

American National Standard

ANSI/AAMI/IEC 60601-2-50:2009

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Medical Electrical Equipment — Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment

Objectives and uses of AAMI standards and recommended practices

It is most important that the objectives and potential uses of an AAMI product standard or recommended practice are clearly understood. The objectives of AAMI's technical development program derive from AAMI's overall mission: the advancement of medical instrumentation. Essential to such advancement are (1) a continued increase in the safe and effective application of current technologies to patient care, and (2) the encouragement of new technologies. It is AAMI's view that standards and recommended practices can contribute significantly to the advancement of medical instrumentation, provided that they are drafted with attention to these objectives and provided that arbitrary and restrictive uses are avoided.

A voluntary *standard* for a *medical device* recommends to the manufacturer the information that should be provided with or on the product, basic safety and performance criteria that should be considered in qualifying the device for clinical use, and the measurement techniques that can be used to determine whether the device conforms with the safety and performance criteria and/or to compare the performance characteristics of different products. Some standards emphasize the information that should be provided with the device, including performance characteristics, instructions for use, warnings and precautions, and other data considered important in ensuring the safe and effective use of the device in the clinical environment. Recommending the disclosure of performance characteristics often necessitates the development of specialized test methods to facilitate uniformity in reporting; reaching consensus on these tests can represent a considerable part of committee work. When a drafting committee determines that clinical concerns warrant the establishment of *minimum* safety and performance criteria, referee tests must be provided and the reasons for establishing the criteria must be documented in the rationale.

A *recommended practice* provides guidelines for the use, care, and/or processing of a medical device or system. A recommended practice does not address device performance *per se*, but rather procedures and practices that will help ensure that a device is used safely and effectively and that its performance will be maintained.

Although a device standard is primarily directed to the manufacturer, it may also be of value to the potential purchaser or user of the device as a frame of reference for device evaluation. Similarly, even though a recommended practice is usually oriented towards healthcare professionals, it may be useful to the manufacturer in better understanding the environment in which a medical device will be used. Also, some recommended practices, while not addressing device performance criteria, provide guidelines to industrial personnel on such subjects as sterilization processing, methods of collecting data to establish safety and efficacy, human engineering, and other processing or evaluation techniques; such guidelines may be useful to health care professionals in understanding industrial practices.

In determining whether an AAMI standard or recommended practice is relevant to the specific needs of a potential user of the document, several important concepts must be recognized:

All AAMI standards and recommended practices are *voluntary* (unless, of course, they are adopted by government regulatory or procurement authorities). The application of a standard or recommended practice is solely within the discretion and professional judgment of the user of the document.

Each AAMI standard or recommended practice reflects the collective expertise of a committee of health care professionals and industrial representatives, whose work has been reviewed nationally (and sometimes internationally). As such, the consensus recommendations embodied in a standard or recommended practice are intended to respond to clinical needs and, ultimately, to help ensure patient safety. A standard or recommended practice is limited, however, in the sense that it responds generally to perceived risks and conditions that may not always be relevant to specific situations. A standard or recommended practice is an important *reference* in responsible decision-making, but it should never *replace* responsible decision-making.

Despite periodic review and revision (at least once every five years), a standard or recommended practice is necessarily a static document applied to a dynamic technology. Therefore, a standards user must carefully review the reasons why the document was initially developed and the specific rationale for each of its provisions. This review will reveal whether the document remains relevant to the specific needs of the user.

Particular care should be taken in applying a product standard to existing devices and equipment, and in applying a recommended practice to current procedures and practices. While observed or potential risks with existing equipment typically form the basis for the safety and performance criteria defined in a standard, professional judgment must be used in applying these criteria to existing equipment. No single source of information will serve to identify a particular product as "unsafe". A voluntary standard can be used as one resource, but the ultimate decision as to product safety and efficacy must take into account the specifics of its utilization and, of course, cost-benefit considerations. Similarly, a recommended practice should be analyzed in the context of the specific needs and resources of the individual institution or firm. Again, the rationale accompanying each AAMI standard and recommended practice is an excellent guide to the reasoning and data underlying its provision.

In summary, a standard or recommended practice is truly useful only when it is used in conjunction with other sources of information and policy guidance and in the context of professional experience and judgment.

