IEC 60601-2-50

Edition 3.0 2020-09
REDLINE VERSION

INTERNATIONAL STANDARD

colour inside

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

IEC 60601-2-50:2020-09 RLV(en)

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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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This redline version of the official IEC Standard allows the user to identify the changes made to the previous edition. A vertical bar appears in the margin wherever a change has been made. Additions are in green text, deletions are in strikethrough red text.

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 third edition cancels and replaces the second edition published in 2009 and Amendment 1:2016. This edition constitutes a technical revision.

This edition includes the following significant technical change with respect to the previous edition: re-dating of normative references.

The text of this International Standard d is based on the following documents:

FDIS	Report on voting
62D/1767/FDIS	62D/1775/RVD

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

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

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

In this document, 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 document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

– “shall” means that compliance with a requirement or a test is mandatory for compliance with this document;
– “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;
– “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 document will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific document. At this date, the document will be

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- withdrawn,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

NOTE The attention of users of this document is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

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 part of IEC 60601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of INFANT PHOTOTHERAPY EQUIPMENT, as defined in 201.3.203, 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 document are not covered by specific requirements in this document, 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 document does not apply to:

– devices supplying heat via BLANKETS, PADS or MATTRESSES in medical use; for information, see ~~IEC 80601-2-35~~ IEC 60601-2-35 [1][2];
– INFANT INCUBATORS; for information, see IEC 60601-2-19 [2];
– INFANT TRANSPORT INCUBATORS; for information, see IEC 60601-2-20 [3];
– INFANT RADIANT WARMERS; for information, see IEC 60601-2-21 [4].

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 and IEC 60601-1:2005/AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.*

2 The figures between brackets refer to the Bibliography.

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 201.2 of this particular standard.

IEC 60601-1-2:2014 applies as modified in Clause 202. IEC 60601-1-3 and IEC 60601-1-10~~3)~~ 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 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 ~~is~~ are 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 standards corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this document 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 document addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of the general standard and applicable collateral standards 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~~ 3.147, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables 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.

~~3) 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 document" 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.

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

~~*Amendment*~~

Addition:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012

Replacement:

IEC 60601-1-2:~~2007~~2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic ~~compatibility~~ disturbances – Requirements and tests*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions ~~given~~ specified in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, ~~apply, except as follows~~ and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

NOTE An index of defined terms is found on page 30. 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 1 to entry: 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 nanometres)
E	irradiance (radiant power incidence per unit area on a surface)
E_{bi}	irradiance for bilirubin (total irradiance for 400 nm to 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)
$\mu W/cm^2$	microwatts per square centimetre (unit of irradiance)
nm	nanometre (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)

Abbreviation	Term
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 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~~ particulate matter

Addition:

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 (see also Table C.1 of the general standard)

Additional subclause:

201.7.2.101 * Safety sign for PATIENT eye shield

A safety sign indicating the requirement 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~~ ISO 7010-M025 in IEC TR 60878:2015.

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, for example 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~~ stating if the INFANT PHOTOTHERAPY EQUIPMENT should not be treated with flammable solutions (antiseptics, cleaning agents, etc.);

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

l) a notice that, due to photochemical 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

Addition:

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~~ shall 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~~ shall be reduced according to the body temperature measurements.

201.7.9.2.13 Maintenance

Addition:

The instructions for use shall also contain:

a) if applicable, 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;

c) the notice that, if there are several lamps in the INFANT PHOTOTHERAPY EQUIPMENT, all lamps ~~have to~~ shall be changed at the same time;

d) the notice that the lamps which are recommended by the MANUFACTURER shall be used and that the use of other lamps, which are not approved by the MANUFACTURER, can influence the safety and effectiveness of the phototherapy;

e) a notice that protective devices intended to prevent the PATIENT from falling off the EFFECTIVE IRRADIATED AREA shall be inspected regularly with respect to their safety function.

201.7.9.2.14 ACCESSORIES, supplementary equipment, used material

Addition:

The instructions for use shall contain details about the maximum permissible weight of auxiliary devices/objects on surfaces mounted on the INFANT PHOTOTHERAPY EQUIPMENT, if shelves are an integrated part of the INFANT PHOTOTHERAPY EQUIPMENT.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard applies.

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of the general standard applies, except as follows:

201.9.2.1 General

Addition:

If the INFANT PHOTOTHERAPY EQUIPMENT can be adjusted in height, it shall not be able to contact the PATIENT by a failure of the locking device.

201.9.5.1 Protective means

Addition:

A protective device for the limitation of radiation, referred to as a filter, shall be removable only by means of TOOLS.

~~*Compliance with this requirement is checked by visual inspection.*~~

~~NOTE~~ If applicable, if the PATIENT is lying directly under the INFANT PHOTOTHERAPY EQUIPMENT, a protection against falling glass splinters is absolutely necessary.

Compliance with this requirement is checked by visual inspection.

201.9.6.2 * Acoustic energy

Replacement:

The noise caused by the INFANT PHOTOTHERAPY EQUIPMENT shall not exceed the level given by the MANUFACTURER in the instructions for use and in no case shall it exceed 60 dB(A).

Compliance with this requirement is checked by the following test:

~~*The microphone of a sound level meter complying with type III requirements of IEC 60651 shall be placed in the position of the PATIENT. The measuring value shall not exceed the values given. The background level shall be at least 10 dB(A) below the measuring value of the INFANT PHOTOTHERAPY EQUIPMENT. The measuring room shall comply with a reverberation test room (ISO 3743).*~~

With the microphone of a sound level meter complying with the requirements of IEC 61672-1 placed in the position of the PATIENT, the measured sound level shall not exceed the specified values. The background level shall be at least 10 dB(A) below the measuring value of the INFANT PHOTOTHERAPY EQUIPMENT.

201.9.8 MECHANICAL HAZARDS associated with support systems

Additional subclause:

201.9.8.101 Supports and mounting brackets for ACCESSORIES

Supports and mounting brackets for ACCESSORIES shall be suitable and of adequate strength for their purpose.

