

CAN/CSA-C22.2 No. 60601-1:08

Medical electrical equipment — Part 1: General requirements for basic safety and essential performance

CSA Preface

This is the second edition of CAN/CSA-C22.2 No. 60601-1, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*, which is an adoption, with Canadian deviations, of the identically titled IEC (International Electrotechnical Commission) Standard 60601-1 (third edition, 2005-12), which incorporates Corrigendum 1:2006. It supersedes the previous edition published in 1990 as CAN/CSA-C22.2 No. 601.1, *Medical Electrical Equipment — Part 1: General Requirements for Safety* (adopted IEC 601-1:1988).

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 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 Applications of Electricity in Health Care under the jurisdiction of the Strategic Steering Committee on Health Care Technology. This Standard has been approved as a National Standard of Canada by the Standards Council of Canada.

Interpretations: The Strategic Steering Committee on Requirements for Electrical Safety has provided the following direction for the interpretation 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’s procedures for interpretation shall be followed to determine the intended safety principle.”

February 2008

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Canadian deviations

Foreword

[Add the following]

The numbering system in the standard uses a space instead of a comma to indicate thousands and uses a comma instead of a period to indicate a decimal point. For example, 1 000 means 1,000 and 1,01 means 1.01.

1 Scope, object and related standards

1.1 Scope

[Add the following]

This standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS designed to be installed in accordance with the *Canadian Electrical Code (CEC), Part I*, CSA C22.1; CAN/CSA-C22.2 No. 0; and CAN/CSA-Z32.

NOTE 1A: In the IEC 60601 standards series adopted for use in Canada, the Canadian-particular standards may modify, replace, or delete requirements contained in this standard as appropriate for the particular ME EQUIPMENT and ME SYSTEMS under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

1.3 Collateral standards

[Replace the second paragraph and Note 1 with the following]

Applicable Canadian collateral standards become normative at the date of their publication and apply together with this standard.

NOTE 1: When evaluating compliance with CAN/CSA-C22.2 No. 60601-1, it is permissible to assess independently compliance with the adopted Canadian collateral standards.

1.4 Particular standards

[Replace this clause with the following]

A requirement of a Canadian-particular safety standard takes precedence over this standard.

2 Normative references

[Replace the first paragraph with the following]

The following referenced documents are indispensable for the application of this document. For dated references, the applicable corresponding Canadian adopted IEC standards shall take precedence. For undated references, the latest edition of the referenced document (including any amendments) applies. All Canadian adopted IEC part 2 standards are referenced with the date of publication.

[Add the following]

CSA (Canadian Standards Association)

B51-03

Boiler, pressure vessel, and pressure piping code

C22.1-06

Canadian Electrical Code, Part I

CAN/CSA-C22.2 No. 0-M91 (R2006)

General requirements — Canadian Electrical Code, Part II

C22.2 No. 21-95 (R2004)

Cord sets and power supply cords

C22.2 No. 42-99 (R2004)

General use receptacles, attachment plugs, and similar wiring devices

C22.2 No. 49-06

Flexible cords and cables

CAN/CSA-E61558-2-1:03

Safety of power transformers, power supply units and similar — Part 2: Particular requirements for separating transformers for general use

CAN/CSA-Z32-04

Electrical safety and essential electrical systems in health care facilities

Z305 series of Standards:

CAN/CSA-Z305.1-92 (R2001)

Nonflammable medical gas piping systems

CAN/CSA-Z305.6-92 (R2007)

Medical oxygen concentrator central supply system for use with nonflammable medical gas piping systems

CAN/CSA-Z305.8-03

Medical supply units

CAN/CSA-Z305.12-98 (R2004)

Guide for the safe storage, handling and use of portable oxygen systems in home, domiciliary and healthcare settings

CAN/CSA-Z5359-04

Low pressure hose assemblies for use with medical gases

CAN/CSA-Z9170-1-00 (R2005)

Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases and vacuum

CAN/CSA-Z9170-2-00 (R2005)

Terminal units for medical gas pipeline systems — Part 2: Terminal units for anaesthetic gas scavenging systems

CAN/CSA-Z10524-02 (R2007)

Pressure regulators and pressure regulators with flow-metering devices for medical gas systems