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Medical Electrical Equipment — Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment

Approved 17 March 2009 by
Association for the Advancement of Medical Instrumentation

Approved 3 April 2009 by
American National Standards Institute, Inc.

Abstract: This standard specifies requirements for infant phototherapy equipment and can also be applied to infant phototherapy equipment used for compensation or alleviation of disease, injury or disability.

Keywords: pediatric equipment, electromedical equipment, medical electrical equipment

AAMI Standard

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Glossary of equivalent standards

International Standards adopted in the United States may include normative references to other International Standards. For each International Standard that has been adopted by AAMI (and ANSI), the table below gives the corresponding U.S. designation and level of equivalency to the International Standard. NOTE: Documents are sorted by international designation.

Other normatively referenced International Standards may be under consideration for U.S. adoption by AAMI; therefore, this list should not be considered exhaustive.

| International designation | U.S. designation | Equivalency |
|--|--|---|
| IEC 60601-1:2005 | ANSI/AAMI ES60601-1:2005 | Major technical variations |
| IEC 60601-1-2:2007 | ANSI/AAMI/IEC 60601-1-2:2007 | Identical |
| IEC 60601-2-2:2009 | ANSI/AAMI/IEC 60601-2-2:2009 | Identical |
| IEC 60601-2-4:2002 | ANSI/AAMI DF80:2003 | Major technical variations |
| IEC 60601-2-19:2009 | ANSI/AAMI/IEC 60601-2-19:2009 | Identical |
| IEC 60601-2-20:2009 | ANSI/AAMI/IEC 60601-2-20:2009 | Identical |
| IEC 60601-2-21:2009 | ANSI/AAMI/IEC 60601-2-21:2009 | Identical |
| IEC 60601-2-24:1998 | ANSI/AAMI ID26:2004 | Major technical variations |
| IEC 60601-2-47:2001 | ANSI/AAMI EC38:2007 | Major technical variations |
| IEC 60601-2-50:2009 | ANSI/AAMI/IEC 60601-2-50:2009 | Identical |
| IEC 80601-2-58:2008 | ANSI/AAMI/IEC 80601-2-58:2008 | Identical |
| IEC/TR 60878:2009 | ANSI/AAMI/IEC TIR60878:2003 | Identical |
| IEC/TR 62296:2009 | ANSI/AAMI/IEC TIR62296:2009 | Identical |
| IEC 62304:2006 | ANSI/AAMI/IEC 62304:2006 | Identical |
| IEC/TR 62348:2006 | ANSI/AAMI/IEC TIR62348:2006 | Identical |
| ISO 5840:2005 | ANSI/AAMI/ISO 5840:2005 | Identical |
| ISO 7198:1998 | ANSI/AAMI/ISO 7198:1998/2001/(R)2004 | Identical |
| ISO 7199:1996 | ANSI/AAMI/ISO 7199:1996/(R)2002 | Identical |
| ISO 8637:2004 | ANSI/AAMI RD16:2007 | Major technical variations |
| ISO 8638:2004 | ANSI/AAMI RD17:2007 | Major technical variations |
| ISO 10993-1:2003 | ANSI/AAMI/ISO 10993-1:2003 | Identical |
| ISO 10993-2:2006 | ANSI/AAMI/ISO 10993-2:2006 | Identical |
| ISO 10993-3:2003 | ANSI/AAMI/ISO 10993-3:2003 | Identical |
| ISO 10993-4:2002 and Amendment 1:2006 | ANSI/AAMI/ISO 10993-4:2002/(R)2009 and Amendment 1:2006/(R)2009 | Identical |
| ISO 10993-5:1999 | ANSI/AAMI/ISO 10993-5:1999 | Identical |
| ISO 10993-6:2007 | ANSI/AAMI/ISO 10993-6:2007 | Identical |
| ISO 10993-7:2008 | ANSI/AAMI/ISO 10993-7:2008 | Identical |
| ISO 10993-9:1999 | ANSI/AAMI/ISO 10993-9:1999/(R)2005 | Identical |
| ISO 10993-10:2002 and Amendment 1:2006 | ANSI/AAMI BE78:2002/(R)2008 ANSI/AAMI BE78:2002/A1:2006/(R)2008 | Minor technical variations Identical |
| ISO 10993-11:2006 | ANSI/AAMI/ISO 10993-11:2006 | Identical |
| ISO 10993-12:2007 | ANSI/AAMI/ISO 10993-12:2007 | Identical |
| ISO 10993-13:1998 | ANSI/AAMI/ISO 10993-13:1999/(R)2004 | Identical |
| ISO 10993-14:2001 | ANSI/AAMI/ISO 10993-14:2001/(R)2006 | Identical |
| ISO 10993-15:2000 | ANSI/AAMI/ISO 10993-15:2000/(R)2006 | Identical |
| ISO 10993-16:1997 | ANSI/AAMI/ISO 10993-16:1997/(R)2009 | Identical |
| ISO 10993-17:2002 | ANSI/AAMI/ISO 10993-17:2002/(R)2008 | Identical |
| ISO 10993-18:2005 | ANSI/AAMI BE83:2006 | Major technical variations |
| ISO/TS 10993-19:2006 | ANSI/AAMI/ISO TIR10993-19:2006 | Identical |
| ISO/TS 10993-20:2006 | ANSI/AAMI/ISO TIR10993-20:2006 | Identical |
| ISO 11135-1:2007 | ANSI/AAMI/ISO 11135-1:2007 | Identical |