Compliance is checked by inspection and by the following test:

A gradually increasing force is applied so as to act vertically through the centre of the supports and mounting brackets, for examples an ACCESSORY shelf in the extended position with a MANUFACTURER'S recommended load. The force is increased from zero in a 5 s to 10 s interval, until it equals three times the recommended load and is sustained for a period of 1 min. There shall be no evidence of damage to the items under test.

201.9.8.3 Strength of PATIENT or OPERATOR support or suspension systems

201.9.8.3.1 * General

Addition:

NOTE The normal load for an INFANT is reduced to 10 kg (see 201.3.202).

Additional subclause:

201.9.8.3.101 Barriers

For devices with an integral bed, suitable barriers shall prevent the PATIENT from falling off. If such protective devices are intended to facilitate access to the PATIENT, as soon as they have been opened or removed, they shall remain in the locked position under test conditions.

The mechanical strength of the barriers shall be maintained under the test conditions given below. It shall not be possible for the barriers to appear to be properly locked or fixed if they are not.

Compliance with this requirement is checked by visual inspection and by the following test:

With all access port doors deliberately made as insecure as possible, without the use of a TOOL, whilst still appearing to be engaged, a horizontal force shall be applied to the centre of the access port door. The force shall be increased gradually from zero to 20 N in an interval of 5 s to 10 s and shall be held at maximum for 5 s.

~~*Additional subclause:*~~

~~**201.9.8.101 Supports and mounting brackets for ACCESSORIES**~~

~~Supports and mounting brackets for ACCESSORIES shall be suitable and of adequate strength for their purpose.~~

~~*Compliance is checked by inspection and by the following test:*~~

~~*A gradually increasing force is applied so as to act vertically through the centre of the supports and mounting brackets, e.g. an accessory shelf in the extended position with a MANUFACTURER'S recommended load. The force is increased from zero in a 5 s to 10 s interval, until it equals three times the recommended load and is sustained for a period of 1 min. There shall be no evidence of damage to the items under test.*~~

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of the general standard applies, except as follows:

201.10.5 * Other visible electromagnetic radiation

Subclause 10.5 of the general standard applies.

201.10.6 * Infrared radiation

Replacement:

Infrared radiation shall not exceed 10 mW/cm^2 (100 W/m^2) for λ between 760 nm and 1 400 nm at any point of the EFFECTIVE IRRADIATED AREA.

Compliance with this requirement is checked by spectral measurement in NORMAL CONDITION *of use after the stabilization period.*

201.10.7 * Ultraviolet radiation

Addition:

Effective ultraviolet irradiance shall not exceed $1{,}0 \times 10^{-5}$ mW/cm^2 ($1{,}0 \times 10^{-4}$ W/m^2) for λ between 180 nm and 400 nm at any point of the EFFECTIVE IRRADIATED AREA.

Compliance with this requirement is checked by spectral measurement in NORMAL CONDITION *of use after the stabilization period.*

201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 of the general standard applies, except as follows:

201.11.1 * Excessive temperatures in ME EQUIPMENT

Addition:

NOTE INFANT PHOTOTHERAPY EQUIPMENT can be used or combined with INFANT INCUBATORS, INFANT TRANSPORT INCUBATORS or INFANT RADIANT WARMERS.

201.11.1.2.2 APPLIED PARTS not intended to supply heat to a PATIENT

Replacement:

The temperature of those surfaces that are intended to come into contact with the PATIENT shall not exceed 40 °C. The temperature of other surfaces that are accessible for the PATIENT shall not exceed 40 °C for metal surfaces and 43 °C for other materials. These requirements shall apply in NORMAL CONDITIONS and SINGLE FAULT CONDITIONS.

Compliance with this requirement is checked by inspection and review of documentation.

201.11.2 * Fire prevention

Subclause 11.2 of the general standard applies.

201.11.8 Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT

Addition:

The ME EQUIPMENT shall be so designed that an interruption and a restoration of the power supply up to 10 min stops the treatment with an information of the OPERATOR or do not change preset values.

Compliance is checked by switching the SUPPLY MAINS off and then switching on and inspecting the ME EQUIPMENT.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 of the general standard applies, except as follows:

201.12.1 Accuracy of controls and instruments

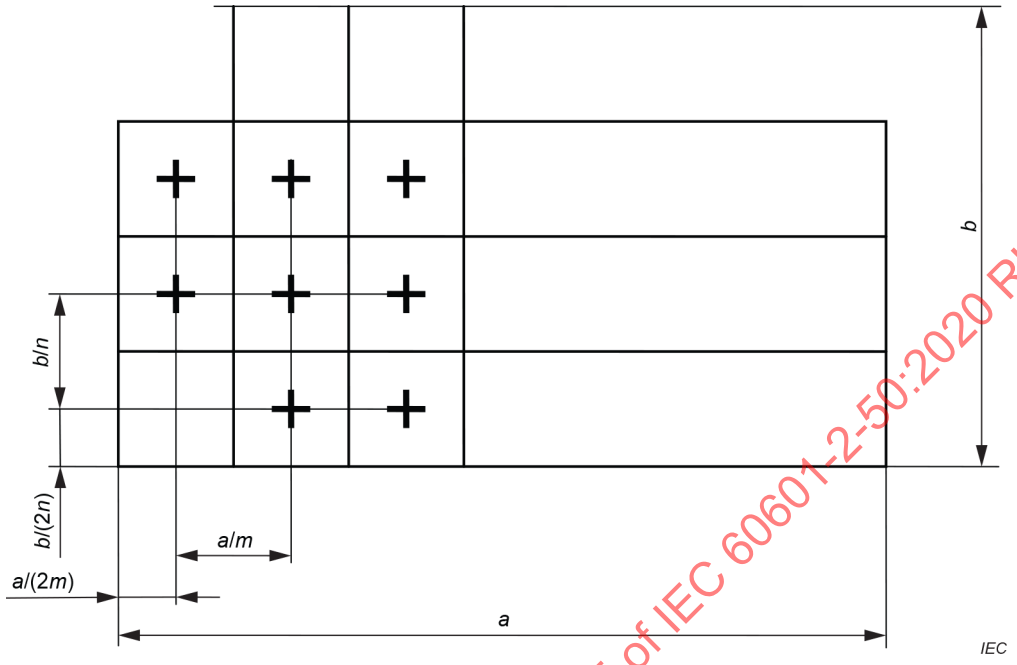
Addition:

201.12.1.101 Irradiance distribution

The distribution of the TOTAL IRRADIANCE FOR BILIRUBIN E_{bi} on the EFFECTIVE IRRADIATED AREA shall be determined. For this purpose, the measuring grid with the measuring points shall be established as follows.

