



CSA C22.2 No. 60601-2-31:20

Medical electrical equipment — Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source
(IEC 60601-2-31:2020, MOD)

CSA C22.2 n° 60601-2-31:20

Appareils électromédicaux — Partie 2-31 : Exigences particulières pour la sécurité de base et les performances essentielles des stimulateurs cardiaques externes à source d'énergie interne
(IEC 60601-2-31:2020, MOD)



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***Medical electrical equipment — Part 2-31:
Particular requirements for the basic safety and
essential performance of external cardiac
pacemakers with internal power source
(IEC 60601-2-31:2020, MOD)***

*Prepared by
International Electrotechnical Commission*



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Medical electrical equipment — Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source

(IEC 60601-2-31:2020, MOD)

CSA Preface

This is the third edition of CSA C22.2 No. 60601-2-31, *Medical electrical equipment — Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source*, which is an adoption, with Canadian deviations, of the identically titled IEC (International Electrotechnical Commission) Standard 60601-2-31 (third edition, 2020-01). It supersedes the previous edition, published in 2009 as CAN/CSA-C22.2 No. 60601-2-31 (adopted IEC 60601-2-31:2008). 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. 60601-2-31” 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 Standard 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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Medical electrical equipment –

Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source

Appareils électromédicaux –

Partie 2-31: Exigences particulières pour la sécurité de base et les performances essentielles des stimulateurs cardiaques externes à source d'énergie interne



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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source

201.1 Scope, object and related standards

Clause 1 of the general standard¹ applies, except as follows:

201.1.1 * Scope

Replacement:

This part of IEC 60601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of EXTERNAL PACEMAKERS powered by an INTERNAL ELECTRICAL POWER SOURCE, hereafter referred to as ME EQUIPMENT.

This document applies to PATIENT CABLES as defined in 201.3.209, but does not apply to LEADS as defined in 201.3.206.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT within the scope of this document are not covered by specific requirements in this document except in 7.2.13 and 8.4.1 of the general standard.

NOTE See also 4.2 of the general standard.

This document does not apply to the implantable parts of ACTIVE IMPLANTABLE MEDICAL DEVICES covered by ISO 14708-1. This document does not apply to EXTERNAL PACEMAKERS which can be connected directly or indirectly to a SUPPLY MAINS.

This document does not apply to transthoracic and oesophageal pacing ME EQUIPMENT and antitachycardia ME EQUIPMENT.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for EXTERNAL PACEMAKERS as defined in 201.3.205.

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.

¹ The general standard is IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.