| International designation | U.S. designation | Equivalency |
|---|--|----------------------------|
| ISO/TS 11135-2:2008 | ANSI/AAMI/ISO TIR11135-2:2008 | Identical |
| ISO 11137-1:2006 | ANSI/AAMI/ISO 11137-1:2006 | Identical |
| ISO 11137-2:2006 (2006-08-01 corrected version) | ANSI/AAMI/ISO 11137-2:2006 | Identical |
| ISO 11137-3:2006 | ANSI/AAMI/ISO 11137-3:2006 | Identical |
| ISO 11138-1: 2006 | ANSI/AAMI/ISO 11138-1:2006 | Identical |
| ISO 11138-2: 2006 | ANSI/AAMI/ISO 11138-2:2006 | Identical |
| ISO 11138-3: 2006 | ANSI/AAMI/ISO 11138-3:2006 | Identical |
| ISO 11138-4: 2006 | ANSI/AAMI/ISO 11138-4:2006 | Identical |
| ISO 11138-5: 2006 | ANSI/AAMI/ISO 11138-5:2006 | Identical |
| ISO/TS 11139:2006 | ANSI/AAMI/ISO 11139:2006 | Identical |
| ISO 11140-1:2005 | ANSI/AAMI/ISO 11140-1:2005 | Identical |
| ISO 11140-3:2007 | ANSI/AAMI/ISO 11140-3:2007 | Identical |
| ISO 11140-4:2007 | ANSI/AAMI/ISO 11140-4:2007 | Identical |
| ISO 11140-5:2007 | ANSI/AAMI/ISO 11140-5:2007 | Identical |
| ISO 11607-1:2006 | ANSI/AAMI/ISO 11607-1:2006 | Identical |
| ISO 11607-2:2006 | ANSI/AAMI/ISO 11607-2:2006 | Identical |
| ISO 11737-1: 2006 | ANSI/AAMI/ISO 11737-1:2006 | Identical |
| ISO 11737-2:1998 | ANSI/AAMI/ISO 11737-2:1998 | Identical |
| ISO 13408-1:2008 | ANSI/AAMI/ISO 13408-1:2008 | Identical |
| ISO 13408-2:2003 | ANSI/AAMI/ISO 13408-2:2003 | Identical |
| ISO 13408-3:2006 | ANSI/AAMI/ISO 13408-3:2006 | Identical |
| ISO 13408-4:2005 | ANSI/AAMI/ISO 13408-4:2005 | Identical |
| ISO 13408-5:2006 | ANSI/AAMI/ISO 13408-5:2006 | Identical |
| ISO 13408-6:2006 | ANSI/AAMI/ISO 13408-6:2006 | Identical |
| ISO 13485:2003 | ANSI/AAMI/ISO 13485:2003 | Identical |
| ISO 14155-1:2003 | ANSI/AAMI/ISO 14155-1:2003/(R)2008 | Identical |
| ISO 14155-2:2003 | ANSI/AAMI/ISO 14155-2:2003/(R)2008 | Identical |
| ISO 14160:1998 | ANSI/AAMI/ISO 14160:1998/(R)2008 | Identical |
| ISO 14161:2000 | ANSI/AAMI/ISO 14161:2000 | Identical |
| ISO 14937:2000 | ANSI/AAMI/ISO 14937:2000 | Identical |
| ISO/TR 14969:2004 | ANSI/AAMI/ISO TIR14969:2004 | Identical |
| ISO 14971:2007 | ANSI/AAMI/ISO 14971:2007 | Identical |
| ISO 15223-1:2007 and A1:2008 | ANSI/AAMI/ISO 15223-1:2007 and A1:2008 | Identical |
| ISO 15225:2000 and A1:2004 | ANSI/AAMI/ISO 15225:2000/(R)2006 and A1:2004/(R)2006 | Identical |
| ISO 15674:2001 | ANSI/AAMI/ISO 15674:2001 | Identical |
| ISO 15675:2001 | ANSI/AAMI/ISO 15675:2001 | Identical |
| ISO 15882:2008 | ANSI/AAMI/ISO 15882:2008 | Identical |
| ISO/TR 16142:2006 | ANSI/AAMI/ISO TIR16142:2005 | Identical |
| ISO 17664:2004 | ANSI/AAMI ST81:2004 | Major technical variations |
| ISO 17665-1:2006 | ANSI/AAMI/ISO 17665-1:2006 | Identical |
| ISO 18472:2006 | ANSI/AAMI/ISO 18472:2006 | Identical |
| ISO/TS 19218:2005 | ANSI/AAMI/ISO 19218:2005 | Identical |
| ISO 22442-1:2007 | ANSI/AAMI/ISO 22442-1:2007 | Identical |
| ISO 22442-2:2007 | ANSI/AAMI/ISO 22442-2:2007 | Identical |
| ISO 22442-3:2007 | ANSI/AAMI/ISO 22442-3:2007 | Identical |
| ISO 25539-1:2003 and A1:2005 | ANSI/AAMI/ISO 25539-1:2003 and A1:2005 | Identical |
| ISO 25539-2:2008 | ANSI/AAMI/ISO 25539-2:2008 | Identical |
| ISO 81060-1:2007 | ANSI/AAMI/ISO 81060-1:2007 | Identical |