The measuring area shall be divided into a number of congruent rectangular or square partial surfaces according to Figure 201.101. The grid is centred to cover the whole EFFECTIVE

IRRADIATED AREA, so that the measuring points are covered by the maximum of the TOTAL IRRADIANCE FOR BILIRUBIN E_{bi}. The measuring points are identical with the centres of the partial surfaces. The distances between the measuring points on the grid shall not exceed 0,1 m.



NOTE *m*, *n* are the number of partial surfaces in the direction of length *a* and width *b*.

Figure 201.101 – Example of a measuring grid

201.12.1.102 Measuring principles

The values of the TOTAL IRRADIANCE FOR BILIRUBIN E_{bi} and their distribution on the EFFECTIVE IRRADIATED AREA shall be measured, using all measuring points as defined in the measuring grid in 201.12.1.101.

These values can be determined either by spectroradiometric measurements followed by an arithmetical evaluation or by measurements with a radiometer whose lens has a limited spectral sensitivity to the INFANT PHOTOTHERAPY EQUIPMENT (see 201.3.203).

201.12.1.103 * Spectral method

With this method, the spectral irradiance E_λ is measured as a function of the wavelength.

The TOTAL IRRADIANCE FOR BILIRUBIN E_{bi} is ~~a result of equation with~~ calculated by the numeric integration of the measured values between the wavelength of 400 nm and 550 nm.

201.12.1.104 Integral method

With the integral method, the TOTAL IRRADIANCE FOR BILIRUBIN E_{bi} is measured with a radiometer~~ whose spectral sensitivity has been adjusted to the total irradiance in the wavelength range between 400 nm and 550 nm~~ calibrated to measure the irradiance of the source spectrum utilized by the INFANT PHOTOTHERAPY EQUIPMENT between 400 nm and 550 nm.

201.12.1.105 * TOTAL IRRADIANCE FOR BILIRUBIN E_{bi} after pre-ageing

The TOTAL IRRADIANCE FOR BILIRUBIN E_{bi} after pre-ageing shall comply with the MANUFACTURER'S instructions for use with a maximum tolerance of ±25 %.

Compliance with this requirement is checked by using the tests of 201.12.1.102 to 201.12.1.104.

201.12.1.106 * Local distribution

The relative local distribution of E_{bi} on the EFFECTIVE IRRADIATED AREA shall comply with the following conditions:

The ratio of $E_{bi\ min}$ to $E_{bi\ max}$ shall be greater than 40 %.

Compliance with this requirement is checked by the following test:

Measurements shall be carried out in the position of measurement (according to 201.12.1.102).

201.12.1.107 * Weighing scale

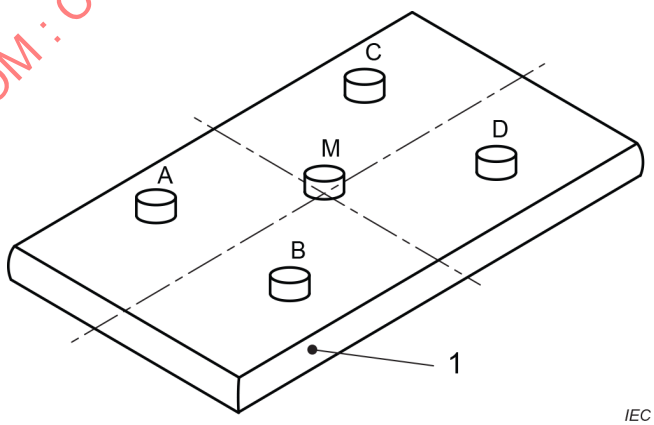
If a weighing scale is supplied as an integral part of the ME EQUIPMENT or as an ACCESSORY specifically for use with the ME EQUIPMENT, the scale-displayed value shall not differ from the test load by more than the MANUFACTURER'S specifications in the ACCOMPANYING DOCUMENTS when operating the ME EQUIPMENT with horizontal MATTRESS orientation. Each value measured shall remain latched on the scale display at the conclusion of any individual measurement cycle and be retained until discarded by the OPERATOR. If the scale may be exposed to an OXYGEN RICH ENVIRONMENT in use, it shall comply with the requirements of 6.5 of the general standard.

NOTE Device calibration ~~may~~ can be able to be both verified and updated by the OPERATOR during usage.

Compliance is checked by the following test:

Test measurements shall be demonstrated using values of (500 ± 1) g and (2 000 ± 1) g. Tests shall be conducted with the ME EQUIPMENT operating at maximum settings.

The accuracy of measurement test shall be verified with the test loads positioned in locations M and A through D in Figure 201.102.



Key

1 MATTRESS

Figure 201.102 – Layout of weight test devices

201.12.4 Protection against hazardous output

Subclause 12.4 of the general standard does not apply.

201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

Clause 13 of the general standard applies, except as follows:

201.13.2 SINGLE FAULT CONDITIONS

Additional subclause:

201.13.2.101 Power supply fluctuation

If the output of the INFANT PHOTOTHERAPY EQUIPMENT increases to a level greater than that stated in 201.10.5, 201.10.6 and 201.10.7 for more than 30 s in a SINGLE FAULT CONDITION, the INFANT PHOTOTHERAPY EQUIPMENT shall switch off automatically.

Compliance with this requirement is checked by inspection.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of the general standard applies.

201.15 Construction of ME EQUIPMENT

Clause 15 of the general standard applies, except as follows:

201.15.3.1 General

Addition:

The lamps of the INFANT PHOTOTHERAPY EQUIPMENT shall be protected against shock and impacts by means of guards (see 201.9.5.1).

201.15.4.4 Indicators

Addition:

201.15.4.4.101 Examination of the lifetime

The INFANT PHOTOTHERAPY EQUIPMENT shall be equipped with a supplementary device that indicates operating hours or how much of the lifetime of the lamp has elapsed.

Compliance with this requirement is checked by inspection.

