



U.S. Department  
of Transportation

Pipeline and Hazardous  
Materials Safety  
Administration

1200 New Jersey Avenue, SE  
Washington, D.C. 20590

JAN 05 2015

Colleen L. Witt  
Manager, Regulatory Affairs  
Philips Respironics  
1740 Golden Mile Highway  
Monroeville, PA 15146

Ref. No. 14-0197

Dear Ms. Witt:

This responds to your October 13, 2014 letter requesting clarification of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) applicable to a portable oxygen concentrator (POC). Specifically, you inquire about obtaining approval from the Pipeline and Hazardous Materials Safety Administration (PHMSA) and the Federal Aviation Administration (FAA) to allow a passenger to carry and operate the POC aboard an aircraft.

According to your letter, the POC (trade name Respironics SimplyGo Mini POC) is a device that is for use by patients requiring high concentrations of oxygen on a supplemental basis. The maximum operating pressure of the Respironics SimplyGo Mini POC is 20.0 pounds per square inch (psig). The Respironics SimplyGo Mini POC is powered by multiple sources, including AC or DC power, and a rechargeable lithium ion battery pack. For the Respironics SimplyGo Mini POC powered by the rechargeable lithium ion battery pack, the standard battery pack has a Watt-hour (Wh) rating of 97.9 (3.4 ampere-hour (Ah) x 3.6 volts (V) x 8 cells). The lithium ion battery pack meets the appropriate testing requirements of the United Nations Manual of Tests and Criteria, and the battery pack is packaged in a manner to prevent short circuits when offered for transport or carried onboard an aircraft. You ask whether the POC is regulated under the HMR.

Based on the information provided in your letter, the Respironics SimplyGo Mini POC is not subject to the HMR as a Division 2.2 non-flammable gas. The standard lithium ion battery pack used to operate the device conforms to § 172.102(c)(1)(i) Special Provision 188, for the transportation of small lithium ion cells and batteries and the POC contains no other hazardous materials. Therefore, the Respironics SimplyGo Mini POC is not subject to any other requirements in the HMR.

Please note that notwithstanding the passenger exception in § 175.10(a)(18) of the HMR, Special Federal Aviation Regulation 106, "*Rules for Use of Portable Oxygen Concentrator Systems on Board Aircraft*" (SFAR 106) apply and are under the purview of the FAA. This response satisfies only one requirement in the FAA approval process before a POC may be operated onboard an aircraft. You may contact Ms. DK Deaderick in FAA's Flight Standards Service at (202) 267-7480 for questions regarding FAA's approval process.

I trust this satisfies your inquiry. Please contact us if we can be of further assistance.

Sincerely,

A handwritten signature in black ink, appearing to read "T. Glenn Foster". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

T. Glenn Foster  
Chief, Regulatory Review and Reinvention Branch  
Standards and Rulemaking Division

Stevens  
\$175.10  
Portable Oxygen  
Concentrator (POC)  
14-0197

**PHILIPS**

Philips Respironics  
1740 Golden Mile Highway  
Monroeville, PA 15146

October 13, 2014

Attn: Charles Betts, Director, Standards and Rulemaking Division  
US Department of Transportation/PHMSA (PHH-10)  
1200 New Jersey Avenue, SE East Building, 2<sup>nd</sup> Floor  
Washington, DC 20590

Re: Request for Determination - Respironics Portable Oxygen Concentrator (POC)

Dear Mr. Betts:

Philips Respironics is preparing to enter the market with a miniature version of the currently sold SimplyGo Portable Oxygen Concentrator (POC) and is requesting an amendment to *Special Federal Aviation Regulation 106 – Rules for use of portable oxygen concentrator systems on board aircraft* (SFAR 106). This amendment would include the Respironics SimplyGo Mini POC in the list of approved POCs for use on board aircraft. SFAR 106 permits passengers to carry on and use certain POCs on board aircraft if the aircraft operator ensures that the conditions specified in the SFAR for their use are met. Section 2 of SFAR 106 requires that PHMSA determine that the POC does not contain hazardous materials and that the requestor includes this determination in the SFAR amendment application. This letter is a request for such a determination and response by PHMSA regarding the applicability of the Hazardous Material Regulations (HMR; 49 CFR Parts 171-180).

#### Background

Philips Respironics is the principal provider of innovative solutions for the global sleep and respiratory markets. Our success spans more than three decades and can be traced to a history deeply rooted in ingenuity and a passion to deliver solutions to those in need. This tradition of innovation, combined with an ability to anticipate market needs, is fundamental to the Company. It has made Philips Respironics a name acknowledged worldwide as a pace-setter in the sleep and respiratory markets.

The Respironics SimplyGo Mini Portable Oxygen Concentrator is for prescription use by patients requiring high concentrations of oxygen on a supplemental basis. It is small, portable and capable of continuous use in the home, institutional, and travel /mobile environments.

Per the US FDA Memorandum #K97-1 “Deciding When to Submit a 510(k) for a change to an Existing Device”, it was determined that a 510(k) was not required to market the SimplyGo Mini device within the United States. This decision was based on the comparison of the SimplyGo Mini device to its predicate device, SimplyGo Portable Oxygen Concentrator. Therefore, the SimplyGo Mini Portable Oxygen Concentrator is cleared under the SimplyGo Portable Oxygen Concentrator premarket notification number 510(k) K111885. A copy of the SimplyGo Portable Oxygen Concentrator 510(k) clearance letter is attached, along with a copy of the SimplyGo Mini User Instruction Manual.

### Performance Specifications and Device Description

The SimplyGo Mini is a portable oxygen concentrator intended to deliver at least 87% pulsed oxygen to the patient. The device has an integrated conserving device which triggers a pulse of oxygen by sensing pressure at the onset of inspiration. The SimplyGo Mini delivers fixed pulse volumes up to a maximum minute volume per setting on the device. The volume of the dose varies based on the user selected settings.

The SimplyGo Mini POC will operate using any of the multiple power sources listed below:

- Rechargeable batteries (single battery and double battery)
- A/C Adapter
- 12v D/C car Adaptor

### Users

The SimplyGo Mini POC will be used by patients requiring supplemental oxygen. These patients are typically COPD patients. The patient using this device will be ambulatory and will be looking to improve their mobility versus other forms of supplemental oxygen. Some patients may have limited vision and hearing.

### Environments of Use

The SimplyGo Mini POC is intended to be used during travel wherever the patient might want to go. Therefore, the device may be used in both good and bad weather conditions. The SimplyGo Mini Portable Oxygen Concentrator is designed to fit easily under the seat of a commercial aircraft, permitting the user to travel by air with their prescribed oxygen therapy.

Specifications

Operating Conditions	Operational temperature: 41° F to 95° F (5° C to 35° C) Relative humidity: 15% to 93% Altitude: up to 10,000 ft. (3048 m.)
Storage Conditions	-4° F to 140° F (-20° C to 60° C) - unit only Relative humidity: up to 93%, non condensing

Oxygen Concentration*	At least 87% at all settings
Flow Settings and Pulse Volumes	Pulse Modes (pulse volumes at 20 breaths per minute) 1 = 11 ml 2 = 22 ml 3 = 33 ml 4 = 44 ml 5 = 50 ml  +/- 15% or 5 ml whichever is greater for 20 consecutive breaths Up to a max of 1000 ml/min +/- 100 ml
User Interface	TFT LCD w/Projective Capacitive Touch Screen
Dimensions	9.4 in x 8.3 in x 3.6 in (single battery) (23.9 cm x 21.1 cm x 9.1 cm)  10.2 in x 8.3 in x 3.6 in (double battery) (25.9 cm x 21.1 cm x 9.1 cm)
Weight	5 lbs (2.3 kg) with single battery installed 6 lbs (2.7 kg) with double battery installed
Audio Alarm	56 decibels or greater when measured at 1 meter
Outlet Pressure	20 psig
*Based on an atmospheric pressure of 14.7 psia (101 kPa) at 70° F (21° C)	

## SimplyGo Mini Battery

Chemistry	Lithium Ion 14.4 VDC (nominal)
Battery Options	Single battery Double battery (equals two single batteries)
Dimensions	7.9 in x 3.6 in x 1.0 in (single battery) (20.1 cm x 9.1 cm x 2.5 cm)  7.9 in x 3.6 in x 1.9 in (double battery) (20.1 cm x 9.1 cm x 4.8 cm)
Weight	1.1 lbs (single battery) (0.50 kg) 2.1 lbs (double battery) (0.95 kg)
Watt-hour Rating per single battery	3.4 Ah x 3.6 V x 8 cells = 97.9 Wh
Battery Duration	4 hours (Pulse setting of 2 at 20 bpm with single battery) 8 hours (Pulse setting of 2 at 20 bpm with double battery)
Charge Time	Maximum recharge time is 4 hours for the single battery and 8 hours for the double battery from fully discharged to fully charged, depending on the power source and usage.