Committee representation

Association for the Advancement of Medical Instrumentation Infant Incubator Committee

This standard was adopted by the Infant Incubator Committee of the Association for the Advancement of Medical Instrumentation. Committee approval of this document does not necessarily imply that all committee members voted for its approval.

At the time this document was published, the **AAMI Infant Incubator Committee** had the following members.

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Nancy A. Pressly

Members: Joseph P. Bagnell, Draeger Medical Systems Inc.

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Andrew Richards, G.E. Healthcare

NOTE--Participation by federal agency representatives in the development of this document does not constitute endorsement by the federal government or any of its agencies.

Background of ANSI/AAMI adoption of IEC 60601-2-50:2009

The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The United States is one of the IEC members that took an active role in the development of this standard.

This standard was developed by the IEC Subcommittee (SC) 62D, Electromedical equipment, maintenance team (MT) 21 on Pediatric equipment. The objective of this standard is to provide the basic safety and essential performance requirements of infant phototherapy equipment and can also be applied to infant phototherapy equipment used for compensation or alleviation of disease, injury or disability.

U.S. participation in this IEC SC is organized through the U.S. Technical Advisory Group for IEC/SC 62D, administered by the Association for the Advancement of Medical Instrumentation on behalf of the US National Committee of the American National Standards Institute. The U.S. made a considerable contribution to this International Standard.

AAMI encourages its committees to harmonize their work with International Standards to the extent possible. Upon review of the final draft International Standard of IEC 60601-2-50:2009, the AAMI Infant Incubator Committee, which serves as the U.S. Technical Advisory sub-Group (sub-TAG) to MT 21, decided to adopt it verbatim as a revision of ANSI/AAMI/IEC 60601-2-50:2006, Medical electrical equipment, Part 2-50: Particular requirements for the safety of infant phototherapy equipment. This is a preview edition of an AAMI guidance document and is intended to allow potential purchasers to evaluate the content of the document and provide feedback to the IEC.