201.16 ME SYSTEMS

Clause 16 of the general standard applies.

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

Clause 17 of the general standard applies.

202 Electromagnetic ~~COMPATIBILITY~~ disturbances – Requirements and tests

IEC 60601-1-2:~~2007~~2014 applies, except as follows:

~~**202.6.2.3 Radiated RF electromagnetic fields**~~

~~**202.6.2.3.1 * Requirements**~~

~~*Replacement:*~~

~~For radiated radio-frequency electromagnetic fields, the INFANT PHOTOTHERAPY EQUIPMENT and/or system shall~~

- ~~continue to perform its intended function as specified by the MANUFACTURER at a level up to 3 V/m for the frequency range of the collateral standard for EMC;~~
- ~~continue to perform its intended function as specified by the MANUFACTURER or fail without creating a safety HARM at a level up to 10 V/m for the frequency range of the collateral standard for EMC.~~

202.8.9 IMMUNITY TEST LEVELS

Addition:

For radiated radio-frequency electromagnetic fields, the INFANT PHOTOTHERAPY EQUIPMENT and/or system shall

- continue to perform its intended function as specified by the MANUFACTURER at a level up to 3 V/m for the frequency range of the collateral standard for EMC.

NOTE INFANT PHOTOTHERAPY EQUIPMENT is not considered suitable for use in a HOME HEALTHCARE ENVIRONMENT.

Annexes

The annexes of the general standard apply.

Annex AA
(informative)

Particular guidance and rationale

~~**Rationale for particular clauses and subclauses**~~

The following are rationales for specific clauses and subclause in this particular standard, with clause and subclause numbers parallel to those in the body of the document. The numbering is, therefore, not consecutive.

The terms and definitions for the photobiological effects of optical radiation have been specified on the assumption of the additive theorems formula of the Bunsen-Roscow law of linear behaviour (see literature in physics), i.e. the sum of the partial irradiations of the different wave ranges is independent of the type of partial radiation.

Subclause 201.1.1 – Scope

Indirect bilirubin is unconjugated bilirubin that is present in the blood. Phototherapy treatment of indirect hyperbilirubinemia decreases bilirubin levels in the bloodstream, thereby reducing the RISK of bilirubin deposition in the brain. By contrast, direct bilirubin is bilirubin that is conjugated by the liver cells. Phototherapy treatment should not be administered for direct hyperbilirubinemia because skin bronzing may occur and this condition may be permanent.

Subclause 201.3.203 – INFANT PHOTOTHERAPY EQUIPMENT

The lower limit was based on the limitation from 201.10.7. The upper limit was based on the *in vitro* bilirubin absorption curve [5].

The spectral content and bandwidth of the bilirubin response curve are a source of controversy; no accepted “standard” curve is available [6].

Subclause 201.4.3 – ESSENTIAL PERFORMANCE

The experts of the working group have determined that there are no ESSENTIAL PERFORMANCE requirements, as defined by the general standard, because there is no HAZARDOUS SITUATION for the PATIENT under any NORMAL or SINGLE FAULT CONDITION. Unlike baby incubators and transport incubators for which THERMAL STABILITY and accuracy of temperature measurements are essential performance requirements with immediate impact on the INFANT if the ESSENTIAL PERFORMANCE is not achieved, blood bilirubin levels change slowly and all requirements addressed in this document for INFANT PHOTOTHERAPY EQUIPMENT are BASIC SAFETY requirements.

Subclause 201.5.4.101 – Pre-ageing

A 5 h ± 15 min pre-ageing time for fluorescent tube lamps and 1 h ± 15 min for high-pressure lamps is required in the standard for solar light (see IEC 60335-2-27).

It is necessary to take into account this pre-ageing time for performances assessment. But it has little matter for the actual condition of use and performances in hospital.

Subclause 201.5.4.104 – Arrangement in space

Knowing that other than flat surfaces of the EFFECTIVE IRRADIATED AREA and the INFANT PHOTOTHERAPY EQUIPMENT are possible, the MANUFACTURER can describe the position and

surface of his INFANT PHOTOTHERAPY EQUIPMENT in the ACCOMPANYING DOCUMENTS if necessary and if it is different from the requirement of this subclause (see also 201.7.9.2.5 a)).

Subclause 201.7.2.101 – ~~Symbol~~ Safety sign for PATIENT eye shield

Some information regarding sheltering parts of the body other than just the eyes are under discussion, but, at the moment, no approved clinical data are available.

Subclause 201.7.9.2.2 i) – Warning and safety notices

"The blue light of overhead phototherapy lamps can hinder clinical observations by masking skin colour changes, such as cyanosis. In addition, blue light may cause discomfort to caregivers, such as eye irritation, nausea, and headaches." [7]

Subclause 201.7.9.2.13 b) – Maintenance

At this time, there is no evidence justifying a maximum irradiance level (see rationale given for subclause 201.10.5); however, it is necessary for the clinician to be aware of the actual irradiance level produced by the INFANT PHOTOTHERAPY EQUIPMENT so that the clinician can adjust the phototherapy treatment protocol (i.e. treatment time) as a function of lamp aging.

Subclause 201.9.6.2 – Acoustic energy

The maximum level of noise cannot be limited by the results of clinical data for safety reasons. The incubator standard (IEC 60601-2-19:2020) requires 60 dB(A). In some countries, the allowable noise level in sleeping rooms is limited to 35 dB(A).

Subclause 201.9.8.3.1 – General

The load has been reduced because 9.8.1 of the general standard shall be met.

Subclause 201.10.5 – Other visible electromagnetic radiation

It has been demonstrated that the effectiveness of phototherapy is dependent upon the spectral distribution and intensity of light used in treatment. Light in the 400 nm to 550 nm spectral range is most effective for photoisomerization of bilirubin [8].

Present clinical research has not demonstrated a need for a maximum limit on the irradiance level in the spectral range from 400 nm to 550 nm delivered during phototherapy, but blue-light HAZARDS have been described (retinal damage, photosensitization and mutagenesis). The American Conference of Governmental Industrial Hygiene gives advice on radiance limits applicable during phototherapy (ACGIH, 1993). Research has demonstrated RISK associated with the amount of infrared irradiation (see 201.10.6) and ultraviolet irradiation (see 201.10.7) which often accompany phototherapy treatment. Consequently, both IR and UV irradiation have been limited in this document [9].

