



U.S. Department
of Transportation

1200 New Jersey Avenue SE
Washington, DC 20590

**Pipeline and Hazardous
Materials Safety
Administration**

DEC 22 2011

Mr. Joseph E. Olsavsky
Philips Respironics
1740 Golden Mile Highway
Monroeville, PA 15146

Ref. No.: 11-0285

Dear Mr. Olsavsky:

This responds to your November 8, 2011 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 Federal Aviation Administration (FAA) approval to allow a passenger to carry the POC aboard an aircraft. According to your letter, the POC (trade name SimplyGo) is a device that is for prescription use by patients requiring high concentrations of oxygen on a supplemental basis. The maximum operating pressure of the SimplyGo POC is 27 pounds per square inch (psi), with a safety relief valve with a lift pressure of 6.5 psi gauge in the gas circuit. The SimplyGo POC is powered by multiple sources, including AC or DC power, and a rechargeable lithium-ion battery pack. For the SimplyGo POC powered by the BAK battery pack, the lithium-ion cells have a lithium content of 0.66 grams per cell, or 7.92 grams of aggregate equivalent lithium content for the battery pack. For the SimplyGo POC powered by the Panasonic battery pack, the lithium-ion cells have a lithium content of 0.630 grams per cell, or 7.56 grams of aggregate equivalent lithium content for the battery pack. The lithium-ion battery packs are types proven to meet the appropriate tests in the United Nations (UN) Manual of Tests and Criteria, and the battery packs are packaged in a manner to prevent short circuits when offered for transport or carried onboard passenger aircraft. You ask whether this device is regulated under the HMR.

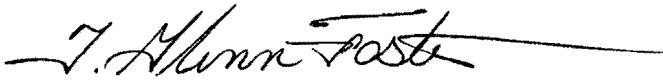
Based on the information provided in your letter, the SimplyGo POC is currently not subject to the HMR because: (1) the pressure of the oxygen in the device does not exceed 200 kPa gauge (29.0 psig/43.8 psia) at 20 °C (68 °F); (2) the lithium-ion battery pack used to operate the device is excepted from the HMR under § 172.102(c)(1), Special provision 188; (3) the POC contains no other materials subject to the HMR; and (4) the battery pack is packaged in a manner to preclude it from creating sparks or generating a dangerous quantity of heat (e.g., by the effective insulation of exposed terminals).

Although the exception in § 175.10(a)(18) of the HMR would apply to a passenger carrying a SimplyGo POC as described above, approval by the FAA is required before it may be used by a passenger onboard an aircraft. The FAA published a final rule on July

12, 2005 (70 FR 40155) regarding these devices. For further assistance, you may contact Mr. Dave Catey, Aviation Safety Inspector for the FAA Air Carrier Operations Branch (AFS-220) by phone at (202)-267-3732 or email at david.catey@faa.gov. In addition, even with FAA approval, an air carrier ultimately determines what may or may not be carried on its aircraft. We suggest that you contact the airlines directly to ensure that the SimplyGo POC may be carried.

I hope 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", with a long horizontal line extending to the right.

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

Nickels
\$ 173.168
\$ 173.21
\$ 173.185
Portable Oxygen
Concentrator
11-0285

PHILIPS

Philips Respironics
1740 Golden Mile Highway
Monroeville, PA 15146

November 8, 2011

Attn: Charles E. Betts — Chief, Standards Development, OHMS
US Department of Transportation
Pipeline and Hazardous Materials Safety Administration (PHMSA)
1200 New Jersey Avenue, SE
Washington, DC 20590

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

Dear Mr. Betts:

Philips Respironics is preparing to enter the market with a new 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), to include the Respironics SimplyGo 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 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. The

device may be used by patients suffering from Chronic Obstructive Pulmonary Disease (COPD) and other respiratory disorders.

The device was cleared for commercial distribution by the US Food and Drug Administration on November 4, 2011 under premarket notification number 510(k) K111885. Copies of the SimplyGo Portable Oxygen Concentrator 510(k) clearance letter and User Instruction Manual are attached.

