instructions included with the Humidifier regarding cleaning.



CONTACT YOUR DEALER FOR FURTHER INFORMATION.

Using Oxygen With This System

It is important that you read, understand and carefully follow these instructions regarding the use of oxygen with your Tranquility Bilevel system.

CAUTION: Oxygen is a prescription gas and should be used only under the supervision or direction of a licensed physician. While using oxygen, keep the Bilevel system and oxygen source away from heat and open flame. Smoking by anyone in the presence of oxygen must not occur.

Set-up
 Attach the oxygen tubing to the hose using the loops included with the Oxygen
 Administration Kit. Thread the oxygen tubing through the holes in the loops.

 Attach the T-adapter between the mask and the hose. Attach one end of the tub-



ing to the T-adapter and the other end to the oxygen source.

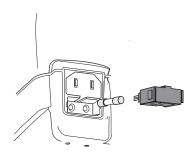
2. Oxygen Use

Turn on the Bilevel unit so that air flow will begin before turning on the flow of oxygen. When turning the Bilevel unit off, always turn the oxygen flow off first and then the Bilevel unit.

NEVER TURN THE BILEVEL UNIT ON OR OFF WITH OXYGEN FLOWING INTO THE UNIT

AC Fuse

If the Bilevel unit power indicator does not light up when the unit is plugged in and turned on, you may need to replace the fuse. When replacing the fuse, make sure that the power cord is not plugged into the electrical outlet. Remove the power cord from the inlet on the rear of the unit. Remove the fuse holder by pressing the two tabs together and pulling out on the tabs. You must replace the fuse with an identically rated fuse. The correct fuse is a T1A, 250V, (1 Amp, 5mm x 20mm, 250 Volt Slo-Blo). Place the new fuse in the fuse holder. Press the holder back into the inlet. Replace the power cord.



Traveling With Your Bilevel System

The Tranquility Bilevel will operate on a range of voltages from 100 VAC to 240 VAC and on 50 or 60 cycles. You do not need to switch from one voltage setting to another. You will need to use a plug adapter in some locations in order to connect the power cord into the available wall outlet. When traveling by airplane, do not check your Bilevel system as baggage because it may be damaged. Always carry this manual with your Bilevel system when you travel. The manual will serve as a reference guide. The manual also serves as a notice that this is a medical device that requires regular use. This notice may be helpful in dealing with Customs agents.

DC Operation

Using the Tranquility Bilevel system with a DC power source will require the use of a Respironics DC to AC Inverter (Part Number 7304). When connecting the DC to AC Inverter, turn off the Bilevel system. Connect the AC power cord to the AC receptacle of the Inverter. Then, plug the DC to AC Inverter into cigarette lighter-type outlet as found in cars, trucks, boats, etc. Under normal conditions, this unit will typically draw less than 3 amperes. The maximum draw for the inverter is listed in the DC to AC Inverter manual. For 10 hours of DC to AC Inverter use this unit will typically consume less than 30 Amp hours.

Altitude Compensation

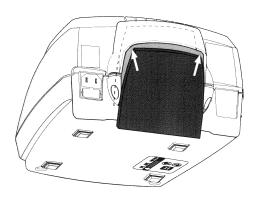
The Tranquility Bilevel unit features a *pressure transducer* that measures pressure delivered to you. The Bilevel also has a *microprocessor* that adjusts the unit if you travel to a different elevation. The unit will adjust the blower speed to compensate for the new elevation. The Bilevel will deliver the prescribed pressures at higher elevations.

MAINTENANCE

Changing the Filter

The Tranquility Bilevel is supplied with a reusable filter. This filter can be removed from the rear of the unit by pulling it out of the filter receptacle. The filter should be washed well with a mild soap and water solution. After washing, rinse it thoroughly with clear water. Allow the filter to dry completely before use. Return the filter to the unit by pressing it against the filter receptacle. Tuck the edges in to place. An optional disposable filter is available for removal of smaller particles.

