IEC 60601-2-50

Edition 2.0 2009-03

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

Appareils électromédicaux –
Partie 2-50: Exigences particulières pour la sécurité de base et les performances essentielles des appareils de photothérapie pour nouveau-nés

IEC 60601-2-50:2009

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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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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.

The contents of the corrigendum of August 2010 have been included in this copy.

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.

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 standard[1)] applies, except as follows:

201.1.1 * Scope

Replacement:

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.

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.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for INFANT PHOTOTHERAPY EQUIPMENT (as defined in 201.3.203), which reduce the safety HAZARDS to PATIENTS and OPERATORS as much as possible and to specify tests for demonstrating compliance with these requirements.

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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.*

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 2 of this particular standard.

IEC 60601-1-2 applies as modified in Clause 202. IEC 60601-1-3 and IEC 60601-1-10[2)] do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix "201" (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix "20x" where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

"Addition" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses or figures which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

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2) IEC 60601-1-10:2007, *Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers*

The term "this standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

NOTE Informative references are listed in the bibliography beginning on page 26.

Clause 2 of the general standard applies, except as follows:

Amendment:

IEC 60601-1-2:2007, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, apply, except as follows:

NOTE An index of defined terms is found beginning on page 28. A list of symbols, abbreviations and acronyms used in this particular standard is given in Table 201.101.

Replacement:

201.3.76
PATIENT
INFANT, as specified under 201.3.202, who is being treated by means of visible radiation from INFANT PHOTOTHERAPY EQUIPMENT, as specified under 201.3.203

Addition:

201.3.201
EFFECTIVE IRRADIATED AREA
Surface on which the PATIENT rests according to the intended position and which is irradiated by the INFANT PHOTOTHERAPY EQUIPMENT

NOTE The EFFECTIVE IRRADIATED AREA is the intended treatment surface which is illuminated by the phototherapy light. The area of 60 cm × 30 cm is used as a standard-sized surface unless specified differently in the ACCOMPANYING DOCUMENTS.

201.3.202
INFANT
PATIENT up to the age of three months and a weight less than 10 kg

201.3.203
*** INFANT PHOTOTHERAPY EQUIPMENT**
ME EQUIPMENT which emits in the main radiation spectrum in the range between 400 nm and 550 nm for reducing the concentration of bilirubin in the body of INFANTS

201.3.204
TOTAL IRRADIANCE FOR BILIRUBIN
***E*bi**
Irradiance equal to the total of all irradiance in the range between 400 nm and 550 nm

Table 201.101 – List of symbols, abbreviations and acronyms

Abbreviation	Term
AAP	American Academy of Pediatrics
°C	Degrees Celsius (unit of temperature)
dB(A)	Decibel A-weighted to human frequency response (a logarithmic measure of sound intensity)
Δ_λ	Bandwidth (in nanometers)
E	Irradiance (radiant power incidence per unit area on a surface)
E_{bi}	Irradiance for bilirubin (total irradiance for 400 nm – 550 nm)
E_{eff}	Effective irradiance
E_λ	Spectral irradiance
EL	Exposure Limit
G_2	Uniformity of irradiance (unitless)
GHz	Gigahertz (unit of frequency)
h	Hour (unit of time)
IR	Infrared radiation (with wavelengths between 700 nm and 1 mm)
IR – A	A region of infrared radiation (with wavelengths between 700 nm and 1 400 nm)
IR – B	B region of infrared radiation (with wavelengths between 1,4 µm and 3 µm)
IR – C	C region of infrared radiation (with wavelengths between 3 µm and 8 µm)
kg	Kilograms (unit of mass)
λ	Lambda (unit of wavelength)
m	Meter (unit of length)
MHz	Megahertz (unit of frequency)
min	Minute (unit of time)
µW/cm^2	Microwatts per square centimetre (unit of irradiance)
nm	Nanometer (unit of length)
N	Newton (unit of force)
s	Second (unit of time)
S_λ	Relative spectral effectiveness (unitless)
UV	Ultraviolet radiation (with wavelength shorter than visible light)
UV – A	Near-ultraviolet region (with wavelengths between 315 nm and 400 nm)
V/m	Volts per meter (unit of electric field intensity)
W/cm^2	Watts per square centimetre (unit of irradiance)
W/m^2	Watts per square meter (unit of irradiance)

201.4 General requirements

Clause 4 of the general standard applies, except as follows:

201.4.3 * ESSENTIAL PERFORMANCE

Replacement:

There are no additional ESSENTIAL PERFORMANCE requirements for INFANT PHOTOTHERAPY EQUIPMENT.

