CSA C22.2 No. 80601-2-13:15
(ISO 80601-2-13:2011, MOD)
National Standard of Canada
(reaffirmed 2020)

CSA C22.2 No. 80601-2-13:15
Medical electrical equipment — Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation
(ISO 80601-2-13:2011, MOD)

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CSA C22.2 No. 80601-2-13:15
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Title: *Medical electrical equipment — Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation*

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Cette Norme Nationale du Canada est disponible en versions française et anglaise.

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. 80601-2-13:15

Medical electrical equipment — Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation

(ISO 80601-2-13:2011, MOD)

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CSA Preface

This is the first edition of CAN/CSA-C22.2 No. 80601-2-13, *Medical electrical equipment — Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation*, which is an adoption, with Canadian deviations, of the identically titled ISO (International Organization for Standardization) Standard 80601-2-13 (first edition, 2011-08-01). It replaces the previous edition, published in 2007 as CAN/CSA-C22.2 No. 60601-2-13, *Medical electrical equipment — Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems* (adopted IEC 60601-2-13:2003+A1:2006). 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 "CAN/CSA-C22.2 No. 80601-2-13" 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+A1:2012, 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 Perioperative Safety under the jurisdiction of the CSA Strategic Steering Committee on Health Care Technology & Systems.

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 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. 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.*

INTERNATIONAL STANDARD

ISO 80601-2-13

First edition
2011-08-01

Medical electrical equipment –

Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation

Appareils électromédicaux –

Partie 2-13: Exigences particulières de sécurité de base et de performance essentielle pour les systèmes d'anesthésie

Reference number
ISO 80601-2-13:2011(E)

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Part 2-13:
Particular requirements for basic safety and essential performance of an anaesthetic workstation

201.1 Scope, object and related standards

IEC 60601-1:2005, Clause 1 applies, except as follows:

201.1.1 * Scope

Replacement:

This International Standard is applicable to the BASIC SAFETY and ESSENTIAL PERFORMANCE of an ANAESTHETIC WORKSTATION for administering inhalational anaesthesia whilst continuously attended by a professional OPERATOR.

This International Standard specifies particular requirements for a complete ANAESTHETIC WORKSTATION and the following ANAESTHETIC WORKSTATION components which, although considered as individual devices in their own right, may be utilized, in conjunction with other relevant ANAESTHETIC WORKSTATION components, to form an ANAESTHETIC WORKSTATION to a given specification:

— ANAESTHETIC GAS DELIVERY SYSTEM;

— ANAESTHETIC BREATHING SYSTEM;

— ANAESTHETIC GAS SCAVENGING SYSTEM;

— ANAESTHETIC VAPOUR DELIVERY SYSTEM;

— ANAESTHETIC VENTILATOR;

— MONITORING EQUIPMENT;

— ALARM SYSTEM;

— PROTECTION DEVICE.

NOTE 1 MONITORING EQUIPMENT, ALARM SYSTEMS and PROTECTION DEVICES are summarized in Table AA.1.

An ANAESTHETIC WORKSTATION supplied complete and its individual components are considered as ME EQUIPMENT or ME SYSTEMS with regard to the general standard.

NOTE 2 The applicability of this International Standard is indicated in Table AA.2.

This International Standard is also applicable to those ACCESSORIES intended by their MANUFACTURER to be connected to an ANAESTHETIC WORKSTATION where the characteristics of those ACCESSORIES can affect the BASIC SAFETY and ESSENTIAL PERFORMANCE of the ANAESTHETIC WORKSTATION.