Performance Specifications and Device Description

The SimplyGo Oxygen Concentrator is a portable oxygen concentrator intended to deliver 87-96% pulsed and continuous flow oxygen to the patient. The device has an integrated conserving device which triggers a breath by sensing pressure at the onset of inspiration. The SimplyGo Oxygen Concentrator has a back up pulsed rate in the event of the patient not triggering the device. In pulse mode, a set volume is delivered with each triggered breath. The volume of the dose varies based on the user selected settings.

The SimplyGo Oxygen Concentrator will operate using any of the multiple power sources listed below:

- Rechargeable batteries
- A/C Adapter
- 12v D/C car Adaptor

Users

The SimplyGo Oxygen Concentrator 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 Oxygen Concentrator 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. These conditions will include the extremes of temperature, rain, humidity, dust and snow. The SimplyGo POC is sized 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 104° F (5° C to 40° C) Relative humidity: 15% to 95%
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	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 95%, non condensing

Oxygen Concentration*	87%-96% at all settings
Flow Settings and Pulse Volumes	<p>Pulse Modes 1 = 12 ml; 1½ = 18 ml; 2 = 24 ml; 2½ = 30 ml; 3 = 36 ml; 3½ = 42 ml; 4 = 48 ml; 4½ = 54 ml; 5 = 60 ml; 5½ = 66 ml; and 6 = 72 ml; +/- 10% or 3 ml whichever is greater (Average of 20 consecutive breaths) up to a max of 2000 ml/min +/- 200 ml</p> <p>Continuous Mode ½ = 500 ml/min; 1 = 1000 ml/min; 1½ = 1500 ml/min; 2 = 2000 ml/min; +/- 10% or 100 ml/min whichever is greater (3 minute running average)</p>
User Interface	Push buttons, back-lit liquid crystal display (LCD)
Dimensions	11.5 in x 10 in x 6 in (29.2 cm x 25.4 cm x 15.2 cm)
Weight	9.9 lbs (4.5 kg) with battery installed
Audio Alarm	50 decibels (nominal) at 39 in. (1 m)
Outlet Pressure	3 psi
*Based on an atmospheric pressure of 14.7 psia (101 kPa) at 70° F (21° C)	

SimplyGo Battery

Chemistry	Lithium Ion 14.4 VDC (nominal)
Dimensions	0.9 in x 7.4 in x 4.6 in (2.7 cm x 18.8 cm x 11.7 cm)
Weight	1.5 lbs. (0.7 kg)
Battery Duration	3 hours (Pulse setting of 2 at 20 bpm)
Charge Time	Approximately 2-3 hours per battery from fully discharged to fully charged, depending on the power source and usage.

AC Power

Type	Philips Respironics 1068987
Input	100 to 240 VAC, 50/60 Hz, 2.0 A
Output	19 VDC, 7.9 A max
Power Consumption	150 W while charging 120 W while not charging

DC Power

Input:	13-19 VDC 7.9 A max
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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.
- RTCA/DO-160F section 21, category M; Emission of Radio Frequency Energy
- ISO 8359, Oxygen Concentrators for Medical use – Safety Requirements.

Classification

The SimplyGo Oxygen Concentrator is classified as:

- IEC Class II Internally Powered Equipment
- Type BF Applied Part
- IPX1: 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 POC and its battery pack:

1. The operating pressure of the SimplyGo POC device is 27 psi gauge (maximum), and a safety relief valve with a lift pressure of 6.5 psi gauge is provided in the gas circuit.
2. The lithium ion battery pack contains less than 8.0 grams of lithium. 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 POC 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 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 excepted 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 portable oxygen concentrator 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)387-7562; by fax at (724)387-7490 or by email at joseph.olsavsky@philips.com.

Sincerely,



Joseph E. Olsavsky, RAC
Sr. Manager - HRC Regulatory Affairs