## AC Power

Type	Philips Respironics Part Number 1116818
Input	100 to 240 VAC, 50/60 Hz
Output	19 VDC, 6.3 A
Power Consumption	120 W while charging

## DC Power

Type	Philips Respironics Part Number 1116819
Input	12-16 VDC
Output	19 +/- 5% VDC, 6.3A

## Standards Compliance

The SimplyGo Mini POC is designed to conform to the following standards:

- IEC 60601-1 3<sup>rd</sup> edition, Medical Electrical Equipment, Part 1: General Requirement for Safety
  - IEC 60601-1-2 Medical Electrical Equipment, Part 1-2: General Requirement for Safety – Collateral Standard: Electromagnetic (EMC) Compatibility – Requirements and tests.
- RTCA/DO-160F section 21, category M; Emission of Radio Frequency Energy
- ISO 8359, Oxygen Concentrators for Medical use – Safety Requirements.
- ISO 80601-2-67, Medical electrical equipment, Part 2-67: Particular requirements for basic safety and essential performance of oxygen-conserving equipment.
- ISO 80601-2-69, Medical electrical equipment, Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment.

## Classification

The SimplyGo Mini POC is classified as:

- IEC Class II Internally Powered Equipment
- Type BF Applied Part
- IP22: Drip Proof Equipment
- Not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- Continuous Operation

Specifically, the following characteristics relate to the SimplyGo Mini POC and its battery pack:

1. The maximum operating pressure of the SimplyGo Mini POC is 20 psig. This maximum operating pressure limit is a shutdown condition controlled by a pressure sensor within the device.
2. Each single lithium ion battery pack satisfies the requirements of § 173.185(c)(1)(i) which states that the Watt-hour rating may not exceed 20 Wh for a lithium ion cell or 100 Wh for a lithium ion battery and be marked with the Watt-hour rating on the outside case. The battery pack meets the requirements of each test in the UN Manual of Tests and Criteria.
3. The lithium ion battery pack satisfies the requirements of § 173.21(c) which states that an electrical device is forbidden for transportation unless it is packaged in a manner to preclude it from creating sparks or generating a dangerous quantity of heat (for example, by the effective

insulation of exposed terminals). The SimplyGo Mini battery pack has no exposed terminals which could be the source of a short circuit. The safety profile of the battery pack includes safety circuit to protect against over current, over voltage and over temperature conditions. In addition, there are also single fault tolerances for both over-current and over-temperature safety protection provided by a current limiting fuse and over-temperature thermal fuse. All safety systems when activated shut down operation of the battery assembly.

Based on the information provided above, we respectfully submit that the SimplyGo Mini POC is not currently subject to the HMR because it meets the following criteria:

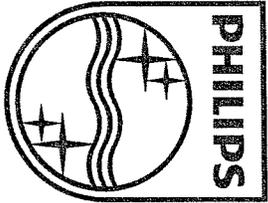
- (1) The pressure of the oxygen in the device does not exceed 40.6 psia at 20°C;
- (2) The lithium ion battery used to operate the device is exempted from the HMR;
- (3) The battery pack is packaged in a manner to preclude it from creating sparks or generating a dangerous quantity of heat (for example, by the effective insulation of exposed terminals);  
and
- (4) The SimplyGo Mini POC contains no other materials subject to the HMR.

Thank you in advance for your assistance, consideration and review of our request. If you require additional information, please feel free to contact me at (724)387-4870; by fax at (724)387-7490 or by email at [colleen.witt@philips.com](mailto:colleen.witt@philips.com).

Sincerely,

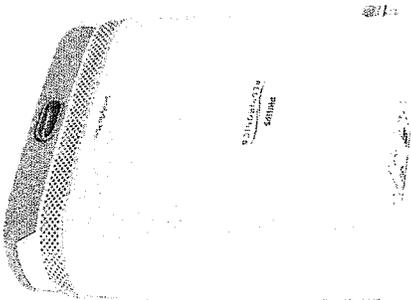


Colleen L. Witt  
Manager, Regulatory Affairs



Respironics Inc.  
1001 Murry Ridge Lane  
Murrysville, PA 15668 USA

REF 1118724  
1117717 R00  
JH 10/08/2014



SimplyGo Mini



**PHILIPS**  
RESPIRONICS

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## **Introduction**

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### **Intended Use**

The Philips Respironics SimplyGo Mini Portable Oxygen Concentrator is for prescription use by patients requiring high concentrations of oxygen on a supplemental basis. It is small, portable, and is capable of continuous use in the home, institutional, and travel /mobile environments.

### **Contraindications**

- This device is not intended to be life-sustaining or life-supporting.
- This device is not intended for newborn and infant use.

### **Device and Accessories Description**

The SimplyGo Mini Portable Oxygen Concentrator, its features, and its accessories are described in detail in this manual. Read and understand it completely before operating the device.

This manual applies to the following accessories:

- AC Power Supply
- AC Power Cord
- DC Power Supply
- Rechargeable Lithium Ion Standard and Extended Batteries
- Carrying Case
- Accessory Bag

This manual does not apply to the following accessory items sold separately:

- Standard Single Lumen Nasal Cannula
- Battery Charger
- SimplyGo Mini Backpack

## SimplyGo Mini User Manual

### SimplyGo Mini System

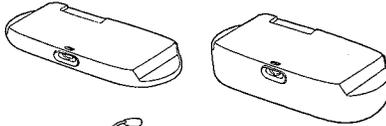
The device comes with the following items. If any are missing, contact your equipment provider.

- SimplyGo Mini Device in Carrying Case with Shoulder Strap

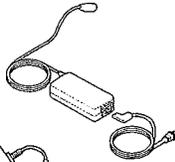


- This User Manual

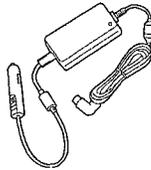
- Standard or Extended Rechargeable Batteries



- AC Power Supply and Cord



- DC Power Supply



- Accessory Bag



## 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.

- The operator should read and understand this entire manual before using the device.
- The device is not intended for life support. 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.
- Geriatric or any other patient unable to communicate discomfort, or hear or see the alarms while using this device, may require additional monitoring.
- If you feel discomfort or are experiencing a medical emergency while undergoing oxygen therapy, seek medical assistance immediately to avoid harm.
- The oxygen delivery settings of the oxygen concentrator should be periodically reassessed for the effectiveness of the therapy.
- Set the device at the prescribed level and do not increase or decrease your flow rate from the prescribed level until you first consult with your physician or healthcare professional.
- Oxygen supports combustion. Oxygen should not be used while smoking or in the presence of an open flame.
- Do not use the device in the presence of a flammable anesthetic mixture in combination with oxygen or air, or in the presence of nitrous oxide.
- 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.
- Only use this device as prescribed. The use of oxygen therapy can be hazardous in some circumstances, so consult your health care practitioner before using the SimplyGo Mini device.
- To ensure that you receive the correct therapeutic amount of oxygen delivery according to your medical condition, the Philips Respironics

## SimplyGo Mini User Manual

### Warnings (continued)

SimplyGo Mini device must be used:

- Only after one or more settings have been individually determined or prescribed for you at your specific activity levels
- With the specific combination of parts and accessories that are in line with the specification of the oxygen concentrator manufacturer and that were used while your settings were determined
- The settings of the Philips Respironics SimplyGo Mini device might not correspond with continuous flow oxygen.
- The settings of other models or brands of oxygen therapy equipment do not correspond with the settings of the Philips Respironics SimplyGo Mini device.
- Use only water-based lotions or salves that are oxygen compatible during setup or use during oxygen therapy. To avoid the risk of fire and burns, never use petroleum or oil-based lotions or salves.
- If you notice any of the following, discontinue use and contact your home care provider:
  - unexplained changes in the performance of this device
  - unusual or harsh sounds
  - dropped or mishandled device or the power supply
  - water spilled into the enclosure
  - broken enclosure
- Oxygen makes it easier for a fire to start and spread. Do not leave the nasal cannula on bed coverings or chair cushions if the oxygen concentrator is turned on, but not in use; the oxygen will make the materials flammable. Turn the oxygen concentrator off when not in use.
- To ensure proper function and to avoid the risk of fire and burns:
  - Use only with Philips Respironics SimplyGo Mini AC power supply.
  - Use only with Philips Respironics SimplyGo Mini batteries.
  - Use only approved SimplyGo Mini accessories.
- Incompatible parts or accessories can result in degraded performance.
- Repairs and adjustments must be performed by Philips Respironics authorized service personnel only. Unauthorized service could cause