Check the condition of the filter prior to each use.



Cleaning The System

The Bilevel unit can be cleaned using a cloth moistened with water and a mild soap solution. Caution: Unplug the unit before cleaning it. Do not place the unit in water. Do not use alcohol or other organic solvents to clean this unit. Let the unit dry completely before plugging it in or operating it.

Routine Maintenance

Other than the cleaning detailed above, no other maintenance is required by the user. NOTE: You should not attempt to open the unit's enclosure; there are no user serviceable components inside. Unauthorized tampering with the unit's enclosure or unauthorized servicing will void the warranty and could result in damage and or personal injury.

TROUBLESHOOTING GUIDE

PROBLEM		POSSIBLE CAUSES	INSTRUCTIONS		
1. Unit does not turn on.		Unit not plugged in to live power source	Check to see if unit is plugged into a live power source.		
		Fuse needs to be replaced.	Call your dealer for a new fuse.		
		Wrong fuse was used.	Call your dealer for a new fuse.		
2.	No air comes out of unit when it is turns on	Filter may be blocked by debris.	Wash or replace filter.		
_		Unit has failed.	Call your dealer		
3.	Air from unit seems warm.	Filter may be blocked by debris.	Wash or replace filter.		
		Inlet vent may be blocked.	Move the unit away from the source of blockage.		
		Room air temperature has increased.	Reduce room air temperature.		

PROBLEM		POSSIBLE CAUSES	INSTRUCTIONS		
4.	Feeling that the pressure is to high or too low	Leak in the system.	Check that the mask is not allowing air to leak and that there are no leaks in the hose. (Pressure check at zero flow.)		
		Filter may be clogged. Unit has failed. Ramp is active.	Wash or replace the filter. Call your dealer. Turn power OFF and then ON to turn off ramp.		
5.	Unit not cycling between between two pressure levels	Unit is set to deliver only one pressure level.	Call your Home Care dealer.		
		Leak at mask or in circuit interfering with triggering.	Fix leaks.		
		Blockage in tubing, filter or air inlet.	Clear blockage.		
6.	Discomfort from the feeling of too much pressure.	Pressure from the Bilevel unit.	A period of adjustment, of up to two- three weeks, may be required. Relax and take slow deep breaths. If discomfort continues after two to three days, call your physician for assistance.		
7.	Air leaks around the nasal mask irritating the eyes.	Mask is not fitting properly.	Try again to fit the mask to your face. If leaks continue, call your dealer.		
		Wrong size nasal mask.	Call Your Dealer.		

PROBLEM		POSSIBLE CAUSES	INSTRUCTIONS		
8.	Skin becomes red where mask touches skin	Headgear too tight.	Adjust the headgear.		
		Wrong size nasal mask.	Call your dealer.		
		General irritation or reaction to the mask material.	Stop use and call your physician.		
9.	Runny nose.	Reaction to air flow.	Stop use and call your physician.		
10.	Dryness of throat or nose.	Inadequate humidity.	Increase humidity or call your physician regarding the use of a humidifier.		
11.	Nasal, sinus, or ear pain.	Sinus infection or middle ear infection.	Stop use and call your physician.		
12.	Return of original symptoms.	Physical condition has changed.	You may need to be retested. Call your physician. Have your dealer check to see that your Bilevel unit is working properly.		

