

July 18th, 2016

Philips Respironics

1001 Murry Ridge Lane

Murrysville, PA 15668

RE: Airline Travel with Philips SimplyGo Mini

To Whom It May Concern:

The Philips Respironics SimplyGo Mini Portable Oxygen Concentrator devices identified in table 1 below are in compliance with the new Federal Aviation Administration (FAA) requirements as established in the FAA Advisory Circular AC 120-951, "Acceptance Criteria for Portable Oxygen Concentrators Used Onboard Aircraft (RRR)"

Table 1. SimplyGo Mini Part Numbers	
Model	Part Numbers
SimplyGo Mini Portable Oxygen Concentrator	1113604, 1113605, 1113607, 1113608

Operating configuration:

- 100-240 VAC 50/60Hz power source
- 12-16 VDC External source
- Detachable Battery

The SimplyGo Mini is a class IIa CE marked medical device that is compliant with the EU regulations, such as the Medical Device Directive (93/42/EEC) and the RoHS Directive (2011/65/EU). The SimplyGo Mini device does not utilize liquid oxygen, oxygen cylinders, or other vesicles used to store oxygen. These units separate oxygen from ambient air and deliver supplementary oxygen to the user.

Philips Respironics has designed, tested, and certified that the SimplyGo Mini devices meet the acceptance criteria for this new ruling regarding the use of portable oxygen concentrators on board aircrafts, which the regulations were updated on June 23, 2016. This new ruling replaces SFAR No 106, "Rules for Use of Portable Oxygen Concentrator Systems On Board Aircraft", which will remain effective until August 22, 2016. Table 2 below outlines the requirements of the new FAA ruling and how the SimplyGo Mini meets the acceptance criteria in order to allow SimplyGo Mini units to be used by patients on board aircrafts.

Per the new requirements and acceptance established, The FAA (Federal Aviation Administration) allows the use of SimplyGo Mini on board commercial airlines, per the new ruling:

http://www.faa.gov/regulations_policies/advisory_circulars/index.cfm/go/document.information/documentID/1029589

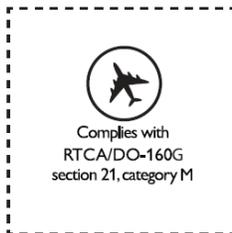
Table 2. Acceptance Criteria for Portable Oxygen Concentrators Used Onboard Aircraft	
The POC manufacturer complies with all FDA requirements to legally market the device in the United States.	The SimplyGo Mini device complies with all FDA requirements and is legally marketed in the United States through 510(k) #K111885
The POC does not contain any hazardous materials subject to the HMR except as provided for in the exceptions for crewmembers and passengers in 49 CFR 175.10 for batteries used to power electronic devices when operator approval is not required	<p>The SimplyGo Mini device does not contain any hazardous materials subject to the Hazardous Materials Regulations, 49 CFR parts 171-180.</p> <p>The SimplyGo Mini batteries (96Wh) are within the 100 Wh power limit for passengers to carry-on board aircrafts.</p>
The maximum oxygen pressure generated by the POC must fall below the threshold for the definition of a compressed gas per the HMR.	The maximum oxygen pressure generated by the SimplyGo Mini device is 20 psig, which is below the 29 psig threshold for maximum oxygen pressure as established in the Hazardous Materials Regulations, 49 CFR parts 171-180.
The POC radio frequency (RF) emissions must fall below the threshold permitted in RTCA standard 160G, Section 21, Category M	The SimplyGo Mini device is compliant to the EMI/RFI requirements of RTCA standard 160G, Section 21, Category M.

Per the new ruling, devices meeting the acceptance criteria outlined above in table 2 must also bear FAA specified labeling that certifies compliance to the acceptance criteria of FAA Advisory Circular AC 120-951, "Acceptance Criteria for Portable Oxygen Concentrators Used Onboard Aircraft (RRR)".

In order to allow passengers to fly with the SimplyGo Mini units, Philips Respironics has created labeling that will be applied to SimplyGo Mini units in order to establish compliance to the new FAA requirements for Portable Oxygen Concentrators. Domestic SimplyGo Mini units will have labels containing an airplane symbol (see below) and the following FAA mandated text in red *“The manufacturer of this POC has determined this device conforms to all applicable FAA acceptance criteria for POC carriage and use on board Aircraft.”* International SimplyGo Mini units will have labels that only have the airplane symbol shown in the illustration below as to avoid issues and confusion with translations.

Philips Respironics devices approved for airline use will have airline use operating instructions included in the User Manual and the following symbol and text on the device.

Label Illustration:



We would like to request proactively that you add SimplyGo Mini to your list of Portable Oxygen Concentrators which are allowed to be used in flight on your webpage below

INSERT WEBPAGE LINK

This will ensure that all of your customers with a SimplyGo Mini unit will have the opportunity to select your airline for future travel while utilizing the unit.

If you have any other questions regarding our products, please feel free to call the Philips Respironics Customer Service department at 1-724-387-4000. You can also use the address:

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

Sincerely,

Colleen Witt
Regulatory Affairs, Manager