CSA C22.2 No. 80601-2-84:21
(ISO 80601-2-84:2020, MOD)
National Standard of Canada

CSA C22.2 No. 80601-2-84:21
Medical electrical equipment — Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment

(ISO 80601-2-84:2020, MOD)

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CSA C22.2 No. 80601-2-84:21
May 2021

Title: *Medical electrical equipment — Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment*

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Although the intended primary application of this Standard is stated in its Scope, it is important to note that it remains the responsibility of the users to judge its suitability for their particular purpose.

National Standard of Canada

CSA C22.2 No. 80601-2-84:21

Medical electrical equipment — Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment

(ISO 80601-2-84:2020, MOD)

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International Organization for Standardization

Reviewed by

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CSA Preface

This is the first edition of CSA C22.2 No. 80601-2-84, *Medical electrical equipment — Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment*, which is an adoption, with Canadian deviations, of the identically titled ISO (International Organization for Standardization) Standard 80601-2-84 (first edition, 2020-07). It replaces CAN/CSA-Z10651-3-98 (adopted ISO 10651-3:1997), *Lung ventilators for medical use — Part 3: Particular requirements for emergency and transport ventilators*. It is one in a series of Standards issued by CSA Group under Part II of the *Canadian Electrical Code*.

For brevity, this Standard will be referred to as "CSA C22.2 No. 80601-2-84" throughout.

This Standard is intended to be used in conjunction with CAN/CSA-C22.2 No. 60601-1:14, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance* (adopted IEC 60601-1:2005, including Amendment 1:2012, with Canadian deviations).

This Standard is considered suitable for use for conformity assessment within the stated scope of the Standard.

This Standard was reviewed for Canadian adoption by the CSA Technical Committee on Consumer and Commercial Products, under the jurisdiction of the CSA Strategic Steering Committee on Requirements for Electrical Safety, and has been formally approved by the Technical Committee. Due to the medical content of this Standard, it was also approved by the CSA Technical Committee on Application of Electricity in Health Care, under the jurisdiction of the CSA Strategic Steering Committee on Health and Well-being.

This Standard has been developed in compliance with Standards Council of Canada requirements for National Standards of Canada. It has been published as a National Standard of Canada by CSA Group.

Interpretations: The Strategic Steering Committee on Requirements for Electrical Safety has provided the following direction for the interpretations of standards under its jurisdiction: "The literal text shall be used in judging compliance of products with the safety requirements of this Standard. When the literal text cannot be applied to the product, such as for new materials or construction, and when a

relevant CSA committee interpretation has not already been published, CSA Group's procedures for interpretation shall be followed to determine the intended safety principle."

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This Standard is subject to review within five years from the date of publication, and suggestions for its improvement will be referred to the appropriate committee. The technical content of IEC and ISO publications is kept under constant review by IEC and ISO. To submit a proposal for change, please send the following information to inquiries@csagroup.org and include "Proposal for change" in the subject line:

a) *Standard designation (number);*
b) *relevant clause, table, and/or figure number;*
c) *wording of the proposed change; and*
d) *rationale for the change.*

Canadian deviations

The following deviations are intended to meet Canadian product requirements and to align with the *Canadian Electrical Code, Part I*.

International Standard ISO 80601-2-84:2020 (first edition) forms the basis for CSA C22.2 No. 80601-2-84, which contains the following deviations in addition to those shown in CAN/CSA-C22.2 No. 60601-1:14.

[Replace all references to "IEC 60601-1" with "CAN/CSA-C22.2 No. 60601-1"]

201.1 Scope, object and related standards

201.1.1 *Scope

[Add the following paragraph]

This Standard applies to ME EQUIPMENT and ME SYSTEMS that are intended to be installed or used in accordance with CSA C22.1, *Canadian Electrical Code, Part I.*

201.2 Normative references

[Add the following]

In this Standard, any reference to International Standards shall be replaced by the relevant National Standard of Canada.