## SimplyGo Mini User Manual

- injury, invalidate the warranty, or result in costly damage.
- Periodically inspect electrical cords, cables, and the power supply for damage or signs of wear. Discontinue use and replace if damaged.
  - To avoid electric shock, unplug the device and remove the batteries before cleaning the bag. DO NOT immerse the device in any fluids.
  - Your home care provider is responsible for performing appropriate preventive maintenance at the intervals recommended by Philips Respironics.
  - For proper operation, your device requires unobstructed ventilation. Always make sure any openings in the case are not obstructed by items which may impede ventilation. Do not place the device in a small closed space (such as a closet). The device should not be used adjacent to or stacked with other equipment. For more information, contact your home care provider.
  - Do not use an extension cord.
  - Device operation above or outside of the voltage, breath rate, temperature, humidity and/or altitude values specified may decrease oxygen concentration levels.
  - Never drop or insert any object into any opening.
  - Be aware that the electrical cord and/or tubing could present a tripping or strangulation hazard.
  - Use only power cords supplied by Philips Respironics for this device. Use of power cords not supplied by Philips Respironics may cause overheating or damage to the device and may result in increased emissions or decreased immunity of the equipment or system.
  - Do not operate without the battery installed and working. If primary power is lost with no battery in place, the device will stop operating without warning the user. If the device must be operated without the battery, the user should be aware that there is no backup power and no warning if primary power is lost.
  - If the SimplyGo Mini device will not be used for a long period of time, remove the battery from the device.
  - Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.
  - Place the device in a location so as to avoid pollutants and fumes.
  - Portable and Mobile RF Communications Equipment can affect Medical Electrical Equipment. See the EMC section of this manual for

## SimplyGo Mini User Manual

distances to observe between RF Generators and the SimplyGo Mini device to avoid interference.

- The use of cables and accessories other than those approved for use by Philips Respironics may negatively affect EMC performance.

## Cautions

A caution represents the possibility of damage to the equipment.

- Do not immerse the device or allow any liquid to enter the enclosure.
- When the device is used in an automobile, disconnect it from the DC auto adapter outlet when the automobile is turned off. Do not operate the device in a non-running vehicle for an extended period of time, as this may deplete the vehicle's battery and prevent the vehicle from starting. Do not allow the device to be connected to the auto adapter outlet while starting the automobile normally or while you are starting the automobile with battery recharging cables. Wait until the automobile starts before connecting the device to the DC power outlet. Secure the device securely when used in any moving vehicle. (The same cautions apply if using the DC adapter outlet on a boat or recreational vehicle.)
- Turn off the device before removing the battery. The device should not be operated without the batteries installed. If the device is operated without the batteries installed, the standard shut-down routine will not be implemented when the power is disconnected prior to turning off the unit. This can result in damage to the device.
- Only use the supplied handle and shoulder strap to carry your device. With every use, verify that the case, shoulder strap and handle are in good condition.

**Note:** Additional warnings, cautions, and notes are located throughout the manual.

## Symbol Key

	Consult accompanying instructions for use		Model number
	No smoking		Serial number
	No oil or grease		Type BF Applied Part
	Keep away from open flames		Rechargeable Battery
	Do not disassemble	<b>IP22</b>	Drip proof equipment
	DC power		AC Power
	Caution: U.S. federal law restricts this device to sale by or on the order of a physician.		Class II (Double Insulated)

**Note:** Also see the section on alarm indicators and screen symbols.

## How to Contact Philips Respironics

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

Respironics Inc.  
1001 Murry Ridge Lane  
Murrysville, PA 15668 USA

## SimplyGo Mini User Manual

### Getting Started

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Attach the shoulder strap(s) to the carrying case.

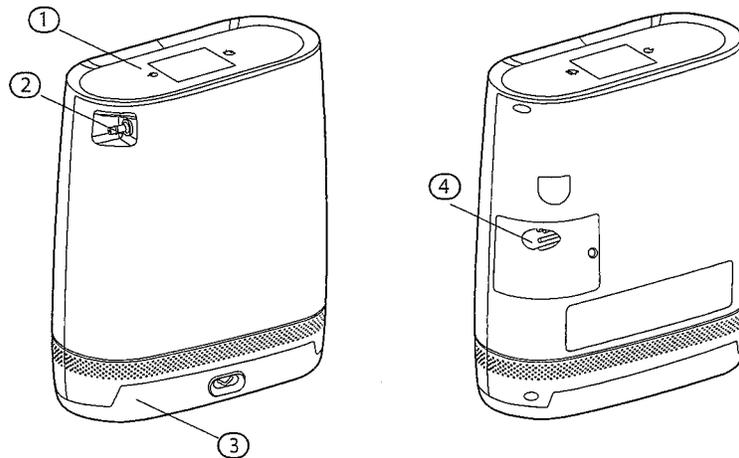
Before using the SimplyGo Mini device for the first time, the SimplyGo Mini standard or extended batteries require an initial uninterrupted charging time of 3.5 hours minimum for the standard and 7 hours minimum for the extended battery. This can be accomplished by installing the battery and using the AC Power Cord, as described in the following pages. Or optionally, you can use the Smart Battery Charger to charge the SimplyGo Mini batteries.

**Note:** Philips Respironics does not recommend using DC power for this initial charging.

**Caution:** Use only Philips Respironics batteries in your SimplyGo Mini device. Using other batteries could damage the device and will void the warranty. Remove the battery if the SimplyGo Mini will not be used for an extended period of time.

### System Overview

Begin by becoming familiar with your SimplyGo Mini device.



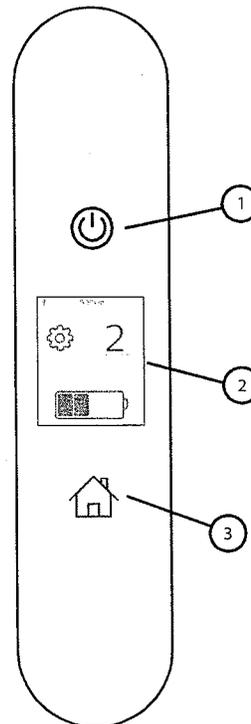
Item	Description	Function
1	Control Panel	TFT LCD with projected capacitive touch screen

## SimplyGo Mini User Manual

2	Patient Cannula Connector	Oxygen output and connection point for patient cannula
3	Rechargeable Battery	Standard or extended rechargeable lithium-ion battery
4	Power Input Connector	Connection point for Philips Respironics-provided external power supplies: AC line voltage, vehicle DC

### Control Panel

Item	Description	Function
1	Power Button	Turns the device On and Off
2	Display Screen	Shows information about the operating status of the device and device settings.
3	Home Button	Accesses the Home screen from any screen.



## SimplyGo Mini User Manual

### Battery Duration Times

The following table displays the approximate battery duration times for the standard and extended rechargeable batteries when the batteries are fully charged.

SETTING	STANDARD BATTERY	EXTENDED BATTERY
1	4.5 hours	9.0 hours
2	3.5 hours	7.0 hours
3	2.5 hours	5.0 hours
4	2.0 hours	4.0 hours
5	1.5 hours	3.0 hours

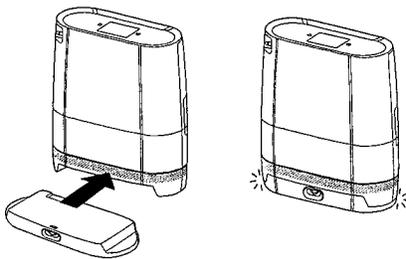
### Inserting and Removing the Batteries

You can use a standard battery or extended battery with your SimplyGo Mini device. They are inserted using the same method. To insert the batteries, complete the following steps:

1. Place your device in a well-ventilated location and make sure it is turned off.

**Note:** The SimplyGo Mini device is shipped from the factory with the battery removed.

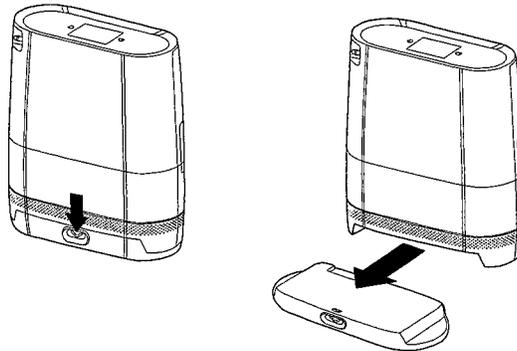
2. Hold the SimplyGo Mini device in one hand, and use your other hand to insert the battery compartment into the bottom of the SimplyGo Mini as shown in the following illustration.



