



AEROSPACE STANDARD

AS8059™

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Carry-On Portable Oxygen Concentrators

RATIONALE

AS8059 has been reaffirmed to comply with the SAE Five-Year Review policy.

TABLE OF CONTENTS

1.	SCOPE.....	2
1.1	Background	2
1.2	Purpose.....	2
2.	REFERENCES.....	2
2.1	Applicable Documents	2
2.1.1	SAE Publications.....	2
2.2	Other Documents	2
2.3	Definitions	3
3.	GENERAL REQUIREMENTS.....	3
3.1	Product Requirements	3
3.2	Hazardous Materials or Conditions.....	4
3.3	Accompanying Documentation	4
3.4	EMC Compatibility.....	6
3.5	Design Requirements	6
3.5.1	General	6
3.5.2	Electrical.....	7
3.5.3	Environmental	7
3.5.4	Labeling.....	7
4.	NOTES.....	7

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Technical Report, please visit
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1. SCOPE

This SAE Aerospace Standard (AS) applies to a personal, portable oxygen concentrator (POC) to be supplied and used by a passenger requiring supplemental oxygen therapy while traveling on board civil, commercial, or personal aircraft. It covers a POC during both self-powered battery operation and while powered from an aircraft seat's electrical power through the use of an accessory adapter. The POC is not intended to be connected to the aircraft's oxygen systems or to be used by any aircraft personnel in any method of treatment or first aid of the general flying public.

1.1 Background

In 2003 the FAA became aware of portable oxygen concentrators (POC) being used by patients who had ambulatory oxygen needs. Historically, providing supplemental oxygen on board commercial aircraft for non-emergency use had been very difficult. It was a logistic problem for the airlines and the traveling public needing supplemental oxygen. Due to safety concerns, passengers were not permitted to bring on board their own high pressure oxygen cylinders or liquid oxygen dewars. POCs safely operate at low internal pressure and have virtually no oxygen storage, providing an opportunity to overcome the logistic and safety issues associated with passengers bringing their own oxygen treatment on board. Thus in 2005, the FAA promulgated SFAR No. 106, which permitted certain POCs to be brought on board for personal use by passengers. The initial SFAR was meant as a temporary regulation until a more permanent standard could be issued for the approval of a POC as safe for use on board aircraft.

1.2 Purpose

The purpose of this standard is to provide guidance on the standards, procedures, rules, and processes needed to approve personal portable oxygen concentrators for safe use of onboard civil and commercial passenger aircraft. The approval process will show air safety of a POC during use on board aircraft as a Medical-Personal Electronic Device (M-PED).

2. REFERENCES

2.1 Applicable Documents

The following publications form a part of this document to the extent specified herein. The latest issue of SAE publications shall apply. The applicable issue of other publications shall be the issue in effect on the date of the purchase order. In the event of conflict between the text of this document and references cited herein, the text of this document takes precedence. Nothing in this document, however, supersedes applicable laws and regulations unless a specific exemption has been obtained.

2.1.1 SAE Publications

Available from SAE International, 400 Commonwealth Drive, Warrendale, PA 15096-0001, Tel: 877-606-7323 (inside USA and Canada) or 724-776-4970 (outside USA), www.sae.org.

AIR6190 Provisions of Medical Oxygen for Aircraft Occupants

2.2 Other Documents

2.2.1 21 CFR Parts 11 and 121 {Docket No." FAA-2004-18596; SFAR No. 106}
Available at: www.gpoaccess.gov

2.2.2 RTCA DO160: Environmental Conditions and Test Procedures for Airborne Equipment
Available at: www.rtca.org

2.2.3 IEC60601-1: Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Requirements
Available at: www.iec.ch

2.2.4 IEC60601-1-2: Electromagnetic Compatibility
Available at: www.iec.ch

2.2.5 UN Manual of Tests and Criteria: Class 9 in Subsection 38.3.
Available at: www.enece.org

2.2.6 UL1642: Standard for Lithium Cells and Batteries
Available at: www.ul.com

2.2.7 EC62133: Secondary Cells and Batteries
Available at: www.iec.ch

2.2.8 Hazardous Materials Regulations (HMR; 49 CFR parts 100-180)
Available at: www.gpoaccess.gov

2.2.9 93/42/EEC Medical Device Directive
Available at: www.eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1993L0042:20071011:EN:PDF

2.3 Definitions

2.3.1 LITHIUM CELL OR BATTERY

A family of cells and batteries that utilize lithium ions for moving charges between the negative and positive electrodes.

2.3.2 LITHIUM CONTENT

For a secondary lithium cell, it is defined in grams of lithium equivalent content and for a battery made of lithium cells, the watt-hour rating.

2.3.3 PORTABLE OXYGEN CONCENTRATOR (POC)

A portable medical device that generates, but does not store, non-life support or non-life sustaining concentrated oxygen therapy gas for supplemental use by an individual under prescription from a licensed medical practitioner.

2.3.4 SHORT CIRCUIT

A direct connection between positive and negative terminals of a cell or battery that provides a virtual zero resistance path for current flow.

2.3.5 WATT-HOUR

A unit of energy equivalent to 1 W of work acting for 1 h of time calculated by multiplying the cell's or battery's nominal voltage by its nominal ampere capacity times 1 h.

3. GENERAL REQUIREMENTS

3.1 Product Requirements

The POC shall meet the following regulations and approvals for medical use of oxygen concentrators.

3.1.1 United States (US) requirements shall be for Food and Drug Administration (FDA) approval for sale of the device class for oxygen concentrators.

3.1.2 European Community (CE) requirements shall be for Medical Device Directive (MDD) listing for class II products.