The publication, Maisels, M. Jeffrey~~, Why Use Homeopathic Doses of Phototherapy, Pediatrics, August 1996, Vol. 98, No. 2, p. 283-287~~ [10] shows that there is a decrease of serum bilirubin when the spectral irradiance has been increased. However, it has not been established that a saturation point exists. Given that the conversion of bilirubin to excretable photoproducts is partly irreversible and follows first-order kinetics, there may not be a saturation point. At this time, there is no evidence justifying a maximum irradiance level.

Subclause 201.10.6 – Infrared radiation

The limits proposed in this document are based upon a review of literature regarding the effect of infrared radiation upon the eyes and skin of humans.

Infrared measurements can be made for λ > 780 nm wavelength (IR-A region) as well as for λ > 1 400 nm (IR-B and IR-C regions).

The IR-A region is associated with potential for damage to the crystalline lens of the eye which may lead to cataract. The IR-B and IR-C regions are almost completely absorbed by the cornea (the outermost layer of the eye) with a resulting potential for burn.

Subclause 201.10.7 – Ultraviolet radiation

The definitions are given in IEC 60050-845. The values comply with the limits given in IEC 60335-2-27:~~1995~~2019. Further information regarding limitation and measuring principles are given in~~: Ultraviolet and Blue-Light Phototherapy – Principles, Sources, Dosimetry and Safety, Report~~ reference [11].

In 1985, the International Radiation Protection Association (IRPA) published limits for UV exposure in adults [12]. This listed limits of 0,1 μW/cm^2 for wavelengths up to 320 nm and 1 000 μW/cm^2 for wavelengths of 320 nm to 400 nm. It should be recognized that these limits are for an eight-hour exposure of adults, whereas phototherapy is used on INFANTS for much longer periods.

See also IRPA Guidelines on protection against non-ionizing radiation [13]. In this publication, the exposure limits (EL) were given for the near-ultraviolet UV-A spectral region (315 nm to 400 nm). The total radiant exposure incident on the unprotected skin should not exceed the values given in Table AA.1.

Values for the relative spectral effectiveness, S_λ, are given up to 400 nm to expand the action spectrum into the UV-A for determining the EL for skin exposure.

To determine the effective irradiance of a broadband source weighted against the peak of the spectral effectiveness curve (peak at 270 nm), to take into account the wavelength dependence of UV radiation upon the eyes and skin, the following weighting formula should be used:

$$E_{\text{eff}} = \sum_{\lambda} E_\lambda \times S_\lambda \times \Delta_\lambda$$

where

E_{eff} is the effective irradiance in W/m^2 normalized to a monochromatic source at 270 nm;

E_λ is the spectral irradiance from measurements in W/m^2;

S_λ is the relative spectral effectiveness of UV radiation on the eyes and skin (unitless);

Δ_λ is the bandwidth in nanometres of the calculation or measurement intervals.

These ELs should be used as guides in the control of exposure to UV sources and as such are intended as upper limits for non-therapeutic and non-elective exposure. The ELs were developed by considering lightly pigmented populations (i.e. Caucasian) with greatest sensitivity and genetic predisposition.

It has been considered that these limits can also be used for the phototherapy of INFANTS, when the above limits are calculated to a 3-day (72-hour) exposure (dividing the 30 J/m^2 by 72 h) and calculated to a constant power of irradiance in watts (W/m^2) (dividing by 3 600 s). This calculation results in a reduced limited spectrum for the UV-A irradiation and respects the uninterrupted phototherapy exposition time of between 24 h and 3 days.

Table AA.1 – UV radiation exposure limits and spectral weighting function

Wavelength	Exposure limit (EL)	Relative spectral effectiveness	Wavelength	Exposure limit (EL)	Relative spectral effectiveness
nm	J/m^2	S_λ	nm	J/m^2	S_λ
180	2 500	0,012	300	100	0,300
190	1 600	0,019	305	500	0,060
200	1 000	0,030	310	2 000	0,015
205	590	0,051	315	$1,0 \times 10^4$	0,003
210	400	0,075	320	$2,9 \times 10^4$	0,001 0
215	320	0,095	325	$6,0 \times 10^4$	0,000 50
220	250	0,120	330	$7,3 \times 10^4$	0,000 41
225	200	0,150	335	$8,8 \times 10^4$	0,000 34
230	160	0,190	340	$1,1 \times 10^5$	0,000 28
235	130	0,240	345	$1,3 \times 10^5$	0,000 24
240	100	0,300	350	$1,5 \times 10^5$	0,000 20
245	83	0,360	355	$1,9 \times 10^5$	0,000 16
250	70	0,430	360	$2,3 \times 10^5$	0,000 13
255	58	0,520	365	$2,7 \times 10^5$	0,000 11
260	46	0,650	370	$3,2 \times 10^5$	0,000 093
265	37	0,810	375	$3,9 \times 10^5$	0,000 077
270	30	1,000	380	$4,7 \times 10^5$	0,000 064
275	31	0,960	385	$5,7 \times 10^5$	0,000 053
280	34	0,880	390	$6,8 \times 10^5$	0,000 044
285	39	0,770	395	$8,3 \times 10^5$	0,000 036
290	47	0,640	400	$1,0 \times 10^6$	0,000 030
295	56	0,540			

Subclause 201.11.1 – Excessive temperatures in ME EQUIPMENT

The limitation of temperatures is given by the other relevant standards for INFANTS (see IEC 60601-2-19:2020, IEC 60601-2-20:2020, IEC 60601-2-21:2021 and ~~IEC 80601-2-35~~IEC 60601-2-35:2020) for BABY INCUBATORS, TRANSPORT INCUBATORS, RADIANT WARMERS and heated MATTRESSES.

The temperatures in ME EQUIPMENT may rise when combined with other heat sources such as phototherapy BLANKETS or PADS. Hence, it is important to specifically consider the impact of such additional heat sources in the RISK MANAGEMENT.

