flo

RESPIRONICS

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RESPIRONICS

EverFlo™

USER MANUAL | MODE D'EMPLOI POUR LE PATIENT | MANUAL DEL PACIENTE | MANUAL DO PACIENTE

Ever*Flo*™ User Manual

Table of Contents

English

Symbol Key

	Follow Instructions for Use		AC Power
	Type BF Applied Part	**REF**	Model Number
	Class II equipment	**SN**	Serial Number
	No smoking		On (Power)
	No oil or grease		Off (Power)
	Do not disassemble	**IPX1**	Drip proof equipment
	General Alarm		Action Required, Check System Notification
CE 0123	European Declaration of Conformity		Compliant with the Waste Electrical and Electronic Equipment/Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (WEEE/RoHS) recycling directives
C SA US	Canadian/US Certification	℞ ONLY	Caution! U.S. federal law restricts this device to sale by or on the order of a physician.

Abbreviations

LED	Light Emitting Diode
LPM	Liters per Minute
OPI	Oxygen Percentage Indicator

Chapter 1: Introduction

Your health care professional has determined that supplemental oxygen is of benefit to you and has prescribed an oxygen concentrator set at a specific flow setting to meet your needs. DO NOT change the flow settings unless your health care professional tells you to do so. Please read and understand this entire manual before using the device.

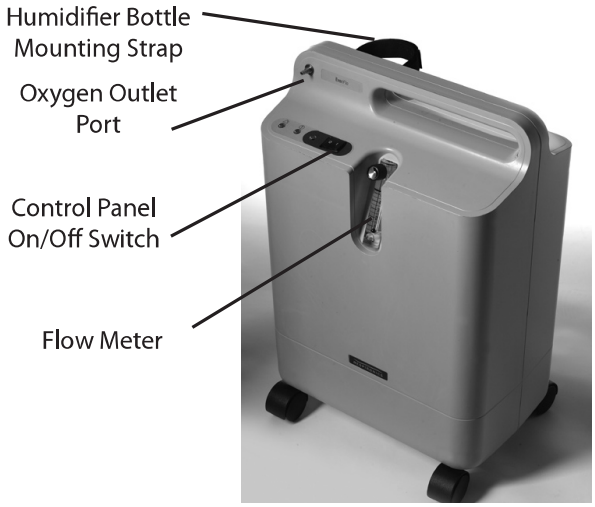
Intended Use

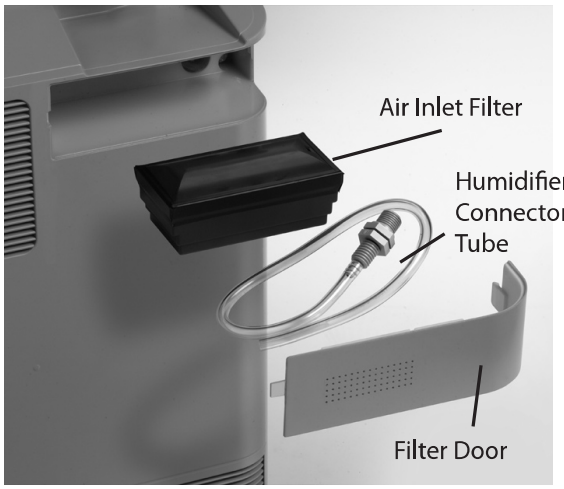
The Ever*Flo*™ Oxygen Concentrator is intended to provide supplemental oxygen to persons requiring oxygen therapy. The device is not intended to be life supporting or life sustaining.

About Your Ever*Flo*

The device produces concentrated oxygen from room air for delivery to a patient requiring low flow oxygen therapy. The oxygen from the air is concentrated using a molecular sieve and a pressure swing adsorption process. Your home care provider will show you how to operate the concentrator and will be available to answer any questions. If you have additional questions or problems, contact your home care provider.

Parts of Your Concentrator





Accessory Equipment and Replacement Parts

Contact your home care provider if you have questions about this equipment. Use only the following Respironics accessories and replacement parts with this device:

- Air Inlet Filter

- Humidifier Connector Tube

Warnings and Cautions

Caution! U.S. federal law restricts this device to sale by or on the order of a physician.