201.5 General requirements for testing of ME EQUIPMENT

Clause 5 of the general standard applies, except as follows:

201.5.4 Other conditions

Additional subclauses:

201.5.4.101 * Pre-ageing

The following general operating conditions shall be taken into account for radiation measurements of INFANT PHOTOTHERAPY EQUIPMENT.

After 5 h of pre-ageing of the radiator source, or after the pre-ageing time specified by the MANUFACTURER, if the MANUFACTURER has specified a different pre-ageing time in the ACCOMPANYING DOCUMENTS, the initial values of TOTAL IRRADIANCE FOR BILIRUBIN E_{bi} for the INFANT PHOTOTHERAPY EQUIPMENT shall be measured at the normal operating conditions for the different irradiance settings defined by the manufacturer.

201.5.4.102 Position of measurements

The radiation measurements shall be taken in the operating position of the lamp of the INFANT PHOTOTHERAPY EQUIPMENT at a distance specified by the MANUFACTURER disclosed in the instructions for use (see 201.7.9.2.9).

201.5.4.103 Stabilization period

The radiation measurements shall be taken when all important parameters for measurements have reached stable conditions. The stabilization period shall be at least 0,5 h, or longer, unless the MANUFACTURER states a different time in the ACCOMPANYING DOCUMENTS.

201.5.4.104 * Arrangement in space

The INFANT PHOTOTHERAPY EQUIPMENT shall be oriented as specified by the MANUFACTURER in the instructions for use (see subclause 201.7.9.2.9).

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies, except as follows:

201.6.3 Protection against harmful ingress of water or particular matter

Additional subclause:

201.6.3.101 INFANT PHOTOTHERAPY EQUIPMENT located under the PATIENT

If INFANT PHOTOTHERAPY EQUIPMENT is located under the PATIENT it shall at least comply with IPX3 specified in IEC 60529.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard applies, except as follows:

201.7.2 Marking on the outside of ME EQUIPMENT or ME EQUIPMENT PARTS

Additional subclause:

201.7.2.101 * Safety sign for PATIENT eye shield

A safety sign for requiring eye shields for the PATIENT shall be used if the PATIENT'S eyes can be exposed to the INFANT PHOTOTHERAPY EQUIPMENT'S radiation. See symbol number Safety 02 in IEC 60878.

201.7.3.1 Heating elements or lamp holders

Addition:

The types of lamps specified or recommended by the MANUFACTURER shall be indicated.

201.7.9.2.2 Warning and safety notices

Addition:

The instructions for use shall also include the following:

a) a statement that the INFANT PHOTOTHERAPY EQUIPMENT should be used only by appropriately trained personnel and under the direction of qualified medical personnel familiar with currently known RISKS and benefits of INFANT PHOTOTHERAPY EQUIPMENT use;

b) a statement by the MANUFACTURER explaining the effect of varying ambient conditions on the PATIENT, e.g. varying ambient temperatures, different radiation sources (sunlight), etc.;

c) if necessary, a notice giving information about the filter and the protective barrier required for NORMAL USE;

d) a notice that some PATIENTS' water balance may be disturbed;

e) a notice that PATIENTS adjacent to the INFANT PHOTOTHERAPY EQUIPMENT may need to be protected, and a notice and details about additional protective measures (e.g. shields, protective glasses);

f) a notice that the PATIENT'S bilirubin values shall be measured regularly;

g) a notice that the use of reflective foils may cause hazardous body temperatures, if relevant to the type of INFANT PHOTOTHERAPY EQUIPMENT;

h) advice to supply the PATIENT with an eye shield, whenever the PATIENT'S eye can be exposed to the INFANT PHOTOTHERAPY EQUIPMENT'S radiation;