**Caution:** Only remove the battery when the SimplyGo Mini is turned off. Never remove the battery while the device is operating.

## SimplyGo Mini User Manual

- To remove the standard or extended battery, push the eject button on the center of the battery compartment down as shown in the following illustration. The battery will release from the device. If the device has been operating, the surfaces may be warm to the touch. This is normal.



- When the standard or extended battery is not installed, you can check the battery gauge on the battery to determine the amount of charge available.

If you are using the standard battery, press the black button on the battery and watch how many LEDs light up. If using the extended battery, press the two black buttons and watch how many LEDs light up. If the batteries are low, you can recharge them. See the *Charging the Battery with AC Power Supply* section.

Standard Battery No. of LEDs	Extended Battery No. of LEDs	Battery Charge
4 LEDs Light:	8 LEDs Light:	75% to 100% full
3 LEDs Light:	6 LEDs Light:	50% to 75% full
2 LEDs Light:	4 LEDs Light:	25% to 50% full
1 LED Lights:	2 LEDs Light:	10% to 25% full
1 LED Blinks 3 Times:	2 LEDs Blink 3 Times:	Battery is less than 10% full and needs to be recharged

## SimplyGo Mini User Manual

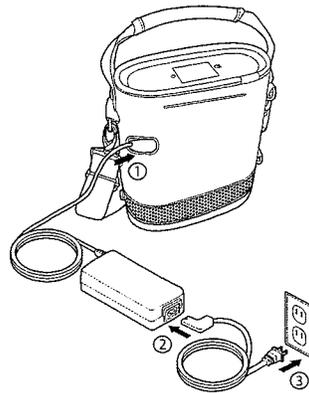
### Charging the Battery with the AC Power Supply

**Important:** The first time you charge the battery, be sure to charge it fully. Do not use the DC power cord to do so; instead use AC power.

**Note:** The battery will begin charging whenever you connect the device to an AC outlet, regardless of whether or not it is in use.

To charge the battery using the AC Power Cord provided with your system, follow these steps.

1. Connect the AC Power Supply's output cable to the SimplyGo Mini power input connector.
2. Connect the AC Power Cord's connector into the AC power supply.
3. Connect the AC Power Cord's plug into an AC outlet installed to meet national or regional electrical code.



**Note:** The AC Power Supply is equipped with a green light, which illuminates as soon as you connect the device to an energized AC power source.

4. When charging is complete (this takes four hours or less for the standard battery), disconnect the AC Power Supply and store it with the AC Power Cord for future use.

**Note:** Replacement and spare batteries are available separately. For information, contact your home care provider.

**Note:** An optional SimplyGo Mini Smart Battery Charger (sold separately) is available for your system. For more information, contact your home care provider.

## **Operating the SimplyGo Mini Device**

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### **Power Options**

**Warning:** Do not use the device without the battery installed and operating.

- To run the device on battery power, make sure the battery is properly inserted and sufficiently charged. (The battery should be fully charged the first time you use it.)
- **To run the device using AC power**, first make sure you have a battery installed. Then, follow these steps:
  1. Connect the output cable of the AC Power Supply to the SimplyGo Mini power input connector.
  2. Connect the AC Power Cord's connector into the AC power supply.
  3. Connect the AC Power Cord's plug into an AC outlet installed to meet national or regional electrical code.

**Note:** • **To run the device using DC power** from an automobile or other motorized vehicle, make sure the battery is installed. Start the vehicle and connect one end of the DC Power Cord to the device's power inlet and the other end into the vehicle's DC electrical outlet.

Because the amount of current available in the vehicle electrical system is limited, the current available to charge the SimplyGo Mini battery will be determined by the operating mode of the device. At high settings, the time required to charge the battery will be much longer, and at the highest settings, it may not charge at all.

### **Device Warm-Up**

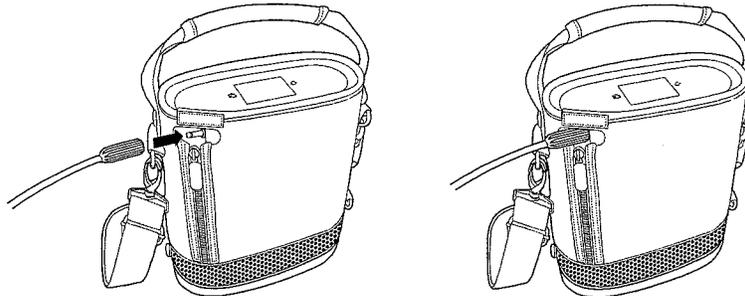
When you turn on your SimplyGo Mini device, it will sense if you are breathing from it. If you are not yet breathing through the cannula, SimplyGo Mini will begin to pulse automatically about once every five seconds. As soon as you begin breathing through the cannula, the device will begin delivering pulses based on your breathing. It may take up to 20 minutes for the SimplyGo Mini output to stabilize within its O<sub>2</sub> purity specifications. However, you may begin breathing from the SimplyGo Mini at any time. During the initial stabilization period, the displayed O<sub>2</sub> setting number will blink. It will stop blinking when the output is stabilized and within the target specification.

## SimplyGo Mini User Manual

### Setting up the Cannula and Tubing

To set up the SimplyGo Mini device, follow these steps.

1. Connect a nasal cannula to the patient cannula connector on the device, as shown. Ensure that the cannula is routed to prevent it from being pinched or kinked to avoid a disruption of oxygen flow.



**Note:** A standard single lumen nasal cannula and tubing (not supplied) should be used to deliver oxygen from the SimplyGo Mini device. The device works with cannula tubing up to 30 ft. (9 m).

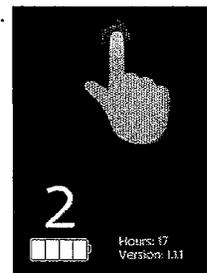
2. Power on the device as described in the next section.
3. Position the nasal cannula on your face, as shown below, and breathe normally through your nose.



### Powering on the Device

1. You can press the Power button once or simply touch the black screen on the device to quickly view your settings. The screen shown here will appear with the following information displayed:

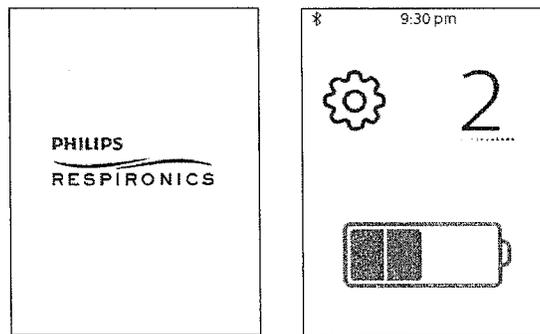
- O<sub>2</sub> setting
- Battery capacity
- Number of hours the device has been used
- Software version



## SimplyGo Mini User Manual

The screen will automatically shut off again after 5 seconds.

2. If you want to fully power on the device, press the Power button a second time. This second press helps prevent unwanted starts or inadvertent changes in oxygen flow. The Philips Respironics splash screen appears briefly followed by the Home screen, both shown below.



Every time it starts up, the device starts producing oxygen to meet the specified setting. It may take up to 20 minutes to reach the specified purity levels for the setting. It is safe to begin breathing from the SimplyGo Mini device immediately. Breathing from the device will cause it to reach oxygen purity levels faster.

**Note:** When it is turned on, the device will automatically start at the oxygen flow rate setting used when the device was last turned off. As a precaution, each time you start the device, verify the flow setting.

### Powering Off the Device

1. To turn the device off, press the Power button and the confirmation screen shown here appears.
2. Press the Power button a second time to turn the device off.

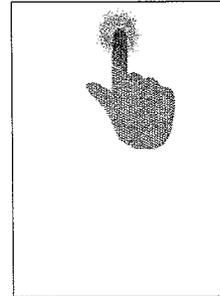
**Note:** If you do not press the Power button a second time, the screen will return to the Home screen.

## SimplyGo Mini User Manual

### Device Backlight

The device features a backlight that turns on automatically whenever:

- You touch the screen
- An alarm occurs
- The device is plugged into an external power supply
- A battery is inserted into the device



The backlight automatically shuts off after one minute of inactivity, as a power-saving feature.

### Navigating the Display Screens

As you access each of the display screens, there are some common actions you can take to move from screen to screen, adjust settings, return to a previous screen, etc.

- Press the Home button (🏠) from any of the display screens if you want to quickly return to the Home screen.
- If a screen has + and - buttons at the bottom, press those to scroll through setting selections and choose the desired setting.
- The Device Tools menus may also have < and > buttons at the bottom. Press these to scroll back and forth through the items you want to modify (for example, the hour and minute settings within the Time menu), and select the data you need to change.