CAN/CSA-Z15002-02 (R2007)

Flow-metering devices for connection to terminal units of medical gas pipeline systems

ASME International (American Society of Mechanical Engineers)

PTC 25-2001

*Pressure Relief Devices***CGA (Compressed Gas Association)**

V-1-2005

Standard for Compressed Gas Cylinder Valve Outlet and Inlet Connections

V-5-2005

*Diameter Index Safety System (Noninterchangeable Low Pressure Connections for Medical Gas Applications)***ISO (International Organization for Standardization)**

32:1977

Gas cylinders for medical use — Marking for identification of content

407:2004

*Small medical gas cylinders — Pin-index yoke-type valve connections***3 Terminology and definitions****3.41 HIGH VOLTAGE***[Replace this clause with the following]*any voltage above 750 V, 1 050 V peak, as defined in the *Canadian Electrical Code (CEC), Part I***4 General requirements****4.8 Components of ME EQUIPMENT***[Replace Items a) and b) with the following]*

- a) the applicable safety requirements of a relevant CSA, IEC, or ISO standard; or
NOTE 1: *For the components, it is not necessary to carry out identical or equivalent tests already performed to check compliance with the component standard.*
- b) where there is no relevant CSA, IEC, or ISO standard, the requirements of this standard have to be applied.
NOTE 2: *If there are neither requirements in this standard nor in a CSA, IEC, or ISO standard, any other applicable source (e.g., standards for other types of devices, national standards) could be used to demonstrate compliance with the RISK MANAGEMENT PROCESS.*

4.10.2 SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS*[Add the following to the end of the first sentence]*and shall be in accordance with the *Canadian Electrical Code (CEC), Part I, CSA C22.1:***7 ME EQUIPMENT identification, marking and documents****7.7.1 to 7.7.5***[Add the following to the end of the first sentence of Clauses 7.7.1 to 7.7.5]*and shall be in accordance with the *Canadian Electrical Code (CEC), Part I, CSA C22.1.*

A PROTECTIVE EARTH CONDUCTOR or a PROTECTIVE EARTH CONNECTION or insulation shall be identified by either green or green and yellow colour. Colours of neutral and POWER SUPPLY CORD conductors shall be in accordance with the *Canadian Electrical Code (CEC), Part I, CSA C22.2 No. 21, and CSA C22.2 No. 49.*

8 Protection against electrical HAZARDS from ME EQUIPMENT

8.7.3 Allowable values

[Add the following as the first sentence]

Allowable values shall be in accordance with the *Canadian Electrical Code (CEC), Part I, CSA C22.1*.

8.11.3 POWER SUPPLY CORDS

8.11.3.2 Types

[Replace the first paragraph with the following]

- a) The MAINS PLUG of non-PERMANENTLY INSTALLED EQUIPMENT shall be
 - i) if molded-on type, hospital grade mains plug complying with CSA C22.2 No. 21;
 - ii) hospital grade disassembly attachment plug type complying with CSA C22.2 No. 42; or
 - iii) Class II equipment having fuses on the line side/sides and neutral and may use a non-polarized attachment plug or a polarized attachment plug — CSA configuration type 1-15P shall be required and shall meet all applicable requirements in CSA C22.2 No. 21 and CSA C22.2 No. 42.

Where a polarized attachment plug is used, the POWER SUPPLY CORD shall be connected to the wiring of the EQUIPMENT on the ungrounded side of the line when any of the following devices are used in the primary circuit:

 - 1) the centre contact of an Edison base lampholder;
 - 2) a single pole switch;
 - 3) an automatic control with a marked off position;
 - 4) a solitary fuse/fuse holder; or
 - 5) any other single pole overcurrent protective device.
- b) Detachable POWER SUPPLY CORD for non-PERMANENTLY INSTALLED EQUIPMENT (cord-connected equipment) shall be of a type that
 - i) can be shown to be unlikely to become detached accidentally, unless it can be shown that detachment will not constitute a safety HAZARD to a PATIENT or OPERATOR;
 - ii) can be shown that the impedance of the earth (ground) circuit contacts will not constitute a safety HAZARD to a PATIENT or OPERATOR; and
 - iii) has a terminal configuration or other constructional feature that will minimize the possibility of its replacement by a detachable POWER SUPPLY CORD which could create a HAZARDOUS SITUATION.
- c) A detachable POWER SUPPLY CORD shall
 - i) comply with the applicable requirements of CSA C22.2 No. 21; and
 - ii) not be smaller than No. 18 AWG, and the mechanical serviceability shall be not less than
 - 1) Type SJ or equivalent for mobile or exposed to abuse ME EQUIPMENT; and
 - 2) Type SV or equivalent for ME EQUIPMENT not exposed to abuse (or Type HPN if required because of temperature).