MAINTENANCE RECORD

			Dates			Notes
Replaced Nasal Interface	/ /	/ /	/ /	/ /	/ /	
Replaced Headgear	/ /	/ /	/ /	/ /	/ /	
Replaced Hose	/ /	/ /	/ /	/ /	/ /	
Replaced Filter	/ /	/ /	/ /	/ /	/ /	
Checked Bilevel Pressure	/ /	/ /	/ /	/ /	/ /	

PATIENT CHECKLIST

As you and your Home Care Dealer discuss the use of your Bilevel system, make sure that you understand the following:

Why your physician has prescribed the Bilevel system

The importance of using your Bilevel System each and every night

How to connect the Hose to the device and to the Nasal Mask

How to put on the Nasal Mask and Headgear to achieve a good fit

The importance of not blocking the Bias Flow Port on the mask

The importance of not blocking the Inlet Vent on the Bilevel unit

How to use the *ComfortControl™*

How to operate the Ramp feature

How to care for the Nasal Mask, Headgear, and Hose

How to clean and/or replace the filter

How to check the operation of the Bilevel unit

What to do if symptoms of obstructive sleep apnea reappear

What to do if you experience any ear, nose or sinus pain

ANNUAL INSPECTION

We recommend that the Home Care Dealer perform a routine inspection of the Bilevel system at least once each year. This service should include: 1. Visually inspecting for any damage; 2. Replacing the filter; 3. Verifying the pressure setting; 4. Checking the condition of the Mask and Headgear.

^{**} Contact your authorized dealer for further information **

SPECIFICATIONS

Bilevel Pressure Approx. 3 to 20 cm H₂O

 Weight
 4.8 lbs., (2.3 kg)

 Height
 5.0" (12.3 cm)

 Length
 9.5" (23.6 cm)

 Width
 7.75" (18.9 cm)

Electrical Requirements 100-120/200-240 VAC

50/60 Hz, 75VA

12 Volts DC with Optional DC to AC Inverter

Warranty 1 year limited

CLASSIFICATION

IEC Class II

Type BF applied part

Protected against vertically falling water (drip proof)

Not suitable for use in the presence of a flammable anesthetic mixture with oxygen or nitrous oxide

Continuous mode of operation

STORAGE AND TRANSPORT

Temperature -25° C to 60° C

Humidity 10 - to 95% noncondensing

Atmospheric Pressure 790-523mm Hg

OPERATING

Temperature 5° C to 40° C

Humidity 10 to 95% noncondensing

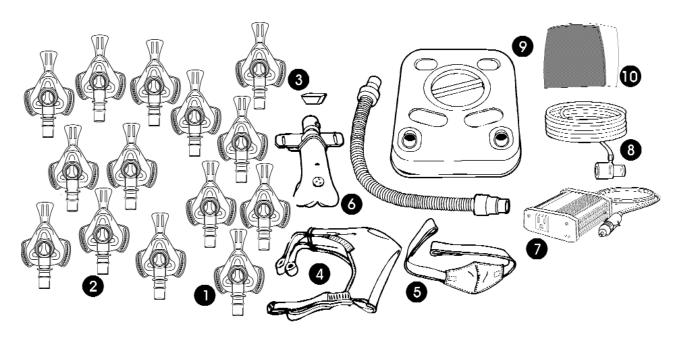
Atmospheric Pressure 790-523mm Hg

ELECTROMAGNETIC COMPATIBILITY

The Tranquility Bilevel (model 1700) is designed to comply with EN 60601-1-2: 1995, Electromagnetic Compatibility - Requirements and Tests. Move the Bilevel away from other electronic equipment if you suspect the electronic equipment is interfering with the operation of the Bilevel or if the Bilevel is interfering with the operation of other electronic equipment.

ACCESSORIES

Respironics offers a full line of accessories and replacement parts for use with the Tranquility Bilevel. These accessories include our standard (1) and Soft Series (2) nasal masks, each available in seven different sizes; a bridge support (3); the Nasal Seal (6), two styles of Headgear (4); and a chin strap (5). Also available are high grade disposable filters and replacements for the standard filter (10); a humidifier (9); and an oxygen administration kit (8) and the DC to AC Inverter (7). Contact your Home Care Dealer in order to obtain these accessories.



GLOSSARY OF TERMS

Anesthesia A drug that is used to control pain.

ComfortControlTM A feature of the Bilevel that allows you to change the way pressure is delivered.