AAMI and ANSI procedures require that standards be reviewed every five years and, if necessary, revised to reflect technological advances that may have occurred since publication.

For a complete copy of this AAMI document, contact AAMI at (877) 249-8226 or visit www.aami.org. The concepts incorporated in this standard should not be considered inflexible or static. This standard, like any other, must be reviewed and updated periodically to assimilate progressive technological developments. To remain relevant, it must be modified as technological advances are made and as new data comes to light.

This standard reflects the conscientious efforts of concerned health care professionals and medical device manufacturers to develop a standard for those performance levels that can be reasonably achieved at this time.

Suggestions for improving this standard are invited. Comments and suggested revisions should be sent to Standards Department, AAMI, 1110 N. Glebe Road, Suite 220, Arlington, VA 22201-4795.

NOTE—This background does not contain provisions of the American National Standard, *Medical electrical equipment – Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment* (ANSI/AAMI/IEC 60601-2-50:2009), but it does provide important information about the development and intended use of the document.

NOTE—Beginning with the IEC foreword on page viii, this American National Standard is identical to IEC 60601-2-50:2009.

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment

FOREWORD

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

International standard IEC 60601-2-50 has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

This second edition cancels and replaces the first edition published in 2000. This edition constitutes a technical revision.

Specific technical changes from the previous edition of this particular standard include:

- requiring graphical representation of the spectral irradiance in the instructions for use (this was previously optional; see 201.7.9.2.5 b));
- requirements for support and mounting brackets for ACCESSORIES (see 201.9.8.101);

- requiring restoration of any preset values upon interruption and restoration of the power supply, if applicable (see 201.11.8); and
- corrections to the first four exposure limits (ELs) listed in Table AA.1.

Minor changes from the previous edition of this particular standard include replacing the figure containing the eye protection symbol with a reference to this same symbol in IEC 60878 (see 201.7.2.101), defining an INFANT (see 201.3.202) and clarifying the titles for subclauses 201.5.4.102 and 201.5.4.103.

The main purpose of this new edition, however, is to provide consistency with the third edition of the general standard. This edition further provides consistency with the four other particular standards related to pediatric equipment for which the committee is responsible.

The text of this particular standard is based on the following documents:

| | |
|---------------|------------------|
| FDIS | Report on voting |
| 62D/736A/FDIS | 62D/765/RVD |

Full information on the voting for the approval of this particular standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

- Requirements and definitions: roman type.
- *Test specifications: italic type.*
- Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

- “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;

- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment*, can be found on the IEC website.

The committee has decided that the contents of this publication will remain unchanged until the maintenance result date indicated on the IEC web site under "<http://webstore.iec.ch>" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

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INTRODUCTION

The minimum safety requirements specified in this particular standard are considered to provide for a practical degree of safety in the operation of INFANT PHOTOTHERAPY EQUIPMENT.

This particular standard amends and supplements IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*, hereinafter referred to as the general standard.

The requirements are followed by specifications for the relevant tests.

A general guidance and rationale for the requirements of this particular standard are given in Annex AA.

It is considered that knowledge of the reasons for these requirements will not only facilitate the proper application of this particular standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, this annex does not form part of the requirements of this standard.

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MEDICAL ELECTRICAL EQUIPMENT –**Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment****201.1 Scope, object and related standards**

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

201.1.1 * Scope

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This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of INFANT PHOTOTHERAPY EQUIPMENT, as defined in 201.3.203 of this standard, also referred to as ME EQUIPMENT.

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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 See also 4.2 of the general standard.

This particular standard specifies safety requirements for INFANT PHOTOTHERAPY EQUIPMENT, but alternate methods of compliance with a specific clause by demonstrating equivalent safety will not be judged as non-compliant if the MANUFACTURER has demonstrated in his RISK MANAGEMENT FILE that the RISK presented by the HAZARD has been found to be of an acceptable level when weighed against the benefit of treatment from the device.

This particular standard does not apply to:

- devices supplying heat via BLANKETS, PADS or MATTRESSES in medical use, for information see IEC 80601-2-35;
- INFANT INCUBATORS; for information see IEC 60601-2-19;
- INFANT TRANSPORT INCUBATORS; for information, see IEC 60601-2-20;
- INFANT RADIANT WARMERS; for information see IEC 60601-2-21.

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