**Note:** If you've reached the limit for a setting, then the < or > buttons will appear gray on the screen and will be disabled.

- The Device Tools menus may also have an ↶ in the top left corner of the screen. Press that arrow to return to the previous screen.

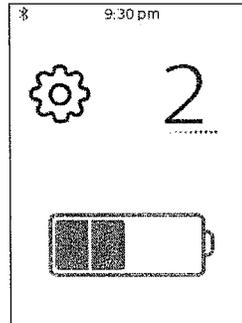
## Viewing and Changing Settings

This section describes how to view and change settings on the SimplyGo Mini device.

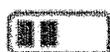
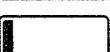
### Home Screen

The Home screen shown here contains three main items:

- Tool icon
- O<sub>2</sub> Setting
- Battery Charge Level



Additionally, the Status bar at the top of the screen displays the following:

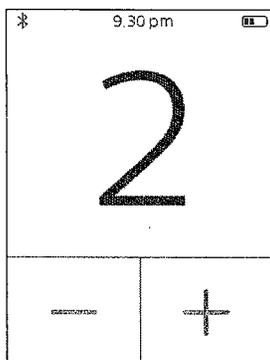
SYMBOL	DESCRIPTION
	The device has detected an active alarm.
	An active alarm has been silenced but not resolved.
	A battery is installed in the device, and AC power is also connected.
	Battery level is normal.
	Battery level is low.
	Battery level is depleted.

## SimplyGo Mini User Manual

### Changing the O<sub>2</sub> Setting

To change the O<sub>2</sub> setting, complete the following steps:

1. Touch the O<sub>2</sub> number shown on the Home screen to access the O<sub>2</sub> Settings screen, shown below.



2. Press the + or - buttons to scroll up and down and increase or decrease the O<sub>2</sub> setting as needed. You can adjust the setting from 1 to 5 in increments of 1.

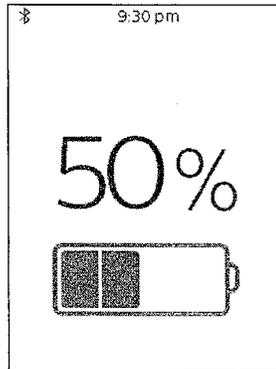
**Note:** When you've reached the setting limit, the + or - symbols will be greyed out to indicate that they are disabled and can no longer be selected.

The device detects when the user begins to take a breath and then delivers a pulsed volume of oxygen during the inhalation period. The volume of the oxygen pulse is dependent on the setting value. If no breath is detected for a period of time, the system automatically delivers the pulsed volume of oxygen determined by the setting number at a fixed rate of 12 breaths per minute. If no breath is detected for 2 minutes, the device signals an alarm and shuts down after 15 minutes if the device is running on battery power.

### Checking the Battery Status

To check the battery status, complete the following steps:

1. Touch the battery symbol on the Home screen to access the Battery Information screen, shown below.

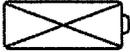


The battery percentage number appears on the screen to indicate how much battery power is left, and the battery level symbol appears below the number.

The table below describes each of the battery symbols:

SYMBOL	DESCRIPTION
	Battery level at 25%
	Battery level at 50%
	Battery level at 75%
	Battery level at 100%
	Battery charging or battery charge complete <b>Note:</b> The green battery bar blocks will scroll while the battery is charging and this symbol appears. Once fully charged, the battery blocks stop scrolling and one long beep sounds.
	Low battery - indicates battery level is below xx%

## SimplyGo Mini User Manual

SYMBOL	DESCRIPTION
	Battery depleted
	AC power connected; no battery installed

## Accessing the Device Tools Menu

There are two device tool menus:

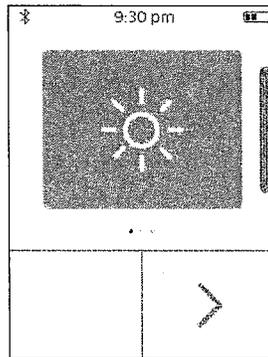
- Brightness menu
- Alarm Log menu

To access the Device Tools menu, complete the following steps:

### Change the Brightness Setting

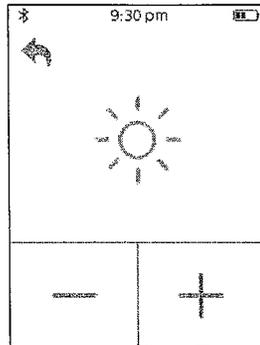
1. Touch the Tool icon (  ) on the Home screen to access the Device Tools Menu. The Brightness menu screen appears first, shown below.

**Note:** You can use the < and > buttons to scroll to the Date and Time Settings menu or Alarm Log menu if desired.



2. Press on the Brightness icon to access the Brightness setting screen, shown below.

## SimplyGo Mini User Manual

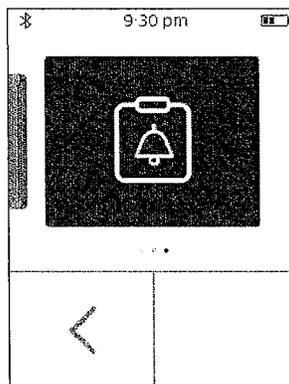


3. Press the + and - buttons to scroll through the three brightness settings and choose the desired brightness.

**Note:** If you want to exit the Device Tools menu and return to the previous screen, press the arrow in the top left corner of the screen.

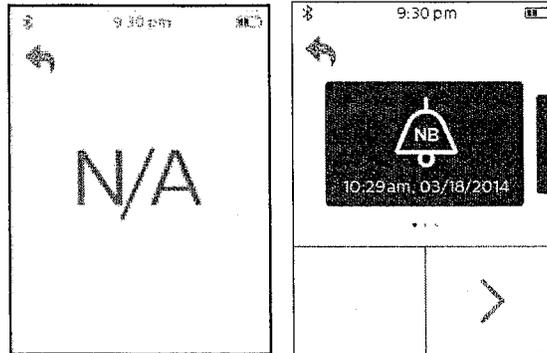
### Access the Alarm Log Menu

1. Press the  to return to the Tools menu, and press the < and > buttons to navigate to the Alarm Log menu, shown below.



2. Press on the Alarm Log tile to access the screens shown below. If no alarms have ever occurred, the screen shown on the left will appear. Otherwise, a screen similar to the one on the right appears.

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3. You can view the type of alarm that occurred and the start time and date of the alarm on the Alarm Log screen.
4. Press the < and > buttons to navigate through the list of alarms in the log history. The log will list at a minimum the 16 most recent alarms.

### Notes:

- The alarm log is maintained between device Power Off and Power On cycles (the time of Power Off is not logged).
- The most recent alarm events in the log from the current Power On session may be lost if the device experiences a total loss of power and improperly shuts down.
- The alarm log maintains the most recent 16 alarms and will discard the oldest data once its memory is full and a new alarm occurs.

## Alarm Indicators and Screen Symbols

Visual, Audio Indicators	Description	What To Do
<p>NEED TO ADD SCREEN TBD</p> <p>1 beep that repeats every 15 seconds</p>	<p><b>No Breath Alarm</b></p> <p>This alarm occurs when a breath is not detected for a period of 2 minutes or more. It can be silenced by pressing the Alarm symbol. This alarm resets itself as soon as a breath is detected. If the device is on battery power and no breath is detected after approximately 15 minutes, the device shuts down to conserve power. (This alarm is inactive for ten minutes after startup.)</p>	<p>Check the connection from the cannula to the device. Make sure the nasal cannula is properly positioned on your face and that you are breathing through your nose. Make sure the cannula tubing is not kinked or obstructed.</p>
<p>NEED TO ADD SCREEN TBD</p> <p>1 beep that repeats every 15 seconds</p>	<p><b>Low Oxygen Concentration Alarm</b></p> <p>This alarm occurs when the device is delivering a lower concentration of oxygen than specified. Note: This alarm occurs when the internal O<sub>2</sub> sensor reads &lt; 82% O<sub>2</sub>. This alarm will turn off if the system is able to recover from the fault and achieve &gt;84% O<sub>2</sub>.</p> <p>If in normal operation, the internal oxygen sensor monitors O<sub>2</sub> purity during the warmup period and then at 1 hour intervals after that.</p>	<p>Change to another source of oxygen and contact your equipment provider.</p>