Subclause 201.11.2 – Fire prevention

During the review of this document, the committee was requested to consider adding a flammability requirement to the INFANT MATTRESS. Because the committee could find no evidence to support an addition of this type, this brief rationale was added to the subclause.

MATTRESSES or PADS usually consist of two materials that serve two different functions. The filler functions to support or cradle the INFANT while the surface material acts as a barrier from the inner material. The primary requirement of the surface material is to present no HAZARD to the PATIENT which could contact the PATIENT under a system SINGLE FAULT CONDITION. In most clinical applications, the outer surface has been observed to be covered with additional coverings consisting of a natural fibre (cotton or materials supplied by PATIENT'S parent) based material which is not specifically flame retardant but functions to further reduce the low

abrasion qualities of the PAD'S cover with the neonate's skin. The primary requirements of the filler material are to provide a comfortable surface for long term stay of the PATIENT.

Since there is no source of ignition inside the canopy of an incubator, the RISK of fire ignition in the area of the MATTRESS is limited since the requirements of 6.5 of the general standard for an OXYGEN RICH ENVIRONMENT has been complied with. No incident has been reported concerning fire ignition inside the canopy of an incubator for many years. Also, even with warming MATTRESSES, additional concerns were discussed around the toxicity of fumes that can be produced by materials that have been treated with flame retardant additives. Therefore, with the exception of elevating (accelerant) the RISK of fire from the cover material, no specific flammability rating is required of the PAD cover and the inner filler.

Subclause 201.12.1.103 – Spectral method

For the definition, see IEC 60050-845:1987, 845-01-16.

Subclause 201.12.1.105 – TOTAL IRRADIANCE FOR BILIRUBIN E_{bi} after pre-ageing

See rationale for 201.7.9.2.13 b).

Subclause 201.12.1.106 – Local distribution

Up to this time, no clinical results and recommendations are available. The value of 0,4 is accepted as an adequate and safe limitation.

Subclause 201.12.1.107 – Weighing scale

Weight scales used in paediatric ME EQUIPMENT have unique requirements that differ significantly from those of weight scales used in general commercial or domestic weighing applications. Absolute accuracy is important, however not to the degree of accuracy (1/1 000) required by commercial scales used for monetary transactions. More important from a clinical application is the information provided by weight trends, demonstrating an increase or decrease trend in the weight of the INFANT. Absolute accuracy is very difficult at best due to electrical leads, tubing, and other PATIENT care devices that cannot be completely eliminated from the measurement.

Because weighing an INFANT is a difficult process requiring both hands of the OPERATOR in the manipulation of the INFANT, it is necessary that the weight reading be held and displayed until such time as the OPERATOR has completed the PROCEDURE. The weight reading should be displayed until the OPERATOR has recorded it or stored it, if electronic storage is an option.

An INFANT needs to be contained in a heated, controlled environment for an extended period of time. Moving an INFANT for any reason can be harmful to the INFANT'S well being. INFANTS often remain in their controlled environment, incubator or radiant warmer, for two or more weeks. During this time it is necessary for the OPERATOR to assure the calibration of the weight scale. Additionally, it may be necessary for the OPERATOR to be able to adjust the calibration, should the weight scale be out of calibration, without the necessity to remove the scale or move the INFANT for calibration.

~~**Subclause 202.6.2.3.1 – Requirements**~~

~~The expert group do not consider the warming therapy devices to be a LIFE SUPPORTING ME EQUIPMENT as defined in the collateral standard IEC 60601-1-2 for EMC.~~

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[1] IEC 60601-2-35:2020, *Medical electrical equipment – Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads and mattresses and intended for heating in medical use*

[2] IEC 60601-2-19:2020, *Medical electrical equipment – Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators*

[3] IEC 60601-2-20:2020, *Medical electrical equipment – Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators*

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~~4) To be published.~~

[11] ~~*Ultraviolet and Blue-Light Phototherapy – Principles, Sources, Dosimetry and Safety*, Report No. 76, The Institute of Physics and Engineering in Medicine, by Brian Diffey and Graham Hart, Fairmount House, 230 Tadcaster Road, YORK, YO24 1ES, ISBN 0904181863~~
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[13] ~~I~~*RPA Guidelines on protection against non-ionizing radiation*, edited by A.S. Duchêne et al. Pergamon Press (1991; ISBN 008360971): Chapter 3: Guidelines on limits of exposure to ultraviolet radiation of wavelengths between 180 nm and 400 nm (incoherent optical radiation), p. 42-52

[14] IEC 60050-845, *International Electrotechnical Vocabulary (IEV) – Chapter 845: Lighting* (available on www.electropedia.org)

[15] IEC 60335-2-27:2019, *Household and similar electrical appliances – Safety – Part 2-27: Particular requirements for appliances for skin exposure to optical radiation*

[16] IEC TR 60878:2015, *Graphical symbols for electrical equipment in medical practice*

[17] IEC 61672-1, *Electroacoustics – Sound level meters – Part 1: Specifications*

[18] IEC 60601-1-10, *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*

[19] IEC 62366-1:2015, *Medical devices – Part 1: Application of usability engineering to medical devices*

[20] IEC 60601-1-11, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

Index of defined terms used in this document

IEC 60601-2-50

Edition 3.0 2020-09

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 60601-2-50:2020-09(en-fr)

CONTENTS

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 third edition cancels and replaces the second edition published in 2009 and Amendment 1:2016. This edition constitutes a technical revision.

This edition includes the following significant technical change with respect to the previous edition: re-dating of normative references.

The text of this International Standard d is based on the following documents:

FDIS	Report on voting
62D/1767/FDIS	62D/1775/RVD

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

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

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

In this document, 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 document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

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

– “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;

– “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 document will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific document. At this date, the document will be

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

NOTE The attention of users of this document is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication.

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.

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 part of IEC 60601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of INFANT PHOTOTHERAPY EQUIPMENT, as defined in 201.3.203, 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 document are not covered by specific requirements in this document, 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 document does not apply to:

– devices supplying heat via BLANKETS, PADS or MATTRESSES in medical use; for information, see IEC 60601-2-35 [1][2];
– INFANT INCUBATORS; for information, see IEC 60601-2-19 [2];
– INFANT TRANSPORT INCUBATORS; for information, see IEC 60601-2-20 [3];
– INFANT RADIANT WARMERS; for information, see IEC 60601-2-21 [4].