Where reference is made to CSA Group publications, such reference shall be considered to refer to the latest edition and all amendments published to that edition. This Standard refers to the following publications, and the years shown indicate the latest editions available at the time of printing:

CSA Group

C22.1:21
Canadian Electrical Code, Part I

C22.2 No. 0:20
General requirements — Canadian Electrical Code, Part II

The following National Standards of Canada, published by CSA Group, are adoptions of or are based on ISO and IEC Standards. The requirements of these CSA Group Standards shall take precedence over the International Standards on which they are based. Any reference within CSA C22.2 No. 80601-2-84 to the International Standard shall be replaced by a reference to the equivalent Canadian Standard.

CAN/CSA-C22.2 No. 60601-1:14 (R2018)
Medical electrical equipment — Part 1: General requirements for basic safety and essential performance [Replaces IEC 60601-1:2005+AMD1:2012]

CAN/CSA-C22.2 No. 60601-1-2:16
Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests
[Replaces IEC 60601-1-2:2014]

CAN/CSA-C22.2 No. 60601-1-6:11 (R2016)
Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral Standard: Usability
[Replaces IEC 60601-1-6:2010+AMD1:2013]

CAN/CSA-C22.2 No. 60601-1-8:08 (R2018)
Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral Standard: General requirements, tests, and guidance for alarm systems in medical electrical equipment and medical electrical systems
[Replaces IEC 60601-1-8:2006+AMD1:2012]

CAN/CSA-C22.2 No. 60601-1-10:09 (R2020)
Medical electrical equipment — Part 1-10: General requirements for basic safety and essential performance — Collateral Standard: Requirements for the development of physiologic closed-loop controllers
[Replaces IEC 60601-1-10:2007+AMD1:2013]

CAN/CSA-C22.2 No. 60601-1-11:15 (R2020)
Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
[Replaces IEC 60601-1-11:2015]

CSA C22.2 No. 60601-1-12:15 (R2020)
Medical Electrical Equipment — Part 1-12: General requirements for basic safety and essential performance — Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the emergency medical services environment
[Replaces IEC 60601-1-12:2014]

CSA IEC 62304:14 (R2019)
Medical device software — Software life cycle processes
[Replaces IEC 62304:2006+AMD1:2015]

CSA ISO 5356-1:15 (R2020)
Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets
[Replaces ISO 5356-1:2015]

CSA ISO 5359:16 (R2020)
Anaesthetic and respiratory equipment — Low-pressure hose assemblies for use with medical gases
[Replaces ISO 5359:2014+AMD1:2017]

CSA ISO 5367:19
Anaesthetic and respiratory equipment — Breathing sets and connectors
[Replaces ISO 5367:2014]

CSA Z7396.1-17
Medical gas pipeline systems — Part 1: Pipelines for medical gases, medical vacuum, medical support gases, and anaesthetic gas scavenging systems
[Replaces ISO 7396-1:2016+AMD1:2017]

CSA ISO 8836:20
Suction catheters for use in the respiratory tract
[Replaces ISO 8836:2019]

CAN/CSA-ISO 9000:16 (R2020)
Quality management systems — Fundamentals and vocabulary
[Replaces ISO 9000:2015]

CAN/CSA-Z9360-1:07 (R2017)
Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans — Part 1: HMEs for use with minimum tidal volumes of 250 ml
[Replaces ISO 9360-1:2000]

CAN/CSA-Z9360-2:07 (R2017)
Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans — Part 2: HMEs for use with tracheostomized patients having minimum tidal volumes of 250 ml
[Replaces ISO 9360-2:2001]

CSA Z10524-1:19
Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow-metering devices
[Replaces ISO 10524-1:2018]

CSA Z10524-3:19
Pressure regulators for use with medical gases — Part 3: Pressure regulators integrated with cylinder valves
[Replaces ISO 10524-3:2018]

CAN/CSA-ISO 14937:11 (R2016)
Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices
[Replaces ISO 14937:2009]

CSA Z17510:15 (R2020)
Medical devices — Sleep apnoea breathing therapy — Masks and application accessories
[Replaces ISO 17510:2015]

CAN/CSA-ISO 17664:18
Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices
[Replaces ISO 17664:2017]