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Visual, Audio Indicators	Description	What To Do
<p>NEED TO ADD SCREEN TBD</p> <p>1 beep that repeats every 15 seconds</p>	<p><b>High Breath Rate Alarm</b></p> <p>This alarm indicates that the user's breath rate is exceeding the maximum pulse rate of the device. The device is still working properly and is still providing the maximum amount of oxygen for the user's setting.</p>	<p>The indicator resets itself when the breath rate is reduced. If this indicator regularly occurs, contact your home care provider.</p>
<p>NEED TO ADD SCREEN TBD</p> <p>1 beep that repeats every 15 seconds</p>	<p><b>Technical Fault Alarm</b></p> <p>This alarm occurs when the device has a general malfunction and the device is no longer operating properly. The device may or may not shut down depending on the severity of the alarm.</p>	<p>Change to another source of oxygen and contact your home care provider.</p>
<p>NEED TO ADD SCREEN TBD</p> <p>1 beep that repeats every 15 seconds</p>	<p><b>Low Battery Alarm</b></p> <p>This alarm occurs when approximately 10 minutes of battery life remains. Remaining battery life is dependent on your device settings and your activity level. The empty battery symbol flashes on-screen.</p>	<p>Replace the battery or connect to a power source.</p>
<p>NEED TO ADD SCREEN TBD</p> <p>1 beep that repeats every 15 seconds</p>	<p><b>No Flow Alarm</b></p> <p>This alarm occurs when the device detects there is no oxygen flowing in the patient cannula.</p>	<p>Check the cannula for kinks or other obstructions that are stopping oxygen flow through it.</p>

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Visual, Audio Indicators	Description	What To Do
<p>NEED TO ADD SCREEN TBD</p> <p>1 beep that repeats every 15 seconds</p>	<p><b>Depleted Battery Alarm</b></p> <p>This alarm occurs when approximately two minutes of battery life remains. The battery symbol flashes on-screen.</p>	<p>Replace or recharge battery.</p>
	<p><b>Alarm Symbol</b></p> <p>This symbol appears when an event occurs that generates an audible alarm.</p>	<p>Refer to the associated alarm indicator also being displayed.</p>
	<p><b>Alarm Silenced Symbol</b></p> <p>This symbol appears when you have pressed the alarm silence button on the control panel to silence an audible alarm.</p>	<p>Refer to the associated alarm indicator also being displayed.</p>
	<p><b>Attention</b></p> <p>This symbol appears when corrective action is required.</p>	<p>If the device is operating in the carrying case, make sure it has been placed correctly in the case so that the outlet vents are not blocked. See the <b>Carrying Case</b> section of this manual.</p> <p>Allow the device to warm up. If the alarm continues, contact your home care provider.</p>

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Visual, Audio Indicators	Description	What To Do
TBD	<p><b>Battery Charging While Almost Empty Symbol</b></p> <p>This battery symbol appears (with the charging bars scrolling) when the battery is almost depleted and recharging.</p>	No action needed.
TBD	<p><b>Battery Charging While Partly Full Symbol</b></p> <p>When a battery symbol similar to this appears (with the charging bars scrolling), the battery is partly full and recharging.</p>	No action needed.
TBD	<p><b>Battery Charge Complete Symbol</b></p> <p>This battery symbol appears when the battery is fully charged.</p>	No action needed.
	<p><b>Power Connection Symbol</b></p> <p>This symbol appears when the device is connected to an AC, DC, or airline power source.</p>	No action needed.
(Power Connection Symbol Disappears)	<p>The Power Connection symbol disappears when the device is disconnected from the power source.</p>	No action needed.

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Visual, Audio Indicators	Description	What To Do
 <p>1st press of the Power button = 1 long beep.</p> <p>2nd press of the Power button to turn device OFF = 3 long beeps</p>	<p><b>On/Off Symbol</b></p> <p>This symbol appears when the device is powered on, or is ready to be turned on or off.</p>	<p>Press the Power button to turn the device on or off.</p> <p><b>Note:</b> To prevent inadvertent starts and stops, the device requires two presses of the Power button to turn it on and off.</p>
<p>TBD</p>	<p><b>Pulse Symbol</b></p> <p>Dotted animation under the setting value indicates that the device detected a breath and delivered a pulse of oxygen.</p>	<p>No action needed.</p>
<p>2.0</p>	<p><b>Flow Control Setting</b></p> <p>The large number on the screen shows the oxygen flow setting (in this example, it is 2). This number can range from 1 to 5 in increments of .5.</p>	<p><b>If this is your flow setting,</b> no action is needed.</p> <p><b>If this is not your flow setting,</b> press the + button to increase this number or press the - button to decrease the number.</p>

## SimplyGo Mini User Manual

### Troubleshooting

The table below lists common problems and actions you can take. If you are unable to resolve a problem, please contact your home care provider.

<b>Problem</b>	<b>Possible Cause</b>	<b>What You Should Do</b>
Device Won't Turn On	Battery is depleted.	Use the AC or DC power cords to operate the device (with the battery inserted) to recharge the battery. If this does not resolve the problem, contact your home care provider.
	Battery is not installed correctly.	Remove the battery and re-install it correctly.
	Power button not pressed twice.	Press the power button twice.
Device Will Not Trigger A Pulse Of Oxygen	SimplyGo Mini is not turned on.	Press the power button twice.
	Cannula tubing is kinked or twisted.	Make sure the tubing is connected properly to the oxygen outlet port and that it is free of any obstruction.
	Device malfunction.	Contact your home care provider.
Oxygen Not At Full Concentration	Device is warming up.	Continue using your device, and wait 20 minutes for the device to deliver oxygen at the prescribed concentration. If the condition persists, contact your home care provider.
Alarm Occurs	The device needs your attention.	See the Alarm Indicators and Screen Symbols section for information about specific alarms and what you should do.

## Caring for your Battery

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Handle your battery with care.

- Do not allow the battery's terminals to touch together as this will cause it to fail.
- Do not immerse the battery in water.
- Do not disassemble or deform the battery.
- Do not expose to, or dispose of, the battery in fire.
- Avoid exposing the battery to excessive physical shock or vibration (dropping, etc.).
- Keep all batteries out of the reach of children.
- Do not use any battery that has been damaged in any way.
- Always charge the battery in accordance with the manufacturer's instructions, using specified chargers only.
- Do not use modified battery chargers.
- An optional, external charger can be purchased to charge the batteries. Contact your home care provider for more information.

## Battery Storage

Lithium ion batteries can be stored from -4° F (-20° C) to 140° F (+60° C) at up to 80% relative humidity. However, they are best stored below 70° F (21° C) in a cool, dry, well-ventilated facility free from corrosive gas or vapor.

Storage at temperatures above 113° F (45° C), such as in a hot car, may degrade battery performance and reduce battery life. Storage at low temperatures may affect initial battery performance.

The optimal temperature range for charging the batteries is 0° F to 113° F (0° C to 45° C) at up to 80% relative humidity. The device will not charge the battery if the battery cells exceed 113° F (45° C). Battery charging will be inhibited until the battery temperature returns to at or below 111° F (44° C).

## **Caring for your SimplyGo Mini System**

### **Cleaning the Device and Rechargeable Battery**

**Warning:** To avoid electrical shock, do not remove the SimplyGo Mini covers. The covers should only be removed by authorized service personnel. Do not apply liquid directly to the covers. Do not use alcohol, solvents, polishes, or any oily substances on the device, as they are flammable.

**Caution:** Do not allow liquids into any of the controls, the interior of the case, or the oxygen tubing connector. If this occurs, contact your home care provider for assistance.

### **Cleaning**

The exterior covers of the device and rechargeable battery should be cleaned between patient use and as needed by performing the following steps:

1. Turn the device off and disconnect from the power source before cleaning.
2. Remove the device from the carrying case.
3. If the battery is removed, wipe the battery bay and battery with a dry cloth.
4. Clean the device exterior using a damp cloth with a mild household cleaner and wipe it dry.

### **Disinfection**

The exterior covers of the device and rechargeable battery should be disinfected between patient use as follows:

1. Clean the device as indicated above.
2. Per the manufacturer's instructions, use a Discide Ultra Towelette to disinfect the exterior of the device and wipe dry.  
(Manufacturer - Palmero, [www.palmerohealth.com](http://www.palmerohealth.com) or equivalent)

## Cleaning the Accessories

Follow the instructions below when cleaning the accessories.

### Carrying Case

If necessary, the carrying case can be washed in a washing machine using a mild laundry detergent. Air dry.

To wash the carrying case by hand, use only warm water and a mild liquid dish detergent:

1. Remove the SimplyGo Mini device from the carrying case.
2. Dampen a cloth in the detergent and water solution and wipe the outside surfaces of the case clean.

### AC and DC Power Supplies/Power Cord

The AC and DC power supplies and power cord should be cleaned as needed.

1. Disconnect cords from device before cleaning.
2. Clean the cords using a cloth with a mild household cleaner and wipe dry.

### Cannula and Tubing

Clean and replace the cannula and tubing as instructed by the manufacturer and your home care provider.

