International

ISO 80601-2-69

Medical electrical equipment —

Part 2-69: Particular requirements for the basic safety and essential performance of oxygen concentrator equipment

Appareils électromédicaux —

Partie 2-69: Exigences particulières pour la sécurité de base et les performances essentielles des dispositifs concentrateurs d'oxygène

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives or www.iec.ch/members_experts/refdocs).

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This document was prepared jointly by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Respiratory devices and related equipment used for patient care*, and Technical Committee IEC/TC 62, *Medical equipment, software, and systems*, Subcommittee SC D, *Particular medical equipment, software, and systems*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 215, *Respiratory and anaesthetic equipment*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 80601-2-69:2020), which has been technically revised.

The main changes compared to the previous edition are as follows:

— updated references, where appropriate;

— harmonization with ISO 20417, where appropriate;

— updated uncertainty of measurement requirements;

— added *marking* requirements for *gas intake port*, external gas sources and MR compatibility;

— requirements for *processing* of the *enclosure*;

— added *cybersecurity* recommendations; and

— updated *connector* requirements.

A list of all parts in the ISO 80601 and IEC 80601 series can be found on the ISO and IEC websites.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html and www.iec.ch/national-committees.

Introduction

Oxygen supplementation can be part of management of *patients* with chronic, acute-on-chronic or acute respiratory disorders. The amount of supplemental oxygen depends on the individual *patient's* needs under various conditions. The managing healthcare team typically prescribes the endpoint of treatment, for example a target value for oxygen saturation. The amount of supplemental oxygen can be controlled by the flowrate.

The goal of long-term oxygen therapy is to keep the oxygen saturation above a target value in *patients* that require supplemental oxygen. The flowrate should be adjusted for rest, exertion and sleep to meet the individual *patient's* needs under these various conditions. Ideally, the resting flowrate is adjusted to maintain SpO_2 greater than the target value as indicated by pulse oximetry.

Supplemental oxygen is supplied by various sources: *medical gas pipeline systems*, *oxygen concentrators*, compressed gas cylinders and liquid oxygen reservoirs. *Oxygen concentrators* produce oxygen-enriched air from room air for delivery to a *patient* requiring oxygen therapy. The most common *oxygen concentrator* uses molecular sieve beds to filter and concentrate oxygen molecules from the ambient air, generating oxygen concentrations of typically 90 % to 96 %. The main component of this type of *oxygen concentrator* is the molecular sieve, which adsorbs nitrogen from air to produce a product gas, which is a mixture of typically up to 95 % oxygen and 5 % of other gases. The periodic adsorbing and purging of nitrogen is referred to as the pressure swing adsorption *process*.

Long-term oxygen therapy has been demonstrated in randomized, controlled clinical trials to prolong survival in *patients* with chronic respiratory disease and documented hypoxemia. Typical sources of therapeutic long-term oxygen therapy include gaseous oxygen from cylinders or from liquid oxygen and oxygen from an *oxygen concentrator*.

In this document, the following print types are used:

— requirements and definitions: roman type;

— *test specifications and terms defined in Clause 3 of the general standard, in this particular document or as noted: italic type*; and

— informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

In referring to the structure of this document, the term.

— "clause" means one of the three numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 201 includes subclauses 201.7, 201.8, etc.); and

— "subclause" means a numbered subdivision of a clause (e.g. 201.7, 201.8 and 201.9 are all subclauses of Clause 201).

References to clauses within this document are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular document are by number only.

In this document, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

For the purposes of this document, the auxiliary verb:

— "shall" indicates a requirement;

— "should" indicates a requirement;

— "may" indicates a permission;

— "can" indicates a possibility or capability; and

— "must" is used to express an external constraint.

Annex C contains a guide to the *marking* and labelling requirements in this document.

Annex D contains a summary of the *symbols* referenced in this document.

Requirements in this document have been decomposed so that each requirement is uniquely delineated. This is done to support automated requirements tracking .

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201.1 Scope, object and related standards

IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 1 applies, except as follows:

NOTE The general standard is IEC 60601-1:2005+AMD1:2012+AMD2:2020.

201.1.1 Scope

IEC 60601-1:2005+AMD1:2012+AMD2:2020, 1.1 is replaced by:

This document specifies requirements for the *basic safety* and *essential performance* of an *oxygen concentrator* in combination with its *accessories*, hereafter referred to as *ME equipment,* intended to increase the oxygen concentration of gas intended to be delivered to a single *patient*. Such *oxygen concentrators* are typically intended for use in the *home healthcare environment* by a single *patient* in various environments including any private and public transportation as well as in commercial aircraft.

NOTE 1 Such *oxygen concentrators* can also be used in professional healthcare facilities.

This document is applicable to a *transit-operable* and non-*transit-operable oxygen concentrator.* This document is applicable to an *oxygen concentrator* integrated into or used with other medical devices, *ME equipment* or *ME systems.*

EXAMPLE 1 An *oxygen concentrator* with integrated oxygen *conserving equipment* function or *humidifier* function.

EXAMPLE 2 An *oxygen concentrator* used with a flowmeter stand.

EXAMPLE 3 An *oxygen concentrator* as part of an anaesthetic system for use in areas with limited logistical supplies of electricity and anaesthetic gases[2].

EXAMPLE 4 An *oxygen concentrator* with an integrated liquid reservoir function or gas cylinder filling system function.

This document is also applicable to those *accessories* intended by their *manufacturer* to be connected to an *oxygen concentrator*, where the characteristics of those *accessories* can affect the *basic safety* or *essential performance* of the *oxygen concentrator*.

NOTE 2 Such *accessories* can include, but are not limited to, *masks*, cannulae, extension tubing, *humidifiers*, carts, carrying cases, external power sources and oxygen *conserving equipment.*

This document does not specify requirements for *oxygen concentrators* for use with a *medical gas pipeline system*.