CSA ISO 19223:19
Lung ventilators and related equipment — Vocabulary and semantics
[Replaces ISO 19223:2019]

CAN/CSA-Z23328-1:04 (R2019)
Breathing system filters for anaesthetic and respiratory use: — Part 1: Salt test method to assess filtration performance
[Replaces ISO 23328-1:2003]

CAN/CSA-Z23328-2:03 (R2018)
Breathing system filters for anaesthetic and respiratory use — Part 2: Non-filtration aspects
[Replaces ISO 23328-2:2002]

CAN/CSA-C22.2 No. 80601-2-12:12 (R2017)
Medical electrical equipment — Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
[Replaces ISO 80601-2-12:2020]

CSA C22.2 No. 80601-2-55:14 (R2019)
Medical electrical equipment — Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
[Replaces ISO 80601-2-55:2018]

CSA C22.2 No. 80601-2-74:19
Medical electrical equipment — Part 2-74: Particular requirements for the basic safety and essential performance of respiratory humidifying equipment
[Replaces ISO 80601-2-74:2017]

CSA IEC 62366-1:15 (R2020)
Medical devices — Part 1: Application of usability engineering to medical devices
[Replaces IEC 62366-1:2015

201.4 General requirements

[Add the following clause]

201.4.1A General

General requirements applicable to these products are provided in CSA C22.2 No. 0.

INTERNATIONAL STANDARD

ISO 80601-2-84

First edition
2020-07

Medical electrical equipment —

Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment

Appareils électromédicaux —

Partie 2-84: Exigences particulières relatives à la sécurité de base et aux performances essentielles des ventilateurs utilisés dans l'environnement des services médicaux d'urgence

Reference number
ISO 80601-2-84:2020(E)

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Contents

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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 ISO documents 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).

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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, *Electrical equipment in medical practice*, Subcommittee 62D, *Electromedical equipment*.

This first edition cancels and replaces ISO 10651-3:1997, which has been technically revised. The main changes compared to the previous edition are as follows:

— extension of the scope to include the *EMS ventilator* and its *accessories*, where the characteristics of those *accessories* can affect the *basic safety* or *essential performance* of the *ventilator for the emergency medical services environment*, and thus not only the *ventilator for the emergency medical services environment* itself;

— identification of *essential performance* for *ventilator for the emergency medical services environment* and its *accessories*;

— modification of the tests for environmental conditions (via IEC 60601-1-12);

— modification of the tests for *alarm conditions* (via IEC 60601-1-8);

— modification of the tests for electromagnetic disturbances (via IEC 60601-1-2);

— addition of the following:

  — tests for ventilation performance;

  — test for instability from unwanted lateral movement;

— test for audible acoustic energy;

— tests for mechanical strength (via IEC 60601-1-12);

— tests for environmental conditions (via IEC 60601-1-12);

— tests for *alarm conditions* (via IEC 60601-1-8);

— tests for electromagnetic disturbances (via IEC 60601-1-2);

— inclusion of the *usability engineering process* (via IEC 60601-1-6);

— new symbols;

— requirements for *ventilator for the emergency medical services environment* as a component of an *ME system*;

— tests for *enclosure* integrity (water ingress via IEC 60601-1-12);

— tests for *cleaning* and *disinfection*;

— determination of probability of component failure during the *expected service life*;

— delivered gas maximum enthalpy requirement;

— performance test and disclosure requirements for other *inflation-types*;

— enhanced inspired oxygen *monitoring equipment* requirements;

— consideration of input gas of Oxygen 93 %;

— use of the vocabulary and semantics of ISO 19223:2019;

— consideration of contamination of the breathing gas delivered to the *patient* from the *gas pathways*.

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

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.

Introduction

This document is a major update of the requirements for a *ventilator for the emergency medical services environment*. It includes harmonizing the requirements from ISO 10651-3, which it replaces, with the third edition of IEC 60601-1 including its first amendment, the fourth edition of IEC 60601-1-2, the second edition of IEC 60601-1-6 including its first amendment, the third edition of IEC 60601-1-8 including its first amendment and the first edition of IEC 60601-1-12.