### Device Storage

Store your device in a place where it will remain clean and dry.

**Caution:** Do not store your device or accessories in extreme temperatures, below -4° F (-20° C) or above 140° F (60° C).

### Device Disposal

Dispose of the device in accordance with local regulations or contact your home care provider.

## SimplyGo Mini Portable Oxygen Concentrator Mobility

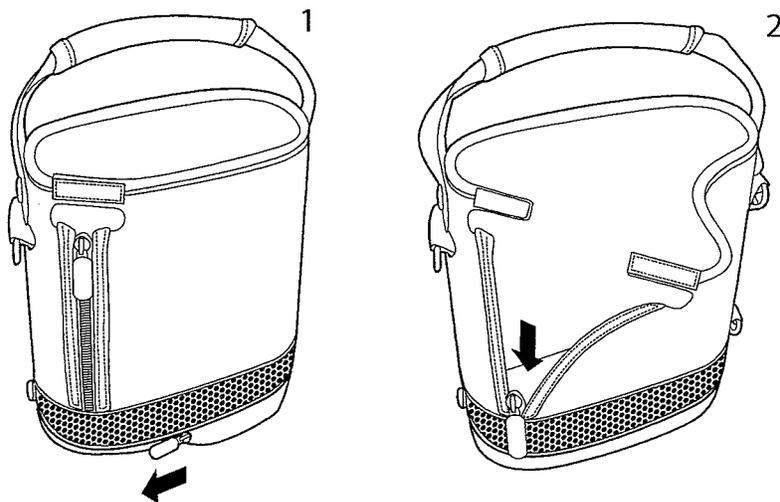
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Your SimplyGo Mini system has been designed to provide you with a source of oxygen that can be carried with you. To enable you to do so, your SimplyGo Mini device has a carrying case bag with it.

### SimplyGo Mini Carrying Case

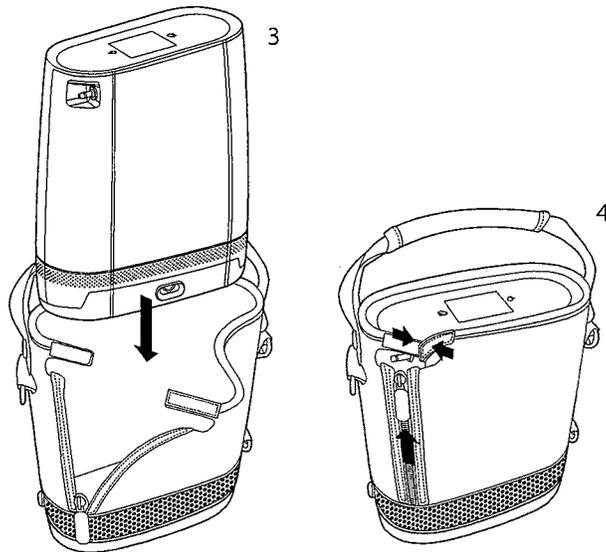
The SimplyGo Mini carrying case allows you to take your supply of oxygen with you as you go about your normal, daily activities. It provides protection for your SimplyGo Mini as well as a carrying strap to transport the device. To place the SimplyGo Mini into its carrying bag:

1. If you are using the device with the extended battery, unzip the bottom of the carrying case to allow for the device to easily slide into the bag. If you are only using the standard battery or AC power, you only need to unzip the side of the bag as shown below.



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2. Insert the device into the top of the bag as shown below, and pull the bag up around the device. Zip the zipper up on the side of the bag to ensure that SimplyGo Mini is firmly installed in the bag and close the Velcro tabs. Check to ensure that the power input and cannula connectors align with their openings in the case.



3. If the extended battery is installed on the SimplyGo Mini, ensure that the bottom zipper is unzipped around the carry bag to allow the required space at the bottom of the carry bag for the extended battery.

## **Traveling With Your System**

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With your SimplyGo Mini system and proper advance planning, you can enjoy traveling within your community and beyond. Before you leave, make sure you pack the following:

- Fully charged battery (and extra batteries for a long trip)
- AC power supply and connector cord
- DC power supply
- Carrying bag

Also, be sure to take the telephone numbers of your home care provider and physician in case of an emergency.

**Note:** If traveling internationally, make sure you have the proper AC power cord for the country you are traveling to.

### **By Motor Vehicle**

Use the SimplyGo Mini DC power supply to plug in your system using the vehicle's cigarette lighter or DC power input. Whenever the SimplyGo Mini system is running from a DC power source, the battery installed in your device will begin recharging. You can also use the SimplyGo Mini device while it is running from a DC power source.

**Caution:** Make sure the vehicle has been started before plugging in your DC power supply. If you operate the SimplyGo Mini system using the DC power cord while the vehicle engine is turned off, you could inadvertently drain the vehicle's battery.

**To run the device using DC power** from an automobile or other motorized vehicle, make sure the battery is installed. Start the vehicle and connect one end of the DC Power Cord to the device's power inlet and the other end into the vehicle's DC electrical outlet.

Because the amount of current available in the vehicle electrical system is limited, the current available to charge the SimplyGo Mini battery will be determined by the operating mode of the device. At high settings the time required to charge the battery will be much longer and at the highest settings, it may not charge at all.

## By Bus or Train

Most bus and train lines allow passengers to use portable oxygen concentrators, but you may need to notify them in advance. When you make your travel arrangements, contact your carrier well before your departure for permission to bring your system and use it on board.

**Note:** Bus and rail carriers outside the United States may have additional requirements for oxygen concentrators. Contact them several weeks before you leave to identify any requirements or specifications that may require your attention.

## On Arrival

When you arrive at your destination, check the status of your system's battery. This is an excellent time to recharge all batteries, so they're ready to go when you need them. The charge level on your batteries can be checked by following the instructions in the *Inserting and Removing the Battery* section of this manual. If a battery requires charging, this can be done as described in the *Charging the Battery with the AC Power Supply* section of this manual.

If you have any questions or concerns about traveling with your SimplyGo Mini system, contact your home care provider.

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### Specifications

Operating Conditions	Operational temperature: 41° F to 95° F (5° C to 35° C) Relative humidity: 15% to 93% Altitude: up to 10,000 ft. (3048 m.)
Storage and Transport Conditions	-4° F to 140° F (-20° C to 60° C) - unit only Relative humidity: up to 93%, non condensing

Oxygen Concentration*	At least 87% at all settings (Maximum of 96%)
Flow Settings and Pulse Volumes	Nominal pulse volume at 20 BPM 1 = 11 ml 2 = 22 ml 3 = 33 ml 4 = 44 ml 5 = 50 ml Maximum minute volume output 1 = 220 ml/min 2 = 440 ml/min 3 = 660 ml/min 4 = 880 ml/min 5 = 1000 ml/min  +/- 25% or 6 ml, whichever is greater (average of 20 consecutive pulses) over the rated environmental range.
Breathing Frequency	Up to 40 BPM
User Interface	TFT LCD with Projective Capacitive Touch Screen
Dimensions	9.4 in x 8.3 in x 3.6 in (standard battery) (23.9 cm x 21.1 cm x 9.1 cm)  10.2 in x 8.3 in x 3.6 in (extended battery) (25.9 cm x 21.1 cm x 9.1 cm)

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Weight	5.0 lbs (2.3 kg) with standard battery installed 6 lbs (2.7 kg) with extended battery installed
Sound Level	42 dBA typical at setting 2 and 20 BPM Maximum Sound Power level of XXX at setting 5 and 20 BPM
Audio Alarm	56 decibels or greater when measured at 1 meter
Outlet Pressure	20 psig
*Based on an atmospheric pressure of 14.7 psia (101 kPa) at 70° F (21° C)	

### SimplyGo Mini Battery

Chemistry	Lithium Ion 14.4 VDC (nominal)
Battery Options	Standard Battery Extended Battery (equals 2 standard batteries)
Dimensions	7.9 in x 3.6 in x 1.0 (standard battery) (20.1 cm x 9.1 cm x 2.5 cm)  7.9 in x 3.6 in x 1.9 in (extended battery) (20.1 cm x 9.1 cm x 4.8 cm)
Weight	1.1 lbs (0.50 kg) (standard battery) 2.1 lbs (0.95 kg) (extended battery)
Watt-hour Rating Per Standard Battery	3.4 Ah x 3.6 V x 8 cells = 97.9 Wh
Battery Duration	4 hours (Pulse setting of 2 at 20 BPM with Standard battery) 8 hours (Pulse setting of 2 at 20 BPM with Extended battery)
Charge Time	Maximum recharge time is 4 hours for the standard battery and 8 hours for the extended battery from fully discharged to fully charged, depending on the power source and usage.