Expiration The act of breathing out

Inspiration The act of breathing in

Interference An electrical signal that may cause the Bilevel to perform in a way that is not intended

Humidifier A device that can be used with the Bilevel to add moisture to the air that you breathe while on the unit

Linear Ramp The steady, gradual increase of pressure up to the set pressure

Microprocessor A computer located in the Bilevel that controls its action

Pressure Transducer A device located in the Bilevel that measures the amount of air pressure that you receive

Ventilator A medical device that assists or supports breathing

LIMITED WARRANTY

Respironics Inc. (Respironics) warrants each new and unused Tranquility Bilevel system (Model 1700) (hereinafter referred as Bilevel system or Unit) to be free from defects in material or workmanship for a period of twelve (12) months from the initial date of purchase from Respironics. For the purpose of this Limited Warranty, the initial date of purchase from Respironics shall be the date of shipment from Respironics to the initial owner of record. Should the Unit be defective in material or workmanship during the term of this Limited Warranty, Respironics, at its option, will repair or replace the defective Bilevel system or component parts. Replacement Units and/or parts do not carry a new warranty and shall only be warranted for the unexpired portion of the original Limited Warranty.

Specifically excluded from this Limited Warranty are ancillary items, including but not limited to, tubing, filters, nasal masks and head-gear. This Limited Warranty does not cover the Bilevel system or any component part thereof (i) which is not operated in accordance with the operating instructions contained in the Patient Manual, as amended from time to time by Respironics, or (ii) which is not maintained in accordance with the all applicable service manuals, regardless of whether such maintenance is designated as required or recommended maintenance.

This Limited Warranty shall be void and not apply:

- A. If the Bilevel system is not installed and connected in accordance with the instructions furnished by Respironics;
- B. If the serial number or letter identification of the Unit or any component part thereof has been altered, defaced or removed, or if purchaser cannot produce a bill of sale or other evidence to verify the initial purchase of the Unit.
- C. To defects arising from misuse, abuse, negligence or accident or from repair, maintenance, adjustment, modification or replacement made by anyone other than authorized Respironics Personnel; and
- D. To any charges for labor or expenses for making field replacement of warranted component parts.

THIS LIMITED WARRANTY IS IN LIEU OF ANY AND ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE; TO THE EXTENT THAT STATE OR FEDERAL LAW PROHIBITS EXCLUSIONS OF IMPLIED WARRANTIES, ANY SUCH IMPLIED WARRANTY IMPOSED BY LAW SHALL BE LIMITED TO A PERIOD OF NINETY (90) DAYS FROM THE DATE OF INITIAL PURCHASE FROM RESPIRONICS.

Respironics' responsibilities hereunder are limited to repair and replacement only. Respironics shall have no obligations or liabilities in connection with the Bilevel system other than as provided herein, including without limitation any and all obligations and/or liabilities for alleged negligence or for strict liability. In no event shall Respironics be liable of any incidental or consequential damages, either direct or contingent.

NOTE: Some states do not allow limitations on how long an implied warranty lasts, so the above limitation may not apply to you.

This Limited Warranty gives you specific rights, and you may also have other rights which vary from state to state.

The terms of this Limited Warranty may not be varied by any person, whether or not purporting to represent or act on behalf of Respironics.

To obtain service under this warranty, the owner of the Bilevel system must promptly notify Respironics of any defect in materials or workmanship and the serial number and date of purchase of the Bilevel system by calling the toll-free number: (800)345-6443. If Respironics determines that repair is required under this Limited Warranty, Respironics shall provide the owner with a Return Authorization Number. The owner must return the Bilevel system or designated parts to Respironics' factory or an authorized service center designated by Respironics. All items returned must be properly packaged, insured and shipped to Respironics, transportation charges prepaid. The costs associated with the return of the Bilevel system or component parts to Respironics for warranty services are not included in the Limited Warranty.



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