NOTE 1A: See CSA C22.2 No. 49 for requirements on the cord types mentioned in Sub-item 2).
- d) Power supply cords shall meet the requirements of the *Canadian Electrical Code, Part I*, as applicable.

Connecting cords between equipment parts shall meet the requirements of the *Canadian Electrical Code, Part I*, as applicable.

8.11.5 Mains fuses and OVER-CURRENT RELEASES

[Add the following as the first sentence]

Mains fuses and OVER-CURRENT RELEASES shall be in accordance with the *Canadian Electrical Code (CEC), Part I, CSA C22.1*.

9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

9.7.5 Pressure vessels

[Add the following]

Pressure vessels shall comply with the requirements of CSA B51, as applicable.

9.7.7 Pressure-relief device

[Add the following]

A pressure-relief device shall also comply as applicable to the requirements of ASME PTC 25 or equivalent Canadian requirements.

15 Construction of ME EQUIPMENT

15.4.1 Construction of connectors

[Add the following item]

- bA) The point of connection of gas cylinders to EQUIPMENT shall be gas specific and clearly identified so that errors are avoided when a replacement is made. Medical gas inlet connectors on EQUIPMENT shall be
- i) gas specific, yoke type, or nut and nipple type valve connections complying with CGA V-1 for pressures over 1 380 kPa (200 psi); or
 - ii) DISS type complying with CGA V-5 for pressures 1 380 kPa (200 psi) or less and configured to permit the supply of medical gases from low-pressure connecting assemblies complying with CAN/CSA-Z5359.

NOTE 1A: Users of this standard should consult the CSA Z305 series of standards, CAN/CSA-Z9170-1, CAN/CSA-Z9170-2, CAN/CSA-Z10524, and CAN/CSA-Z15002 for further information regarding inlet connectors; ISO 407 for requirements addressing yoke-type valve connections; and ISO 32 for colour coding.

15.4.8 Internal wiring of ME EQUIPMENT

[Add the following]

Internal wiring of ME EQUIPMENT shall be in accordance with the *Canadian Electrical Code (CEC), Part I*, CSA C22.1.

16 ME SYSTEMS

16.1 General requirements for the ME SYSTEMS

[Replace the third paragraph with the following]

An ME SYSTEM shall provide

- within the PATIENT ENVIRONMENT, the level of safety equivalent to ME EQUIPMENT complying with this standard; and
- outside the PATIENT ENVIRONMENT, the level of safety equivalent to equipment complying with their respective CSA, IEC, or ISO safety standards.

[Replace the seventh paragraph with the following]

Non-ME EQUIPMENT, when used in an ME SYSTEM, shall comply with CSA, IEC, or ISO safety standards that are relevant to that equipment.

16.9.2.1 MULTIPLE SOCKET OUTLET

[Replace the first sentence of Item c) with the following]

- c) The MULTIPLE SOCKET-OUTLET shall comply with the requirements of CSA C22.2 No. 42, CSA C22.2 No. 49, and the following requirements.

[Replace the first dashed sub-item in Item d) with the following]

- The separating transformer shall comply with the requirements of CAN/CSA-E61558-2-1 with a rated output not exceeding
 - 1 kVA for single-phase transformers; and
 - 5 kVA for polyphase transformers.

The separating transformer shall also have a degree of protection not exceeding IPX4.

