



**CSA C22.2 No. 60601-2-36:16**

**Medical electrical equipment — Part 2-36: Particular requirements for the basic safety and essential performance of equipment for extracorporeally induced lithotripsy**  
(IEC 60601-2-36:2014, MOD)

**CSA C22.2 n° 60601-2-36:16**

**Appareils électromédicaux — Partie 2-36 : Exigences particulières pour la sécurité de base et les performances essentielles des appareils pour lithotritie créée de façon extracorporelle**  
(IEC 60601-2-36:2014, MOD)



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# National Standard of Canada

CSA C22.2 No. 60601-2-36:16

**Medical electrical equipment — Part 2-36:  
Particular requirements for the basic safety and  
essential performance of equipment for  
extracorporeally induced lithotripsy  
(IEC 60601-2-36:2014, MOD)**

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# CSA C22.2 No. 60601-2-36:16

## **Medical electrical equipment — Part 2-36: Particular requirements for the basic safety and essential performance of equipment for extracorporeally induced lithotripsy**

(IEC 60601-2-36:2014, MOD)

### **CSA Preface**

This is the second edition of CAN/CSA-C22.2 No. 60601-2-36, *Medical electrical equipment — Part 2-36: Particular requirements for the basic safety and essential performance of equipment for extracorporeally induced lithotripsy*, which is an adoption, with Canadian deviations, of the identically titled IEC (International Electrotechnical Commission) Standard 60601-2-36 (second edition, 2014-04). It supersedes the previous edition, published in 1998 as CAN/CSA-C22.2 No. 60601.2.36 (adopted IEC 60601-2-36:1997). 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. 60601-2-36” 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 Applications of Electricity in Health Care 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 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. To submit a proposal for change, please send the following information to [inquiries@csagroup.org](mailto: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

## NORME INTERNATIONALE

**Medical electrical equipment –  
Part 2-36: Particular requirements for the basic safety and essential performance  
of equipment for extracorporeally induced lithotripsy**

**Appareils électromédicaux –  
Partie 2-36: Exigences particulières pour la sécurité de base et les performances  
essentielles des appareils pour lithotritie créée de façon extracorporelle**

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## MEDICAL ELECTRICAL EQUIPMENT –

### Part 2-36: Particular requirements for basic safety and essential performance of equipment for extracorporeally induced lithotripsy

#### 201.1 Scope, object and related standards

Clause 1 of the general standard<sup>1</sup> applies, except as follows:

##### 201.1.1 Scope

*Replacement:*

This particular standard applies to BASIC SAFETY and ESSENTIAL PERFORMANCE of equipment for EXTRACORPOREALLY INDUCED LITHOTRIPSY as defined in 201.3.206 including equipment for other medical applications of therapeutic extracorporeally induced focused PRESSURE PULSES, hereafter referred to as ME EQUIPMENT. The applicability of this particular standard is limited to components directly involved in the LITHOTRIPSY treatment, such as but not limited to, the generator of the PRESSURE PULSE, PATIENT support device, and their interactions with imaging and monitoring devices. Other devices, such as PATIENT treatment planning computers, X-ray and ultrasonic devices, are excluded from this standard because they are treated in other applicable IEC standards.

This particular standard does not apply to:

- ULTRASOUND PHYSIOTHERAPY EQUIPMENT intended to be used for physiotherapy;
- ULTRASOUND equipment intended to be used for high intensity therapeutic ULTRASOUND (HITU) and other therapy equipment as described in Annex AA;

##### 201.1.2 \* Object

*Replacement:*

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements of equipment for EXTRACORPOREALLY INDUCED LITHOTRIPSY as defined in 201.3.206 including equipment for other medical applications of therapeutic extracorporeal focused PRESSURE PULSES.

##### 201.1.3 Collateral standards

*Addition:*

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-2:2007 applies as modified in Clause 202. IEC 60601-1-3 and IEC 60601-1-10<sup>2</sup> do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

<sup>1</sup> The general standard is IEC 60601-1:2005/A1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

<sup>2</sup> IEC 60601-1-10:2007, *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*