*i) the warning notice that the OPERATOR may experience some effects during prolonged exposure to the area irradiated by the INFANT PHOTOTHERAPY EQUIPMENT;

k) a notice that blue light can hinder clinical observations by masking skin color changes, such as cyanosis;

j) a notice in case it is not allowed to treat the INFANT PHOTOTHERAPY EQUIPMENT with flammable solutions (antiseptics, cleaning agents, etc.);

l) a notice that, due to photo effects, drugs and infusion liquids shall not be stored in the radiation area;

m) a statement advising the OPERATOR of any RISKS associated with operating the INFANT PHOTOTHERAPY EQUIPMENT in the presence of gases that can support combustion (e.g. oxygen, nitrous oxide, anaesthetic agents), and how to properly use the INFANT PHOTOTHERAPY EQUIPMENT in the presence of these gases.

201.7.9.2.5 ME EQUIPMENT description

Additions:

The instructions for use shall also contain:

a) a graphical representation, including figures, of the size of the EFFECTIVE IRRADIATED AREA and its position with respect to the INFANT PHOTOTHERAPY EQUIPMENT;
b) a graphical representation of the spectral intensity distribution for the INFANT PHOTOTHERAPY EQUIPMENT over the wavelength range defined in 201.3.203. The TOTAL IRRADIANCE FOR BILIRUBIN E_{bi} emitted by the INFANT PHOTOTHERAPY EQUIPMENT shall be integrated over wavelength intervals of 5 nm or less for the wavelength range defined in 201.3.203;
c) the spectral sensitivity function curve of the measurement device if the integral method for TOTAL IRRADIANCE FOR BILIRUBIN E_{bi} emitted by the INFANT PHOTOTHERAPY EQUIPMENT is measured under the condition of 201.12.1.104;
d) the pre-ageing time, if the time is different from 5 h;
e) the stabilization period, if the period is different from 0.5 h; and
f) the maximum noise level measured under the condition of 201.9.6.2.

If alternative types of lamps are recommended by the MANUFACTURER, all the requirements of this subclause apply for each type of lamp.

201.7.9.2.9 Operating instructions

Addition:

a) The TOTAL IRRADIANCE FOR BILIRUBIN E_{bi} as measured according to the MANUFACTURER'S instructions shall be stated along with information on how this TOTAL IRRADIANCE FOR BILIRUBIN E_{bi} is affected by the distance between the INFANT PHOTOTHERAPY EQUIPMENT and the EFFECTIVE IRRADIATED AREA;
b) The instructions for use shall contain information about the distance between the INFANT PHOTOTHERAPY EQUIPMENT and the EFFECTIVE IRRADIATED AREA. If the distance between the INFANT PHOTOTHERAPY EQUIPMENT and the EFFECTIVE IRRADIATED AREA is adjustable, the MANUFACTURER has to describe how the OPERATOR can keep to the permissible distances;
c) The instructions for use shall inform the OPERATOR about the necessity of temperature measurements on the PATIENT, if the INFANT PHOTOTHERAPY EQUIPMENT will influence the body temperature of the PATIENT;
d) The instructions for use shall inform the OPERATOR about the impact of INFANT PHOTOTHERAPY EQUIPMENT on the heat supply in thermotherapy devices (INFANT INCUBATORS, INFANT TRANSPORT INCUBATORS, INFANT RADIANT WARMERS, devices supplying heat via BLANKETS, PADS or MATTRESSES) and on the PATIENT'S body temperature when the INFANT PHOTOTHERAPY is used in combination with one of these warming therapy devices;
e) The instructions for use shall inform the OPERATOR that the use of the baby controlled mode of the INFANT INCUBATOR, INFANT TRANSPORT INCUBATORS an INFANT RADIANT WARMER or devices supplying heat via BLANKETS, PADS or MATTRESSES is recommended when the INFANT PHOTOTHERAPY is used in combination with one of these warming therapy devices, otherwise the set air temperature of the incubator or the heater output of the INFANT RADIANT WARMER or HEATED MATTRESS has to be reduced according to the body temperature measurements.

201.7.9.2.13 Maintenance

Addition:

The instructions for use shall also contain

a) details informing the OPERATOR about the limited lifetime of the radiation source;
*b) information about how to measure the TOTAL IRRADIANCE FOR BILIRUBIN E_{bi} and about its rate of decay versus hours used and provide a recommendation of when the light source should be verified and replaced;