Norme nationale du Canada

CAN/CSA-C22.2 n° 60601-1:08
Appareils électromédicaux — Partie 1 :
Exigences générales pour la sécurité de base
et les performances essentielles

Préparée par
la Commission Électrotechnique Internationale



Révisée par



**ASSOCIATION CANADIENNE
DE NORMALISATION**

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CAN/CSA-C22.2 n° 60601-1:08

Appareils électromédicaux — Partie 1 : Exigences générales pour la sécurité de base et les performances essentiels

Préface CSA

Ce document constitue la deuxième édition de la CAN/CSA-C22.2 n° 60601-1, *Appareils électromédicaux — Partie 1 : Exigences générales pour la sécurité de base et les performances essentielles*. Il s'agit de l'adoption, avec exigences propres au Canada, de la norme CEI (Commission Électrotechnique Internationale) 60601-1 (troisième édition, 2005-12), y compris les révisions du Corrigendum 1:2006, qui porte le même titre. Il remplace l'édition précédente publiée en 1990 et intitulée CAN/CSA-C22.2 n° 601.1, *Appareils électromédicaux — Première partie : Règles générales de sécurité* (norme CEI 601-1:1988 adoptée).

Cette norme est jugée convenable à l'évaluation de la conformité selon le domaine d'application établi dans la norme.

Cette norme a été révisée en vue de son adoption pour le Canada par le Comité technique CSA sur les produits commerciaux et grand public, sous l'autorité du Comité directeur stratégique sur les exigences en matière de sécurité électrique, et a été officiellement approuvée par le Comité technique. Parce que cette norme touche à des concepts médicaux, elle a aussi été approuvée par le Comité technique CSA sur les installations électriques dans les établissements de santé, sous l'autorité du Comité directeur stratégique sur la technologie des soins de santé. Cette norme a été approuvée en tant que Norme nationale du Canada par le Conseil canadien des normes.

Interprétations : Le Comité directeur stratégique sur les exigences en matière de sécurité électrique a émis la directive qui suit quant à l'interprétation des normes qui relèvent de sa compétence : «Il convient de s'appuyer sur le texte littéral pour juger de la conformité des produits aux exigences de sécurité de cette norme. Si le texte littéral ne s'applique pas à un produit, en raison d'un nouveau matériel ou d'une nouvelle construction, et si aucune interprétation pertinente n'a été produite par un comité CSA compétent, il convient de consulter les procédures CSA en matière d'interprétation afin de déterminer l'intention quant au principe de sécurité.»

Février 2008

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Exigences propres au Canada

Avant-propos

[Cette exigence propre au Canada ne s'applique pas à la version française]

1 Domaine d'application, objet et normes connexes

1.1 Domaine d'application

[Ajouter ce qui suit]

Cette norme vise la SÉCURITÉ DE BASE et les PERFORMANCES ESSENTIELLES des APPAREILS ÉLECTROMÉDICAUX et des SYSTÈMES ÉLECTROMÉDICAUX conçus pour être installés conformément au *Code canadien de l'électricité (CCÉ)*, Première partie, CSA C22.1 ; à la CAN/CSA-C22.2 n° 0 ; et à la CAN/CSA-Z32.

NOTE 1A : Dans la série de normes CEI 60601 adoptées pour le Canada, il se peut que les normes canadiennes modifient, replacent ou abrogent des exigences contenues dans cette norme et applicables aux APPAREILS ÉLECTROMÉDICAUX et aux SYSTÈMES ÉLECTROMÉDICAUX visés. De même, il se peut que les normes canadiennes ajoutent des exigences visant la SÉCURITÉ DE BASE et les PERFORMANCES ESSENTIELLES.

1.3 Normes collatérales

[Remplacer le deuxième paragraphe et la note 1 par ce qui suit]

Les normes collatérales canadiennes pertinentes deviennent normatives à la date de leur publication et elles s'appliquent au même titre que la présente norme.

NOTE 1 : Au moment de l'évaluation de la conformité à la CAN/CSA-C22.2 n° 60601-1, il est permis d'évaluer de manière indépendante la conformité aux normes collatérales canadiennes adoptées.

1.4 Normes particulières

[Remplacer l'article par ce qui suit]

Une exigence d'une norme de sécurité canadienne particulière a préséance sur la présente norme.

2 Références normatives

[Remplacer le premier paragraphe par ce qui suit]

Les ouvrages de référence énumérés ici sont indispensables à la mise en application de ce document. Si les ouvrages de référence sont datés, la norme CEI adoptée au Canada correspondante doit avoir préséance. Si les ouvrages de référence ne sont pas datés, la plus récente édition du document cité en référence (y compris les mises à jour) s'applique. Toutes les normes CEI constituant la partie 2 et adoptées au Canada sont assorties d'une date de publication.

