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**CSA C22.2 No. 60601-2-64:15**
(IEC 60601-2-64:2014, MOD)
National Standard of Canada
Norme nationale du Canada
*(reaffirmed/confirmée en 2020)*

**CSA C22.2 No. 60601-2-64:15**
**Medical electrical equipment — Part 2-64: Particular requirements for the basic safety and essential performance of light ion beam medical electrical equipment**
(IEC 60601-2-64:2014, MOD)

**CSA C22.2 nº 60601-2-64:15**
**Appareils électromédicaux — Partie 2-64 : Exigences particulières pour la sécurité de base et les performances essentielles des appareils électromédicaux par faisceau d'ions légers**
(IEC 60601-2-64:2014, MOD)



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## *CSA C22.2 No. 60601-2-64:15*
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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. 60601-2-64:15*

***Medical electrical equipment — Part 2-64: Particular requirements for the basic safety and essential performance of light ion beam medical electrical equipment***

*(IEC 60601-2-64:2014, MOD)*

*Prepared by*
*International Electrotechnical Commission*

*Reviewed by*

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# ***Medical electrical equipment — Part 2-64: Particular requirements for the basic safety and essential performance of light ion beam medical electrical equipment***
# *(IEC 60601-2-64:2014, MOD)*

## *CSA Preface*

This is the first edition of CAN/CSA-C22.2 No. 60601-2-64, *Medical electrical equipment — Part 2-64: Particular requirements for the basic safety and essential performance of light ion beam medical electrical equipment*, which is an adoption, with Canadian deviations, of the identically titled IEC (International Electrotechnical Commission) Standard 60601-2-64 (first edition, 2014-09). 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. 60601-2-64" 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 Application 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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a) *Standard designation (number);*
b) *relevant clause, table, and/or figure number;*
c) *wording of the proposed change; and*
d) *rationale for the change.*

CONTENTS

# MEDICAL ELECTRICAL EQUIPMENT –

## Particular requirements for the basic safety and essential performance of LIGHT ION BEAM ME EQUIPMENT

### 201.1 Scope, object and related standards

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

#### 201.1.1 Scope

*Replacement:*

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of LIGHT ION BEAM ME EQUIPMENT, hereafter referred to as ME EQUIPMENT, used for treatment of PATIENTS.

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.

This particular standard, with the inclusion of TYPE TESTS and SITE TESTS, applies respectively to the manufacture and some installation aspects of LIGHT ION BEAM ME EQUIPMENT

– intended for RADIOTHERAPY in human medical practice, including those in which the selection and DISPLAY of operating parameters can be controlled automatically by PROGRAMMABLE ELECTRONIC SUBSYSTEMS (PESS),
– that, in NORMAL USE, deliver a RADIATION BEAM of LIGHT IONS having ENERGY PER NUCLEON in the range 10 MeV/n to 500 MeV/n,

and

– intended to be
  – for NORMAL USE, operated under the authority of appropriately licensed or QUALIFIED PERSONS by OPERATORS having the required skills for a particular medical application, for particular SPECIFIED clinical purposes maintained in accordance with the recommendations given in the INSTRUCTIONS FOR USE,
  – subject to regular quality assurance performance and calibration checks by a QUALIFIED PERSON.

NOTE 1 In this particular standard, all references to installation refer to installation in the RESPONSIBLE ORGANIZATION'S premises.

NOTE 2 In this particular standard, all references to ABSORBED DOSE refer to ABSORBED DOSE in water.

NOTE 3 Information regarding x-ray image guidance can be found in IEC 60601-2-68 (under development).

NOTE 4 IEC 61217 gives guidance on the designation of ME EQUIPMENT movements, the marking of scales, their zero positions and the direction of movement with increasing value (see 201.7.4.101).

#### 201.1.2 Object

*Replacement:*

[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*