



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)

CSA C22.2 n° 60601-2-62:15

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, MOD)



Standards Council of Canada
Conseil canadien des normes

Legal Notice for Standards

Canadian Standards Association (operating as “CSA Group”) develops standards through a consensus standards development process approved by the Standards Council of Canada. This process brings together volunteers representing varied viewpoints and interests to achieve consensus and develop a standard. Although CSA Group administers the process and establishes rules to promote fairness in achieving consensus, it does not independently test, evaluate, or verify the content of standards.

Disclaimer and exclusion of liability

This document is provided without any representations, warranties, or conditions of any kind, express or implied, including, without limitation, implied warranties or conditions concerning this document’s fitness for a particular purpose or use, its merchantability, or its non-infringement of any third party’s intellectual property rights. CSA Group does not warrant the accuracy, completeness, or currency of any of the information published in this document. CSA Group makes no representations or warranties regarding this document’s compliance with any applicable statute, rule, or regulation.

IN NO EVENT SHALL CSA GROUP, ITS VOLUNTEERS, MEMBERS, SUBSIDIARIES, OR AFFILIATED COMPANIES, OR THEIR EMPLOYEES, DIRECTORS, OR OFFICERS, BE LIABLE FOR ANY DIRECT, INDIRECT, OR INCIDENTAL DAMAGES, INJURY, LOSS, COSTS, OR EXPENSES, HOWSOEVER CAUSED, INCLUDING BUT NOT LIMITED TO SPECIAL OR CONSEQUENTIAL DAMAGES, LOST REVENUE, BUSINESS INTERRUPTION, LOST OR DAMAGED DATA, OR ANY OTHER COMMERCIAL OR ECONOMIC LOSS, WHETHER BASED IN CONTRACT, TORT (INCLUDING NEGLIGENCE), OR ANY OTHER THEORY OF LIABILITY, ARISING OUT OF OR RESULTING FROM ACCESS TO OR POSSESSION OR USE OF THIS DOCUMENT, EVEN IF CSA GROUP HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, INJURY, LOSS, COSTS, OR EXPENSES.

In publishing and making this document available, CSA Group is not undertaking to render professional or other services for or on behalf of any person or entity or to perform any duty owed by any person or entity to another person or entity. The information in this document is directed to those who have the appropriate degree of experience to use and apply its contents, and CSA Group accepts no responsibility whatsoever arising in any way from any and all use of or reliance on the information contained in this document.

CSA Group is a private not-for-profit company that publishes voluntary standards and related documents. CSA Group has no power, nor does it undertake, to enforce compliance with the contents of the standards or other documents it publishes.

Intellectual property rights and ownership

As between CSA Group and the users of this document (whether it be in printed or electronic form), CSA Group is the owner, or the authorized licensee, of all works contained herein that are protected by copyright, all trade-marks (except as otherwise noted to the contrary), and all inventions and trade secrets that may be contained in this document, whether or not such inventions and trade secrets are protected by patents and applications for patents. Without limitation, the unauthorized use, modification, copying, or disclosure of this document may violate laws that protect CSA Group’s and/or others’ intellectual property and may give rise to a right in CSA Group and/or others to seek legal redress for such use, modification, copying, or disclosure. To the extent permitted by treaty or by law, CSA Group reserves all intellectual property rights in this document.

Patent rights

Attention is drawn to the possibility that some of the elements of this standard may be the subject of patent rights. CSA Group shall not be held responsible for identifying any or all such patent rights. Users of this standard are expressly advised that determination of the validity of any such patent rights is entirely their own responsibility.

Authorized use of this document

This document is being provided by CSA Group for informational and non-commercial use only. The user of this document is authorized to do only the following:

If this document is in electronic form:

- load this document onto a computer for the sole purpose of reviewing it;
- search and browse this document; and
- print this document if it is in PDF format.

Limited copies of this document in print or paper form may be distributed only to persons who are authorized by CSA Group to have such copies, and only if this Legal Notice appears on each such copy.

In addition, users may not and may not permit others to

- alter this document in any way, or remove this Legal Notice from the attached standard;
- sell this document without authorization from CSA Group; or
- make an electronic copy of this document.