Warnings

A warning represents the possibility of harm to the operator or patient.

- For proper operation, your concentrator requires unobstructed ventilation. The ventilation ports are located at the rear base of the device and at the side air inlet filter. Keep the device at least 6 to 12 inches (15 to 30 cm) away from walls, furniture, and especially curtains that could impede adequate airflow to the device. Do not place the concentrator in a small closed space (such as a closet).
- Do not remove the covers of this device. Servicing must be referred to an authorized and trained Respironics home care provider.
- In the event of an equipment alarm or if you are experiencing any signs of discomfort consult your home care provider and/or your health care professional immediately.
- Oxygen generated by this concentrator is supplemental and should not be considered life supporting or life sustaining. In certain circumstances oxygen therapy can be hazardous; any user should seek medical advice prior to using this device.
- Where the prescribing health care professional has determined that an interruption in the supply of oxygen, for any reason, may have serious consequences to the user, an alternate source of oxygen should be available for immediate use.
- Oxygen vigorously accelerates combustion and should be kept away from heat or open flame. Not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- Do not smoke, allow others to smoke or have open flames near the concentrator when it is in use.
- Do not use oil or grease on the concentrator or its components as these substances, when combined with oxygen, can greatly increase the potential for a fire hazard and personal injury.
- Do not use the oxygen concentrator if either the plug or power cord is damaged. Do not use extension cords or electrical adapters.
- Do not attempt to clean the concentrator while it is plugged into an electrical outlet.
- Device operation above or outside of the voltage, LPM, temperature, humidity and/or altitude values specified may decrease oxygen concentration levels.
- Your home care provider is responsible for performing appropriate preventive maintenance at the intervals recommended by the device manufacturer.

Cautions

A caution represents the possibility of damage to the equipment.

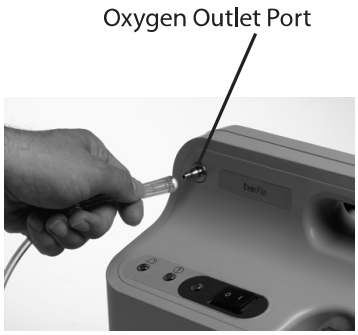
- Do not place liquids on or near the device.
- If liquid is spilled on the device, turn the power off and unplug from electrical outlet before attempting to clean up spill. Call your home care provider if device does not continue to work properly.

Chapter 2: Operating Instructions

Warning: Do not use extension cords or electrical adapters.

1. Select a location that allows the concentrator to draw in room air without being restricted. Make sure that the device is at least 6 to 12 inches (15 to 30 cm) away from walls, furniture, and especially curtains that could impede adequate airflow to the device. Do not place the device near any heat source.

2. After reading this entire manual, plug the power cord into an electrical outlet.



3A. If you are <u>not</u> using a humidifier, connect your nasal cannula to the Oxygen Outlet Port, as shown on the right.

3B. If you <u>are</u> using a humidifier, follow these steps:

a. Open the filter door on the back of the device.

b. Remove the humidifier connector tube from the back of the filter door and replace the filter door, as shown on the right.

c. Loosen the velcro strap that holds the humidifier bottle in place on top of the device and remove the bottle.

d. Fill your humidifier bottle according to the manufacturer's instructions.

e. Mount the filled humidifier on the top of the EverFlo device inside the velcro strap, as shown in the illustration on the right.

f. Tighten the velcro strap around the bottle and secure it so it is held firmly in place.

g. Connect the humidifier connector tube (that you retrieved from the filter door) to the top of the humidifier, as shown here.