[Ajouter ce qui suit]

CSA (Association canadienne de normalisation)

B51-03

Code sur les chaudières, les appareils et les tuyauteries sous pression

C22.1-06

Code canadien de l'électricité, Première partie

CAN/CSA-C22.2 n° 0-M91 (confirmée en 2006)

Exigences générales — Code canadien de l'électricité, Deuxième partie

C22.2 n° 21-95 (confirmée en 2004)

Cord sets and power supply cords

C22.2 n° 42-99 (confirmée en 2004)

General use receptacles, attachment plugs, and similar wiring devices

C22.2 n° 49-06

Flexible cords and cables

CAN/CSA-E61558-2-1:03

Sécurité des transformateurs, blocs d'alimentation et analogues — Partie 2 : Règles particulières pour les transformateurs d'isolement à enroulement séparés pour usage général

CAN/CSA-Z32-04

Sécurité en matière d'électricité et réseaux électriques essentiels des établissements de santé

Série des normes Z305 :

CAN/CSA-Z305.1-92 (confirmée en 2001)

Réseaux de canalisations de gaz médicaux inflammables

CAN/CSA-Z305.6-92 (confirmée en 2007)

Centrale d'alimentation en oxygène médical avec concentrateur, pour réseaux de canalisations des gaz médicaux ininflammables

CAN/CSA-Z305.8-03

Modules d'alimentation pour gaz médicaux

CAN/CSA-Z305.12-98 (confirmée en 2004)

Entreposage, manipulation et utilisation sans danger d'appareils portatifs d'alimentation en oxygène dans les habitations et les établissements de santé

CAN/CSA-Z5359-04

Low pressure hose assemblies for use with medical gases

CAN/CSA-Z9170-1-00 (confirmée en 2005)

Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases and vacuum

CAN/CSA-Z9170-2-00 (confirmée en 2005)

Terminal units for medical gas pipeline systems — Part 2: Terminal units for anaesthetic gas scavenging systems

CAN/CSA-Z10524-02 (confirmée en 2007)

Pressure regulators and pressure regulators with flow-metering devices for medical gas systems

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Flow-metering devices for connection to terminal units of medical gas pipeline systems

ASME International (American Society of Mechanical Engineers)

PTC 25-2001

*Pressure Relief Devices***CGA (Compressed Gas Association)**

V-1-2005

Standard for Compressed Gas Cylinder Valve Outlet and Inlet Connections

V-5-2005

*Diameter Index Safety System (Noninterchangeable Low Pressure Connections for Medical Gas Applications)***ISO (Organisation internationale de normalisation)**

32:1977

Bouteilles à gaz pour usages médicaux — Marquage pour l'identification du contenu

407:2004

Petites bouteilles à gaz médicaux — Raccords de robinets du type à étrier avec ergots de sécurité

3 Terminologie et définitions

3.41 HAUTE TENSION

[Remplacer l'article par ce qui suit]

toute tension supérieure à 750 V, 1 050 V valeur de crête, telle que définie dans le *Code canadien de l'électricité, Première partie*

4 Exigences générales

4.8 Composants des APPAREILS EM

[Remplacer les alinéas a) et b) par ce qui suit]

- a) les exigences de sécurité pertinentes d'une norme CSA, CEI ou ISO ; ou
NOTE 1 : Pour les composants, il n'est pas nécessaire de réaliser des essais identiques ou équivalents déjà réalisés pour vérifier la conformité avec la norme du composant.
- b) en l'absence de norme CSA, CEI ou ISO pertinente, la présente norme doit s'appliquer.
NOTE 2 : En l'absence d'exigences à la fois dans la présente norme et dans les normes CSA, CEI ou ISO, toute autre source pertinente (par exemple des normes applicables à d'autres types d'appareils, des normes nationales) pourrait être utilisée pour démontrer la conformité avec le PROCESSUS DE GESTION DES RISQUES.

