



CAIRE Inc.
2200 Airport Industrial Dr., Ste. 500 | Ball Ground, GA 30107 | USA
Ph 770-721-7700 | Fax 770-721-7701
www.cairemedical.com

Portable Oxygen Concentrators Used On Board Aircraft

On May 24, 2016 the **Federal Aviation Administration (Agency or FAA)** issued a final rule to replace the existing process by which the Agency approves portable oxygen concentrators (POC) for use on board aircraft in air carrier operations. ***This final rule replaced the existing FAA approval process*** in Special Federal Aviation Regulation (SFAR) No. 106 to currently allow passengers to use a POC on board an aircraft ***if the POC satisfies the acceptance criteria and labeling requirement stated in the final rule***¹. The labeling requirement only affects POCs intended for use on board aircraft that ***were not*** previously approved prior to May 24th ruling for use on aircraft by the FAA². The FreeStyle® Comfort® is the only CAIRE product that has been released after the May 24, 2016 ruling and is therefore not included on the SFAR 106 listing. ***The FreeStyle® Comfort® is labelled according to FAA labelling requirements.***

POC models identified in existing SFAR No. 106 satisfy the acceptance criteria and are exempt from the labeling requirement³, therefore the new label requirements in the final rule do not apply to the following CAIRE Inc. portable oxygen concentrators approved by the FAA for use on board aircraft prior to May 24, 2016⁴:

AirSep® Focus™;
AirSep® FreeStyle®;
AirSep® FreeStyle® 5;
AirSep® LifeStyle™;
SeQual® Eclipse®;
SeQual® eQuinox™ Oxygen System (model 4000);
SeQual® Oxywell Oxygen System (model 4000);
SeQual® SAROS™

The Final Rule made conforming amendments to the Department of Transportation's Air Carrier Access Act to require carriers to continue to permit SFAR-approved POCs, regardless of whether they are labeled^{5,6}.

Neal Maloy
Director – Quality and Regulatory
CAIRE Inc.

¹Executive Summary; A. Overview of Final Rule; Acceptance Criteria for Portable Oxygen Concentrators Used On Board Aircraft; Final Rule, 81 Federal Register 100 (24 May, 2016), pp. 33098.

²Summary; Acceptance Criteria for Portable Oxygen Concentrators Used On Board Aircraft; Final Rule, 81 Federal Register 100 (24 May, 2016), pp. 33098.

³Executive Summary; Table 1-Comparison of Final Rule Acceptance Criteria and Labeling Requirement with related SFAR No. 106 Requirements; Acceptance Criteria for Portable Oxygen Concentrators Used On Board Aircraft; Final Rule, 81 Federal Register 100 (24 May, 2016), pp. 33099.

⁴Part 121- Operating Requirements: Domestic, Flag, and Supplemental Operations; 121.574 Oxygen and portable oxygen concentrators for medical use by passengers, (e) Portable oxygen concentrators—(1) Acceptance criteria; (v); Acceptance Criteria for Portable Oxygen Concentrators Used On Board Aircraft; Final Rule, 81 Federal Register 100 (24 May, 2016), pp. 33118.

⁵IV. Discussion of Public Comments and Final Rule; K. Nondiscrimination on the Basis of Disability in Air Travel Mandatory Acceptance of POCs That Meet FAA Acceptance Criteria; Acceptance Criteria for Portable Oxygen Concentrators Used On Board Aircraft; Final Rule, 81 Federal Register 100 (24 May, 2016), pp. 33114.

⁶Summary; Acceptance Criteria for Portable Oxygen Concentrators Used on Board Aircraft; Correction, 81 Federal Register 128 (5 July 2016), pp. 43463.