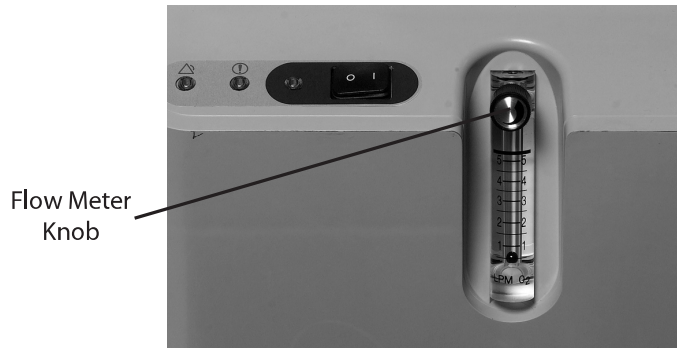
h. Connect the other end of the humidifier connector tube to the oxygen outlet port.

i. Connect your cannula to the humidifier bottle according to the humidifier bottle manufacturer's specifications

English

4. Press the power switch to the On [I] position. Initially, all the LEDs will illuminate and the audible alert will beep for a few seconds. After that time, only the green LED should remain lit. The device typically takes 10 minutes to reach oxygen purity specifications.

5. Adjust the flow to the prescribed setting by turning the knob on the top of the flow meter until the ball is centered on the line marking the specific flow rate.



6. Be sure oxygen is flowing through the cannula. If it is not, refer to the Troubleshooting Guide in this manual.
7. Put on the cannula as directed by your home care provider.
8. When you are not using the oxygen concentrator, press the power switch to the Off [O] position.

Chapter 3: Cleaning & Maintenance

Warning: It is important to unplug the device before you perform any cleaning.

Caution: Excess moisture may impair the proper operation of the device.

Cleaning

Periodically, use a damp cloth to wipe down the exterior case of the EverFlo device. If you use medical disinfectants, be sure to follow the manufacturer's instructions.

If you are using a humidifier, clean your device according to your home care provider's or manufacturer's instructions.

Service

The EverFlo Oxygen Concentrator contains no user-servicable parts.

Warning: Do not remove the covers of this device. Servicing must be referred to an authorized and trained Respironics home care provider.

How to Contact Respironics

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

Respironics
1001 Murry Ridge Lane
Murrysville, PA 15668
USA

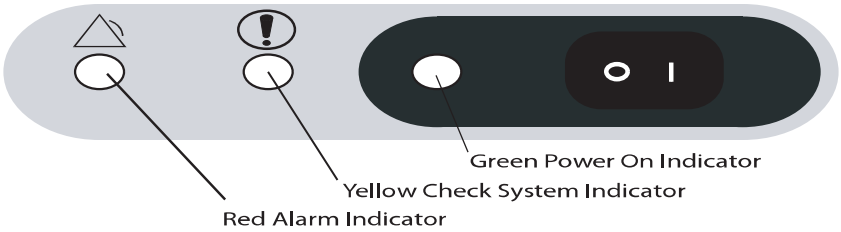
Respironics Deutschland
Gewerbestrasse 17
82211 Herrsching
Germany

Visit the EverFlo web site at: www.everflo.respironics.com

Chapter 4: Alarms and Troubleshooting

Alarm and Indicators

The device has an audible alarm and three LED indicators, as shown below.



Audible Alarm / Colored LED	Possible Cause	Your Action
The Audible Alarm is beeping continuously. None of the LEDs are illuminated.	The device is turned on but is not operating. Often this indicates that the device is not plugged in or there is a power failure.	Check the power outlet and verify that the device is plugged in. If the problem continues, connect to a back up oxygen source and call your home care provider.
Red LED illuminates continuously and the Audible Alarm is beeping continuously.	The device has detected a system malfunction.	Immediately turn off the device and wait 5 minutes. Restart the device. If the condition persists turn the unit off, connect to a back up oxygen source, and call your home care provider.
All 3 LEDs illuminate continuously and the Audible Alarm is beeping continuously.	The device has detected a system malfunction.	Immediately turn off the device, connect to a back up oxygen source, and call your home care provider.
Yellow LED illuminates continuously. The Red LED is blinking and the Audible Alarm is beeping periodically.	The device has detected an impeded oxygen flow condition.	Follow the troubleshooting guide on the next page. Connect to a back up oxygen source and call your home care provider if your troubleshooting actions fail to end this alert condition.
Yellow LED illuminates continuously. The Red LED is off and the Audible Alarm is silent.	The device has detected a low oxygen condition. (For OPI units only.)	Continue using the unit but call your home care provider about this condition.
Green LED illuminates continuously. The other LEDs are off and the Audible Alarm is silent.	The device is turned on and working properly.	Take no action.