If you do not agree with any of the terms and conditions contained in this Legal Notice, you may not load or use this document or make any copies of the contents hereof, and if you do make such copies, you are required to destroy them immediately. Use of this document constitutes your acceptance of the terms and conditions of this Legal Notice.



Standards Update Service

CSA C22.2 No. 60601-2-62:15 December 2015

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

To register for e-mail notification about any updates to this publication

- go to store.csagroup.org
- click on **Product Updates**

The **List ID** that you will need to register for updates to this publication is **124 03**.

If you require assistance, please e-mail techsupport@csagroup.org or call 416-747-2233.

Visit CSA Group's policy on privacy at www.csagroup.org/legal to find out how we protect your personal information.

Canadian Standards Association (operating as “CSA Group”), under whose auspices this National Standard has been produced, was chartered in 1919 and accredited by the Standards Council of Canada to the National Standards system in 1973. It is a not-for-profit, nonstatutory, voluntary membership association engaged in standards development and certification activities.

CSA Group standards reflect a national consensus of producers and users — including manufacturers, consumers, retailers, unions and professional organizations, and governmental agencies. The standards are used widely by industry and commerce and often adopted by municipal, provincial, and federal governments in their regulations, particularly in the fields of health, safety, building and construction, and the environment.

Individuals, companies, and associations across Canada indicate their support for CSA Group’s standards development by volunteering their time and skills to Committee work and supporting CSA Group’s objectives through sustaining memberships. The more than 7000 committee volunteers and the 2000 sustaining memberships together form CSA Group’s total membership from which its Directors are chosen. Sustaining memberships represent a major source of income for CSA Group’s standards development activities.

CSA Group offers certification and testing services in support of and as an extension to its standards development activities. To ensure the integrity of its certification process, CSA Group regularly and continually audits and inspects products that bear the CSA Group Mark.

In addition to its head office and laboratory complex in Toronto, CSA Group has regional branch offices in major centres across Canada and inspection and testing agencies in eight countries. Since 1919, CSA Group has developed the necessary expertise to meet its corporate mission: CSA Group is an independent service organization whose mission is to provide an open and effective forum for activities facilitating the exchange of goods and services through the use of standards, certification and related services to meet national and international needs.

For further information on CSA Group services, write to
CSA Group
178 Rexdale Boulevard
Toronto, Ontario, M9W 1R3
Canada



A National Standard of Canada is a standard developed by a Standards Council of Canada (SCC) accredited Standards Development Organization, in compliance with requirements and guidance set out by SCC. More information on National Standards of Canada can be found at www.scc.ca.

SCC is a Crown corporation within the portfolio of Innovation, Science and Economic Development (ISED) Canada. With the goal of enhancing Canada's economic competitiveness and social well-being, SCC leads and facilitates the development and use of national and international standards. SCC also coordinates Canadian participation in standards development, and identifies strategies to advance Canadian standardization efforts.

Accreditation services are provided by SCC to various customers, including product certifiers, testing laboratories, and standards development organizations. A list of SCC programs and accredited bodies is publicly available at www.scc.ca.

Standards Council of Canada
600-55 Metcalfe Street
Ottawa, Ontario, K1P 6L5
Canada



Standards Council of Canada
Conseil canadien des normes

Cette Norme Nationale du Canada est disponible en versions française et anglaise.

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.

®A trademark of the Canadian Standards Association, operating as “CSA Group”

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
International Electrotechnical Commission



Reviewed by



A trademark of the Canadian Standards Association,
operating as "CSA Group"



Published in December 2015 by CSA Group
A not-for-profit private sector organization
178 Rexdale Boulevard, Toronto, Ontario, Canada M9W 1R3

To purchase standards and related publications, visit our Online Store at store.csagroup.org
or call toll-free 1-800-463-6727 or 416-747-4044.

ICS 11.040.01; 17.140.50
ISBN 978-1-4883-0276-3

© 2015 Canadian Standards Association
All rights reserved. No part of this publication may be reproduced in any form whatsoever
without the prior permission of the publisher.

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)

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."

© 2015 Canadian Standards Association

All rights reserved. No part of this publication may be reproduced in any form whatsoever without the prior permission of the publisher. IEC material is reprinted with permission. Where the words "this International Standard" appear in the text, they should be interpreted as "this National Standard of Canada".

