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CSA C22.2 No. 60601-2-62:15
(IEC 60601-2-62:2013, MOD)
National Standard of Canada
Norme nationale du Canada
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CSA C22.2 No. 60601-2-62:15
Medical electrical equipment — Part 2-62: Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) equipment
(IEC 60601-2-62:2013, MOD)

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Appareils électromédicaux — Partie 2-62 : Exigences particulières pour la sécurité de base et les performances essentielles des appareils ultrasonores thérapeutiques de haute intensité (HITU)
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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. 60601-2-62:15

Medical electrical equipment — Part 2-62: Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) equipment

(IEC 60601-2-62:2013, MOD)

Prepared by
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Reviewed by

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CSA Preface

This is the first edition of CAN/CSA-C22.2 No. 60601-2-62, *Medical electrical equipment – Part 2-62: Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) equipment*, which is an adoption, with Canadian deviations, of the identically titled IEC (International Electrotechnical Commission) Standard 60601-2-62 (first edition, 2013-07). 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. 60601-2-62" 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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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.*

IEC 60601-2-62

Edition 1.0 2013-07

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –
Part 2-62: Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) equipment

Appareils électromédicaux –
Partie 2-62: Exigences particulières pour la sécurité de base et les performances essentielles des appareils ultrasonores thérapeutiques de haute intensité (HITU)

IEC 60601-2-62:2013

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-62: Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) equipment

201.1 Scope, object and related standards

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

201.1.1 Scope

Addition:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of HIGH INTENSITY THERAPEUTIC ULTRASOUND EQUIPMENT as defined in 201.3.218, hereafter referred to as ME EQUIPMENT.

This International Standard adds or replaces clauses listed in the IEC 60601-1 that are specific for HIGH INTENSITY THERAPEUTIC ULTRASOUND EQUIPMENT.

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.

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

NOTE 1 See also 4.2 of the general standard.

NOTE 2 As, in HITU fields, the acoustic waveform is expected to be extremely distorted due to non-linear propagation effects, the ultrasonic measurements are to be made under quasi linear conditions and then extrapolated following procedures given in IEC/TS 62556. See also IEC/TS 61949

This standard can also be applied to:

– therapeutic equipment for thrombolysis through exposure to high-intensity therapeutic ultrasound;
– therapeutic equipment for the treatment of occluding feeding vessels through exposure to high-intensity focused ultrasound;
– equipment intended to be used for relieving cancer pain due to bone metastases.

This particular standard does not apply to:

- ULTRASOUND EQUIPMENT intended to be used for physiotherapy (use: IEC 60601-2-5 [1][2)] and IEC 61689);
- ULTRASOUND EQUIPMENT intended to be used for lithotripsy (use: IEC 60601-2-36 [2]);
- ULTRASOUND EQUIPMENT intended to be used for dedicated hyperthermia devices;
- ULTRASOUND EQUIPMENT intended to be used for phacoemulsification.

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

2) Numbers in square brackets refer to the Bibibliography.