Troubleshooting Guide

Problem	Why it Happened	What to Do
The device is not working when it is turned on. (The Audible Alarm is beeping. All LEDs are off.)	The power cord plug is not properly inserted into the electrical outlet.	Make sure the device is properly plugged in to the electrical outlet.
	The unit is not receiving power from the electrical outlet.	Check your household outlet fuse or circuit.
	Internal part failure.	Connect to a back up oxygen source and contact your home care provider.
The device is not working when it is turned on. (The Audible Alarm is beeping and all 3 LEDs are illuminated.)	Internal part failure.	Connect to a back up oxygen source and contact your home care provider.
Impeded oxygen flow indication is activated. (The Yellow LED illuminates continuously, the Red LED is blinking and the Audible Alarm is beeping.)	The airflow to the device is impeded or blocked.	Remove any items that appear to be blocking the airflow into the device.
	The flow meter knob is completely closed.	Turn the flow meter knob counterclockwise to center the ball on the prescribed LPM flow.
	The oxygen tubing is kinked and blocking the delivery of oxygen.	Check to see that the tubing is not kinked or blocked. Replace if necessary.
Limited oxygen flow to the user without any fault indication. (All LEDs are off and the Audible Alarm is silent.)	The oxygen tubing or cannula is faulty.	Inspect and replace the items if necessary.
	There is a poor connection to a device accessory.	Ensure that all connections are free from leaks.

Chapter 5: Specifications

Environmental

	Operating	Storage
Temperature	55 to 90° F (13 to 32° C)	-30 to 160° F (-34 to 71° C)
Relative Humidity	Up to 95%, noncondensing	Up to 95%, noncondensing
Altitude	0 to 7500 ft. (0 to 2286 m)	N/A

Physical

Dimensions 28.8 in. x 15 in. x 9.5 in. (58 cm x 38 cm x 24 cm)

Weight 31 lbs. (14.1 kg)

Standards Compliance

This device is designed to conform to the following standards:

- IEC 60601-1 Medical Electrical Equipment, Part 1: General Requirement for Safety
- IEC 60601-1-2 2nd edition, Medical Electrical Equipment, Part 1-2: General Requirement for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.
- ISO 8359 Oxygen Concentrators for Medical Use - Safety Requirements

Electrical

AC Power Consumption

1020000, 1020001 120 VAC ±10%, 360 W, 60 Hz
1020002, 1020003

1020004, 1020005 230 VAC ±10%, 290 W, 50/60 Hz

Oxygen

Oxygen Concentration* 93% ± 3% from 0.5 to 5 LPM

* Device operation above or outside of the voltage, LPM, temperature, humidity and/or altitude values specified may decrease oxygen concentration levels.

Classification

The EverFlo Oxygen Concentrator is classified as:

- IEC Class II Equipment
- Type BF Applied Part
- IPX1 Drip Proof
- Not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- Continuous Operation

Disposal

Dispose of the device in accordance with local regulations.

WEEE/RoHS Recycling Directives

If you are subject to the WEEE/RoHS recycling directives, refer to www.respironics.com for the passport for recycling this product.

Appendix A: EMC Information

Guidance and Manufacturer's Declaration - Electromagnetic Emissions: This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment - Guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/Flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration - Electromagnetic Immunity: This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input-output lines	±2 kV for supply mains ±1 kV for input/output lines	Mains power quality should be that of a typical home or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV for common mode	Mains power quality should be that of a typical home or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical home or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical hospital or home environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity: This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1.2\sqrt{P}$ 150 kHz to 80 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey **a**, should be less than the compliance level in each frequency range **b**. Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.
a: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the device.
b: Over the frequency range 150 kHz to 80 MHz, the field strengths should be less than 3 V/m.

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and This Device: The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this device as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum Power Output of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

English

Limited Warranty

Respironics, Inc. warrants that the Ever*Flo*™ Oxygen Concentrator device shall be free from defects of workmanship and materials and will perform in accordance with the product specifications for a period of three (3) 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.

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