4.10.2 RÉSEAU D'ALIMENTATION pour APPAREILS EM et SYSTÈMES EM

[Ajouter ce qui suit à la fin de la première phrase]

et doivent être conformes au *Code canadien de l'électricité, Première partie*, CSA C22.1 :

7 Identification, marquage et documentation des APPAREILS EM

7.7.1 à 7.7.5

[Ajouter ce qui suit à la fin de la première phrase des articles 7.7.1 à 7.7.5]

et être conforme au *Code canadien de l'électricité, Première partie, CSA C22.1*.

Un CONDUCTEUR DE TERRE DE PROTECTION ou une CONNEXION DE TERRE DE PROTECTION ou l'isolant doit être de couleur verte ou verte et jaune. La couleur des conducteurs neutres et des conducteurs des CÂBLES D'ALIMENTATION doit être conforme au *Code canadien de l'électricité, Première partie, à la CSA C22.2 n° 21 et à la CSA C22.2 n° 49*.

8 Protection contre les DANGERS d'origine électrique provenant des APPAREILS EM

8.7.3 Valeurs admissibles

[Ajouter ce qui suit comme première phrase]

Les valeurs admissibles doivent être conformes au *Code canadien de l'électricité, Première partie, CSA C22.1*.

8.11.3 CÂBLES D'ALIMENTATION

8.11.3.2 Types

[Remplacer le premier paragraphe par ce qui suit]

- a) Une FICHE RÉSEAU d'un appareil non INSTALLÉ DE FAÇON PERMANENTE doit être
 - (i) si elle est de type moulé, de qualité hôpital et conforme à la CSA C22.2 n° 21 ;
 - (ii) si elle n'est pas de type moulé, de qualité hôpital conforme à la CSA C22.2 n° 42 ; ou
 - (iii) un appareillage de classe II doté de fusibles des côtés secteur et neutre et d'une fiche non polarisée ou polarisée — obligatoirement de configuration CSA 1-15P et conforme à toutes les exigences pertinentes des normes CSA C22.2 n° 21 et CSA C22.2 n° 42.

Si l'appareil est doté d'une fiche polarisée, le CÂBLE D'ALIMENTATION doit être raccordé au câblage de l'APPAREIL du côté non mis à la terre du secteur si un des dispositifs suivants est utilisé dans le circuit primaire :

 - (1) le contact central d'une douille de lampe à vis ;
 - (2) un interrupteur unipolaire ;
 - (3) un dispositif pouvant être mis automatiquement dans la position arrêt ;
 - (4) un fusible/porte-fusible unique ; ou
 - (5) tout autre dispositif unipolaire de protection contre les surintensités.
- b) Un CÂBLE D'ALIMENTATION NON FIXÉ À DEMEURE d'un appareil non INSTALLÉ DE FAÇON PERMANENTE (appareil raccordé par cordon) doit être d'un type
 - (i) qui est peu susceptible de se détacher accidentellement, à moins que l'on puisse démontrer que s'il se détache cela ne mettra pas en danger le PATIENT ni l'OPÉRATEUR ;
 - (ii) pour lequel l'impédance des contacts du circuit de mise à la terre ne constitue pas un DANGER pour le PATIENT ou l'OPÉRATEUR ; et
 - (iii) dont la borne ou les autres caractéristiques de construction sont conçues pour réduire au minimum le risque qu'il soit remplacé par un CÂBLE D'ALIMENTATION NON FIXÉ À DEMEURE ce qui pourrait créer une SITUATION DANGEUREUSE.

- c) Un CÂBLE D'ALIMENTATION NON FIXÉ À DEMEURE
- (i) doit être conforme à la CSA C22.2 n° 21 ; et
 - (ii) ne doit pas être de grosseur inférieure à 18 AWG, et doit être au moins
 - (1) de type SJ ou l'équivalent s'il s'agit d'APPAREILS EM mobiles ou exposés aux mauvais traitements ; et
 - (2) de type SV ou l'équivalent s'il s'agit d'APPAREILS EM non exposés aux mauvais traitements (ou de type HPN si la température l'exige).
- NOTE 1A** : Voir la CSA C22.2 n° 49 pour les exigences visant les types de cordon mentionnés au paragraphe 2).
- d) Les CÂBLES D'ALIMENTATION doivent être conformes au *Code canadien de l'électricité, Première partie*, le cas échéant.