## SimplyGo Mini User Manual

### AC Power

Type	Philips Respironics REF 1116818
Input	100 to 240 VAC, 50/60 Hz
Output	19 VDC, 6.3 A max
Power Consumption	120 W while charging

### DC Power

Type	Philips Respironics REF 1116819
Input	12-16 VDC
Output	19 +/- 5% VDC, 6.3 A

## Standards Compliance

The 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 (EMC) Compatibility – Requirements and tests.
- IEC 60601-1 3rd edition, Medical Electrical Equipment, Part 1: General Requirements for Safety
- ISO 8359, Oxygen Concentrators for Medical use – Safety Requirements.
- ISO 10993-1, Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing (Biocompatibility)
- ISO 18779, Medical Devices for Conserving Oxygen and Oxygen Mixtures: Particular Requirements
- ISO 80601-2-67, Medical electrical equipment, Part 2-67: Particular requirements for basic safety and essential performance of oxygen-conserving equipment
- ISO 80601-2-69, Medical electrical equipment, Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment

## **Classification**

The SimplyGo Mini is classified as:

- IEC Class II Internally Powered Equipment
- Type BF Applied Part
- IP22: Drip Proof Equipment
- Not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
- Continuous Operation

## SimplyGo Mini User Manual

### EMC Information

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
SimplyGo Mini is intended for use in the electromagnetic environment specified below. The user of SimplyGo Mini should assure that 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 that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
SimplyGo Mini is intended for use in the electromagnetic environment specified below. The user of SimplyGo Mini should assure that 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 Power Supply Lines ±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 Line to Line ±2 kV Line to Ground	±1 kV Line to Line ±2 kV Line to Ground	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 Seconds	<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 Seconds	Mains power quality should be that of a typical home or hospital environment. If the user of the Device required continued operation during power mains interruptions, it is recommended that the Device be powered from an uninterruptible power supply or 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 home or hospital environment.
Note: $U_T$ is the A.C. mains voltage prior to application of the test level.			

## SimplyGo Mini User Manual

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
SimplyGo Mini is intended for use in the electromagnetic environment specified below. The user of SimplyGo Mini should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	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.  <b>Recommended separation distance</b>  $d = 1.2\sqrt{P}$ 150 kHz to 80 MHz  $d = 0.35\sqrt{P}$ 80 MHz to 800 MHz $d = 0.7\sqrt{P}$ 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, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup> Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	10 V/m <sup>c</sup>	
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 strength 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, field strengths should be less than 3 V/m.		
c	SimplyGo Mini incorporates a robust design and conforms with Radiated RF Immunity Test up to 10 V/m between 80 MHz and 2.5 GHz while the test requirement is 3 V/m.		

Recommended Separation Distance Between Portable and Mobile RF Communication Equipment and the Device			
SimplyGo Mini is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The user of SimplyGo Mini can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and SimplyGo Mini as recommended below, according to the maximum output power of the communications equipment.			
Rated Maximum Output Power of Transmitter (Watts)	Separation Distance According to Frequency of Transmitter (meters)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 0.35\sqrt{P}$	800 MHz to 2.5 GHz $d = 0.7\sqrt{P}$
0.01	0.12	0.04	0.07
0.1	0.37	0.11	0.22
1	1.17	0.35	0.70
10	3.69	1.11	2.21
100	11.67	3.50	7.00
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 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.		

## SimplyGo Mini User Manual

# Limited Warranty

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Respironics, Inc. ("Respironics") warrants the SimplyGo Mini Portable Oxygen Concentrator System (the "Product") as set forth in the following paragraphs.

### Limited Warranty

Respironics warrants that the Product, except as otherwise stated herein, is free from defects in materials and workmanship under normal and proper use and when correctly maintained in accordance with applicable instructions, for a period equal to the warranty period purchased with the device, or if not otherwise specified, for a period of two (2) years from the date of shipment.

### Products Not Under Warranty

Accessories and replacement parts, including, but not limited to, filters and fuses, are not covered under this warranty. However, Respironics warrants that the battery in the Product will be free from defects in material and workmanship, under normal and proper use and when correctly maintained in accordance with applicable instructions, for a period of 90 days from the date of shipment by Respironics to the original purchaser. This warranty does not apply to batteries that are dropped, misused, altered or otherwise damaged after they are shipped.

### Limitations

If any Product purchased from Respironics fails to conform to the warranties set forth herein during the Warranty Period, as determined by Respironics in its sole discretion, Respironics may discharge its warranty obligation by repairing or replacing the Product, in Respironics' sole discretion. This may be accomplished by installing new or remanufactured assemblies or components, or by other repairs deemed appropriate in the sole discretion of Respironics. The choice of repair or replacement by Respironics shall be the sole and exclusive remedy of the original purchaser. Respironics reserves the right, in its sole discretion, to refund the purchase price in lieu of repair or replacement of the Product. In no event shall Respironics' maximum liability under these warranties exceed the price paid to Respironics by the original purchaser for the Product.

### Conditions

This warranty does not cover damage or injury whether to the Product or to personal property or persons caused by accident, misuse, abuse, negligence, failure to install in accordance with Respironics' installation instructions, failure to operate under conditions of normal use and in accordance with the terms of the operating manual and instructions, failure to maintain in accordance with the applicable service manuals, or alteration or any defects not related to materials or workmanship of the Product. This warranty does not cover damage which may occur in shipment. This warranty does not apply to any Product or individual part of a Product that may have been repaired or altered by anyone other than Respironics or an authorized Respironics service center. This warranty does not apply to any Product which is not purchased new.

### Exclusions of Warranties

EXCEPT AS SET FORTH IN THIS LIMITED WARRANTY, RESPIRONICS MAKES NO WARRANTIES, EXPRESSED OR IMPLIED, STATUTORY OR OTHERWISE, REGARDING THE PRODUCT, ITS QUALITY OR PERFORMANCE. RESPIRONICS SPECIFICALLY DISCLAIMS THE IMPLIED WARRANTY OF MERCHANTABILITY AND THE IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT SHALL RESPIRONICS BE LIABLE FOR THE COST OF PROCUREMENT OF SUBSTITUTE PRODUCTS OR FOR ANY INDIRECT, SPECIAL, CONSEQUENTIAL, PUNITIVE, EXEMPLARY OR INCIDENTAL DAMAGES (INCLUDING, BUT NOT LIMITED TO, COMMERCIAL LOSS OR LOST REVENUES), FOR ANY CAUSE OF ACTION, WHETHER IN CONTRACT OR TORT, AND WHETHER OR NOT RESPIRONICS WAS AWARE OR SHOULD HAVE BEEN AWARE OF THE POSSIBILITY OF THESE DAMAGES. EXCEPT FOR THE OBLIGATIONS UNDER THIS LIMITED WARRANTY, RESPIRONICS SHALL NOT HAVE ANY OBLIGATION OR LIABILITY FOR ANY OTHER LOSS, DAMAGE OR INJURY RESULTING DIRECTLY OR INDIRECTLY FROM THE PRODUCT. PURCHASER'S SOLE AND EXCLUSIVE REMEDY FOR BREACH OF THE WARRANTIES SET FORTH IN THIS DOCUMENT SHALL BE AS PROVIDED IN THE PARAGRAPH DESCRIBING LIMITATIONS.

Purchaser is cautioned that no person or entity is authorized to make any warranties on behalf of Respironics and any such alleged warranties are hereby disclaimed by Respironics.

Respironics Inc.  
1001 Murry Ridge Lane  
Murrysville, PA 15668 USA



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

Mr. Joseph E. Olsavsky  
Sr. Manager, Regulatory Affairs  
Respironics Incorporated  
1740 Golden Mile Highway  
Monroeville, Pennsylvania 15146

NOV - 4 2011

Re: K111885  
Trade/Device Name: Respironics SimplyGo Oxygen Concentrator  
Regulation Number: 21 CFR 868.5440  
Regulation Name: Portable Oxygen Generator  
Regulatory Class: II  
Product Code: CAW  
Dated: October 6, 2011  
Received: October 7, 2011

Dear Mr. Olsavsky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

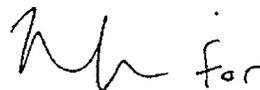
Page 2 – Mr. Olsavsky

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.  
Director  
Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

Section 6.0 Indications for Use

Indications for Use

510(k) Number (if known): K111885

Device Name: Respironics SimplyGo Oxygen Concentrator

The Respironics SimplyGo Portable Oxygen Concentrator is for prescription use by patients requiring high concentrations of oxygen on a supplemental basis. It is small, portable and is capable of continuous use in the home, institutional, and travel /mobile environments.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number: K111885 Tab 6 Page 1 of 1