



## Travel Compliance Letter for Rhythm Healthcare Portable Oxygen Concentrators

To whom it may concern:

Rhythm Healthcare's Portable Oxygen Concentrators are medical devices prescribed for use on or by the order of a physician and are cleared for sale by the U.S. Food and Drug Administration, a branch of the Federal Government of the United States of America.

May 24, 2016, the FAA and DOT published portable oxygen concentrator amendments to 14 CFR 1.1, 1.2, 121.574, 125.219, and 135.91. Additionally, the amendments resulted in the removal of Special Federal Aviation Regulation No. 106 effective August 22, 2016.

The final rule replaces the existing process by which the Federal Aviation Administration (Agency or FAA) approves portable oxygen concentrators (POC) for use on board aircraft in air carrier operations, and certain other operations using large aircraft. Prior to the rulemaking project FAA assessed each POC make and model on a case-by-case basis and if FAA determined that a particular POC was safe for use on board an aircraft, FAA conducted rulemaking to identify the specific POC model in an FAA regulation (SFAR 106).

The final rule titled, Oxygen and portable oxygen concentrators for medical use by passengers replaces the previous process and allows passengers to use a POC on board an aircraft if the POC satisfies certain acceptance criteria and bears a label indicating conformance with the acceptance criteria. The labeling requirement only affects POCs intended for use on board aircraft that were not previously approved in SFAR 106. Additionally, the rulemaking eliminated redundant operational requirements and paperwork requirements related to the physician's statement.

All Rhythm Healthcare POC Devices Below Display the Following Verbiage on the Unit:

**The manufacturer of this POC has determined this device conforms to all applicable FAA acceptance criteria for POC carriage and use on board aircraft.**

As a result, the rulemaking reduced burdens for POC manufacturers, passengers who use POCs while traveling, and affected aircraft operators. This final rule also makes conforming amendments to the Department of Transportation's (Department or DOT) rule implementing the Air Carrier Access Act (ACAA) to require carriers to accept all POC models that meet FAA acceptance criteria as detailed in the rule.

### FAA Compliant Devices

Description	Model
Rhythm Healthcare Portable Oxygen Concentrator	P2-S4
Rhythm Healthcare Portable Oxygen Concentrator	P2
Rhythm Healthcare Portable Oxygen Concentrator	P2-E6
Rhythm Healthcare Portable Oxygen Concentrator	P2-E7

**Note:** Pursuant to DOT requirements in part 382, air carriers may require an individual to bring enough batteries to power the device for at least **150%** of the expected maximum flight duration. **Individual airlines should be consulted prior to flight to confirm requirements.**

Please contact Rhythm Healthcare Customer Service (877)-843-6464 with any questions.