In this document, the following print types are used:

— Requirements and definitions: roman type;

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

— 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 five numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 201 includes subclauses 201.7, 201.8, etc.);

— “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” means that conformance with a requirement or a test is mandatory for conformance with this document;

— “should” means that conformance with a requirement or a test is recommended but is not mandatory for conformance with this document;

— “may” is used to describe permission (e.g. a permissible way to achieve conformance with a requirement or test);

— "can" is used to describe 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.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

Medical electrical equipment —

Part 2-84: Particular requirements for basic safety and essential performance of ventilators for the emergency medical services environment

201.1 Scope, object and related standards

Clause 1 of the general standard applies, except as follows:

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

201.1.1 * Scope

Replacement:

This document applies to the *basic safety* and *essential performance* of an *EMS ventilator* in combination with its *accessories*, hereafter also referred to as *ME equipment:*

— intended for *patients* who need differing levels of support from artificial ventilation including *ventilator-dependent patients*;

— intended to be operated by a *healthcare professional operator*;

— intended for use in the *EMS environment*; and

— intended for invasive or non-invasive ventilation.

NOTE 1 An *EMS ventilator* can also be used for transport within a *professional healthcare facility*.

* An *EMS ventilator* is not considered to utilize a *physiologic closed loop-control system* unless it uses a physiological *patient* variable to adjust the ventilation therapy settings.

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

NOTE 2 If a clause or subclause is specifically intended to be applicable to *ME equipment* only, or to *ME systems* only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to *ME equipment* and to *ME systems*, as relevant.

Hazards inherent in the intended physiological function of *ME equipment* or *ME systems* within the scope of this document are not covered by specific requirements in this document except in IEC 60601-1:2005, 7.2.13 and 8.4.1.

NOTE 3 Additional information can be found in IEC 60601-1:2005+AMD1:2012, 4.2.

This document does not specify the requirements for the following:

— *ventilators* or *accessories* intended for *ventilator-dependent patients* in critical care applications, which are given in ISO 80601-2-12.

— *ventilators* or *accessories* intended for *ventilator-dependent patients* in the *home healthcare environment*, which are given in ISO 80601-2-72[3].

— *ventilators* or *accessories* intended for anaesthetic applications, which are given in ISO 80601-2-13[4].

— *ventilators* or *accessories* intended for ventilatory support equipment (intended only to augment the ventilation of spontaneously breathing *patients*), which are given in ISO 80601-2-79[5] and ISO 80601-2-80[6] [1].

— obstructive sleep apnoea therapy *ME equipment*, which are given in ISO 80601-2-70[7].

— *operator*-powered resuscitators, which are given in ISO 10651-4[8].

— gas-powered emergency resuscitators, which are given in ISO 10651-5[9].

— *continuous positive airway pressure* (*CPAP*) *ME equipment* .

— high-frequency jet *ventilators* (HFJVs), which are given in ISO 80601-2-87[11].

— high-frequency oscillatory *ventilators* (HFOVs)[10], which are given in ISO 80601-2-87[11].

NOTE 4 An *EMS ventilator* can incorporate high-frequency jet or high-frequency oscillatory *ventilation-modes*.

— cuirass or “iron-lung” *ventilators*.

201.1.2 Object

Replacement:

The object of this particular document is to establish *basic safety* and *essential performance* requirements for an *EMS ventilator,* as defined in 201.3.201, and its *accessories*.

Accessories are included because the combination of the *EMS ventilator* and the *accessories* needs to have acceptable *risk*. *Accessories* can have a significant impact on the *basic safety* or *essential performance* of an *EMS ventilator*.

NOTE 1 This document has been prepared to address the relevant *essential principles of safety and performance* of ISO 16142-1:2016 as indicated in Annex CC.

NOTE 2 This document has been prepared to address the relevant general safety and performance requirements of European regulation (EU) 2017/745.

[1] ISO 80601-2-79 and ISO 80601-2-80 replace ISO 10651-6, which has been withdrawn.