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 and IEC 60601-1:2005/AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.*

2 The figures between brackets refer to the Bibliography.

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 201.2 of this particular standard.

IEC 60601-1-2:2014 applies as modified in Clause 202. IEC 60601-1-3 and IEC 60601-1-10 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 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 are 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 standards corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this document 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 document addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of the general standard and applicable collateral standards 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 3.147, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables 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.

The term "this document" 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.

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

Addition:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012

Replacement:

IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions specified in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

NOTE An index of defined terms is found on page 29. 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 1 to entry: 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 nanometres)
E	irradiance (radiant power incidence per unit area on a surface)
E_{bi}	irradiance for bilirubin (total irradiance for 400 nm to 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)
$\mu W/cm^2$	microwatts per square centimetre (unit of irradiance)
nm	nanometre (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 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 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 particulate matter

Addition:

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 (see also Table C.1 of the general standard)

Additional subclause:

201.7.2.101 * Safety sign for PATIENT eye shield

A safety sign indicating the requirement for 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 ISO 7010-M025 in IEC TR 60878:2015.

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, for example 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;

j) a notice stating if the INFANT PHOTOTHERAPY EQUIPMENT should not be treated with flammable solutions (antiseptics, cleaning agents, etc.);

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

l) a notice that, due to photochemical 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

Addition:

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 shall 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 shall be reduced according to the body temperature measurements.

201.7.9.2.13 Maintenance

Addition:

The instructions for use shall also contain:

a) if applicable, 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;

c) the notice that, if there are several lamps in the INFANT PHOTOTHERAPY EQUIPMENT, all lamps shall be changed at the same time;

d) the notice that the lamps which are recommended by the MANUFACTURER shall be used and that the use of other lamps, which are not approved by the MANUFACTURER, can influence the safety and effectiveness of the phototherapy;

e) a notice that protective devices intended to prevent the PATIENT from falling off the EFFECTIVE IRRADIATED AREA shall be inspected regularly with respect to their safety function.

201.7.9.2.14 ACCESSORIES, supplementary equipment, used material

Addition:

The instructions for use shall contain details about the maximum permissible weight of auxiliary devices/objects on surfaces mounted on the INFANT PHOTOTHERAPY EQUIPMENT, if shelves are an integrated part of the INFANT PHOTOTHERAPY EQUIPMENT.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard applies.

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of the general standard applies, except as follows:

201.9.2.1 General

Addition:

If the INFANT PHOTOTHERAPY EQUIPMENT can be adjusted in height, it shall not be able to contact the PATIENT by a failure of the locking device.

201.9.5.1 Protective means

Addition:

A protective device for the limitation of radiation, referred to as a filter, shall be removable only by means of TOOLS.

If applicable, if the PATIENT is lying directly under the INFANT PHOTOTHERAPY EQUIPMENT, a protection against falling glass splinters is absolutely necessary.

Compliance with this requirement is checked by visual inspection.

201.9.6.2 * Acoustic energy

Replacement:

The noise caused by the INFANT PHOTOTHERAPY EQUIPMENT shall not exceed the level given by the MANUFACTURER in the instructions for use and in no case shall it exceed 60 dB(A).

Compliance with this requirement is checked by the following test:

With the microphone of a sound level meter complying with the requirements of IEC 61672-1 placed in the position of the PATIENT, the measured sound level shall not exceed the specified values. The background level shall be at least 10 dB(A) below the measuring value of the INFANT PHOTOTHERAPY EQUIPMENT.

201.9.8 MECHANICAL HAZARDS associated with support systems

Additional subclause:

201.9.8.101 Supports and mounting brackets for ACCESSORIES

Supports and mounting brackets for ACCESSORIES shall be suitable and of adequate strength for their purpose.

Compliance is checked by inspection and by the following test:

A gradually increasing force is applied so as to act vertically through the centre of the supports and mounting brackets, for examples an ACCESSORY shelf in the extended position with a MANUFACTURER'S recommended load. The force is increased from zero in a 5 s to 10 s interval, until it equals three times the recommended load and is sustained for a period of 1 min. There shall be no evidence of damage to the items under test.

201.9.8.3 Strength of PATIENT or OPERATOR support or suspension systems

201.9.8.3.1 * General

Addition:

NOTE The normal load for an INFANT is reduced to 10 kg (see 201.3.202).

Additional subclause:

201.9.8.3.101 Barriers

For devices with an integral bed, suitable barriers shall prevent the PATIENT from falling off. If such protective devices are intended to facilitate access to the PATIENT, as soon as they have been opened or removed, they shall remain in the locked position under test conditions.

The mechanical strength of the barriers shall be maintained under the test conditions given below. It shall not be possible for the barriers to appear to be properly locked or fixed if they are not.

Compliance with this requirement is checked by visual inspection and by the following test:

With all access port doors deliberately made as insecure as possible, without the use of a TOOL, whilst still appearing to be engaged, a horizontal force shall be applied to the centre of the access port door. The force shall be increased gradually from zero to 20 N in an interval of 5 s to 10 s and shall be held at maximum for 5 s.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of the general standard applies, except as follows:

201.10.5 * Other visible electromagnetic radiation

Subclause 10.5 of the general standard applies.

201.10.6 * Infrared radiation

Replacement:

Infrared radiation shall not exceed 10 mW/cm^2 (100 W/m^2) for λ between 760 nm and 1 400 nm at any point of the EFFECTIVE IRRADIATED AREA.

Compliance with this requirement is checked by spectral measurement in NORMAL CONDITION *of use after the stabilization period.*

201.10.7 * Ultraviolet radiation

Addition:

Effective ultraviolet irradiance shall not exceed $1{,}0 \times 10^{-5}$ mW/cm^2 ($1{,}0 \times 10^{-4}$ W/m^2) for λ between 180 nm and 400 nm at any point of the EFFECTIVE IRRADIATED AREA.

Compliance with this requirement is checked by spectral measurement in NORMAL CONDITION *of use after the stabilization period.*

201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 of the general standard applies, except as follows:

201.11.1 * Excessive temperatures in ME EQUIPMENT

Addition:

NOTE INFANT PHOTOTHERAPY EQUIPMENT can be used or combined with INFANT INCUBATORS, INFANT TRANSPORT INCUBATORS or INFANT RADIANT WARMERS.