Inquiries regarding this National Standard of Canada should be addressed to
CSA Group

178 Rexdale Boulevard, Toronto, Ontario, Canada M9W 1R3
1-800-463-6727 • 416-747-4000

www.csagroup.org

To purchase standards and related publications, visit our Online Store at store.csagroup.org or call toll-free 1-800-463-6727 or 416-747-4044.

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.

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
essentielle des appareils ultrasonores thérapeutiques de haute intensité (HITU)**

CONTENTS

FOREWORD.....	4
INTRODUCTION.....	6
201.1 Scope, object and related standards.....	7
201.2 Normative references	9
201.3 Terms and definitions	9
201.4 General requirements.....	21
201.5 General requirements for testing of ME EQUIPMENT.....	22
201.6 Classification of ME EQUIPMENT and ME SYSTEMS	23
201.7 ME EQUIPMENT identification, marking and documents.....	23
201.8 Protection against electrical HAZARDS from ME EQUIPMENT.....	25
201.9 Protection against mechanical hazards of ME EQUIPMENT and ME SYSTEMS.....	25
201.10 Protection against unwanted and excessive radiation HAZARDS.....	25
201.11 Protection against excessive temperatures and other HAZARDS.....	28
201.12 Accuracy of controls and instruments and protection against hazardous outputs.....	28
201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT.....	30
201.14 Programmable ELECTRICAL MEDICAL SYSTEMS (PEMS).....	30
201.15 Construction of ME EQUIPMENT	30
201.16 ME systems.....	30
201.17 * Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	30
202 Electromagnetic compatibility – Requirements and tests	30
Annexes	33
Annex AA (informative) Particular guidance and rationale.....	34
Annex BB (informative) Targeting	38
Annex CC (informative) HITU – specific risks.....	41
Annex DD (informative) Determining locations of HITU fields for measurement.....	46
Annex EE (informative) Guidance in classification according to CISPR 11	57
Annex FF (informative) Note on using a saline or water bath for EMI testing	58
Bibliography.....	61
Figure 201.101 – Schematic diagram showing the relationship between the various defined surfaces and distances for an ULTRASONIC TRANSDUCER with water stand-off distance when applied to a PATIENT. [IEC 61157 Ed2]	20
Figure 201.102 – Parameters for describing a focusing transducer of a known geometry.....	20
Figure 201.103 – Example set-up for the measurement of the unwanted ultrasound radiation on the side-wall (the handle) of the transducer	27
Figure DD.1 – Illustration of target, intermediate (shaded or yellow) region and safe regions defined by boundaries 1 and 2.	46
Figure DD.2 – Exposure time vs temperature increase above 37 °C for three different bioeffects threshold exposures shown as solid curves.	47
Figure DD.3 – Two-layer model with target	51
Figure DD.4 – TEMPORAL-AVERAGE INTENSITY (in dB) corrected for absorption vs transverse dimension in the focal plane	54

Figure DD.5 – TEMPORAL-AVERAGE INTENSITY (in dB) vs axial distance z (mm) for a beam from a spherical focusing transducer with a radius of 20 mm and a geometric focal length of 40 mm at 1 MHz.....	55
Figure DD.6 – Overlapping multiple exposure regions in a target region depicted by the dark ellipse	56
Figure FF.1 – Representing the patient or operator impedance.	58
Figure FF.2 – Possible setup for artificial hand for HITU equipment.	59
Figure FF.3 – Showing copper band in saline.	60
Table 201.101 – List of symbols & abbreviations.....	21
Table 201.102 – Distributed ESSENTIAL PERFORMANCE requirements	22
Table CC.1 – Hazards related to image to focus misalignment.....	41
Table CC.2 – Hazards related to use of HITU device by unskilled or untrained personnel or reasonably foreseeable misuse	41
Table CC.3 – Hazards arising from improper acoustic energy	42
Table CC.4 – Lack of, or inadequate, specification for maintenance including inadequate specification of post-maintenance functional checks.....	43
Table CC.5 – Miscellaneous hazards	43
Table CC.6 – Data transfer errors	43
Table CC.7 – HITU transducer failure	44
Table CC.8 – Generator failure	44
Table CC.9 – Cooling system failure	44
Table CC.10 – Software gets stuck in endless loop	44
Table CC.11 – Wrong calculations by computer.....	45

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 standard¹⁾ 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.

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 Bibliography.