Les cordons servant à raccorder des composants doivent être conformes au *Code canadien de l'électricité, Première partie*, le cas échéant.

8.11.5 Coupe-circuit et DISJONCTEURS

[Ajouter ce qui suit comme première phrase]

Les fusibles ou les DISJONCTEURS doivent être conformes au *Code canadien de l'électricité, Première partie*, CSA C22.1.

9 Protection contre les DANGERS MÉCANIQUES des APPAREILS EM et SYSTÈMES EM

9.7.5 Réservoirs sous pression

[Ajouter ce qui suit]

Les réservoirs ou appareils sous pression doivent être conformes à la CSA B51, le cas échéant.

9.7.7 Soupape de sécurité

[Ajouter ce qui suit]

Une soupape de sécurité doit aussi, le cas échéant, être conforme à l'ASME PTC 25 ou aux exigences canadiennes équivalentes.

15 Construction de l'APPAREIL EM

15.4.1 Construction des connecteurs

[Ajouter l'alinéa suivant]

- bA) Le point de connexion des bouteilles de gaz à l'APPAREIL doit être spécifique à un gaz et indiqué de façon non équivoque de façon à éviter les erreurs au moment du remplacement. Les connecteurs de gaz médicaux sur l'APPAREIL doivent être
- (i) spécifiques à un gaz, de type à étrier, ou un robinet à écrou et mamelon conformes à la CGA V-1 pour des pressions supérieures à 1 380 kPa (200 lb/po²) ; ou

- (ii) de type DISS conformes à la CGA V-5 pour des pressions égales ou inférieures à 1 380 kPa (200 lb/po²)

et dont la configuration permet l'alimentation en gaz médicaux à partir de connexions basse pression conformes à la CAN/CSA-Z5359.

NOTE 1A : Les utilisateurs de cette norme sont invités à consulter la série de normes CSA Z305, la CAN/CSA-Z9170-1, la CAN/CSA-Z9170-2, la CAN/CSA-Z10524 et la CAN/CSA-Z15002 pour en savoir plus sur les connecteurs d'entrée ; l'ISO 407 pour les exigences visant les raccordements de type étrier ; et l'ISO 32 pour le codage en couleurs.

15.4.8 Câblage interne des APPAREILS EM

[Ajouter ce qui suit]

Le câblage interne des APPAREILS EM doit être conforme au *Code canadien de l'électricité, Première partie*, CSA C22.1.

16 SYSTÈMES EM

16.1 Exigences générales pour les SYSTÈMES EM

[Remplacer le troisième paragraphe par ce qui suit]

Un SYSTÈME EM doit fournir :

- dans l'ENVIRONNEMENT DU PATIENT, le niveau de sécurité équivalent à l'APPAREIL EM conforme à cette norme ; et
- en dehors de l'ENVIRONNEMENT DU PATIENT, le niveau de sécurité équivalent aux appareils conformes aux normes de sécurité pertinentes CSA, CEI ou ISO.

[Remplacer le septième paragraphe par ce qui suit]

Les APPAREILS non EM utilisés dans un SYSTÈME EM doivent être conformes aux normes de sécurité CSA, CEI ou ISO qui sont applicables à ces appareils.

16.9.2.1 SOCLES DE PRISES MULTIPLES

[Remplacer la première phrase de l'alinéa c) par ce qui suit]

- c) Le SOCLE DE PRISES MULTIPLES doit être conforme à la CSA C22.2 n° 42, à la CSA C22.2 n° 49 et aux exigences suivantes.

[Remplacer le premier tiret de l'alinéa d) par ce qui suit]

- Le transformateur de séparation doit être conforme à la CAN/CSA-E61558-2-1 et avoir une puissance maximale de sortie assignée de
 - 1 kVA dans le cas de transformateurs monophasés ; et
 - 5 kVA dans le cas de transformateurs polyphasés.
- Le transformateur de séparation doit aussi avoir un degré de protection d'au plus IPX4.



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NORME INTERNATIONALE

**Medical electrical equipment –
Part 1: General requirements for basic safety and essential performance**

**Appareils électromédicaux –
Partie 1: Exigences générales pour la sécurité de base et les performances
essentiels**

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

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