201.11.1.2.2 APPLIED PARTS not intended to supply heat to a PATIENT

Replacement:

The temperature of those surfaces that are intended to come into contact with the PATIENT shall not exceed 40 °C. The temperature of other surfaces that are accessible for the PATIENT shall not exceed 40 °C for metal surfaces and 43 °C for other materials. These requirements shall apply in NORMAL CONDITIONS and SINGLE FAULT CONDITIONS.

Compliance with this requirement is checked by inspection and review of documentation.

201.11.2 * Fire prevention

Subclause 11.2 of the general standard applies.

201.11.8 Interruption of the power supply / SUPPLY MAINS to ME EQUIPMENT

Addition:

The ME EQUIPMENT shall be so designed that an interruption and a restoration of the power supply up to 10 min stops the treatment with an information of the OPERATOR or do not change preset values.

Compliance is checked by switching the SUPPLY MAINS off and then switching on and inspecting the ME EQUIPMENT.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 of the general standard applies, except as follows:

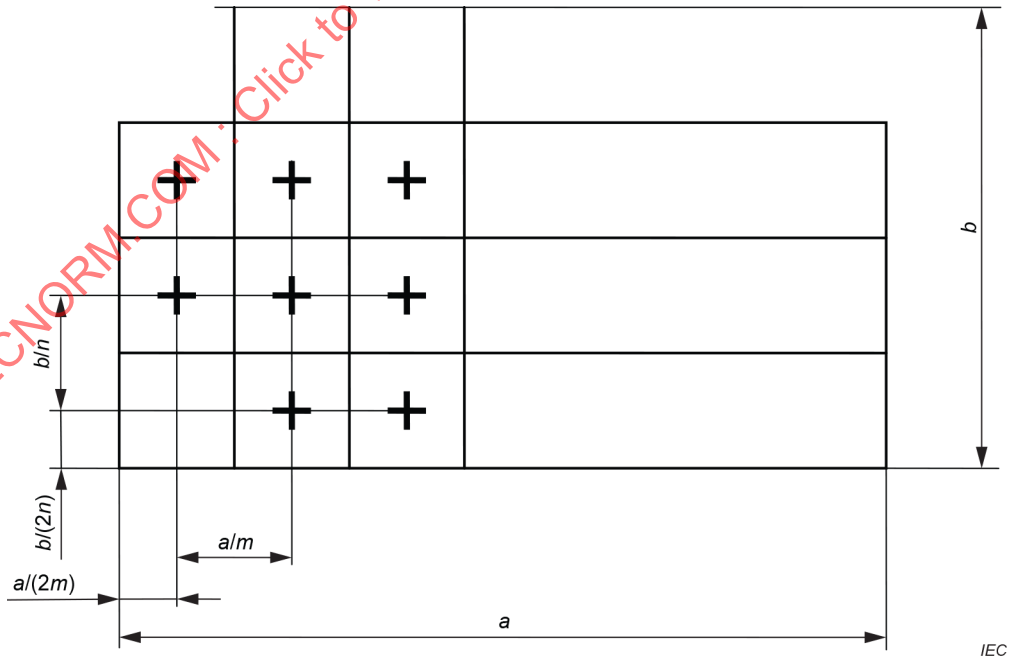
201.12.1 Accuracy of controls and instruments

Addition:

201.12.1.101 Irradiance distribution

The distribution of the TOTAL IRRADIANCE FOR BILIRUBIN E_{bi} on the EFFECTIVE IRRADIATED AREA shall be determined. For this purpose, the measuring grid with the measuring points shall be established as follows.

The measuring area shall be divided into a number of congruent rectangular or square partial surfaces according to Figure 201.101. The grid is centred to cover the whole EFFECTIVE IRRADIATED AREA, so that the measuring points are covered by the maximum of the TOTAL IRRADIANCE FOR BILIRUBIN E_{bi}. The measuring points are identical with the centres of the partial surfaces. The distances between the measuring points on the grid shall not exceed 0,1 m.



NOTE *m*, *n* are the number of partial surfaces in the direction of length *a* and width *b*.

Figure 201.101 – Example of a measuring grid

201.12.1.102 Measuring principles

The values of the TOTAL IRRADIANCE FOR BILIRUBIN E_{bi} and their distribution on the EFFECTIVE IRRADIATED AREA shall be measured, using all measuring points as defined in the measuring grid in 201.12.1.101.

These values can be determined either by spectroradiometric measurements followed by an arithmetical evaluation or by measurements with a radiometer whose lens has a limited spectral sensitivity to the INFANT PHOTOTHERAPY EQUIPMENT (see 201.3.203).

201.12.1.103 * Spectral method

With this method, the spectral irradiance E_{λ} is measured as a function of the wavelength.

The TOTAL IRRADIANCE FOR BILIRUBIN E_{bi} is calculated by the numeric integration of the measured values between the wavelength of 400 nm and 550 nm.

201.12.1.104 Integral method

With the integral method, the TOTAL IRRADIANCE FOR BILIRUBIN E_{bi} is measured with a radiometer calibrated to measure the irradiance of the source spectrum utilized by the INFANT PHOTOTHERAPY EQUIPMENT between 400 nm and 550 nm.

201.12.1.105 * TOTAL IRRADIANCE FOR BILIRUBIN E_{bi} after pre-ageing

The TOTAL IRRADIANCE FOR BILIRUBIN E_{bi} after pre-ageing shall comply with the MANUFACTURER'S instructions for use with a maximum tolerance of ±25 %.

Compliance with this requirement is checked by using the tests of 201.12.1.102 to 201.12.1.104.

201.12.1.106 * Local distribution

The relative local distribution of E_{bi} on the EFFECTIVE IRRADIATED AREA shall comply with the following conditions:

The ratio of $E_{bi\ min}$ to $E_{bi\ max}$ shall be greater than 40 %.

Compliance with this requirement is checked by the following test:

Measurements shall be carried out in the position of measurement (according to 201.12.1.102).

201.12.1.107 * Weighing scale

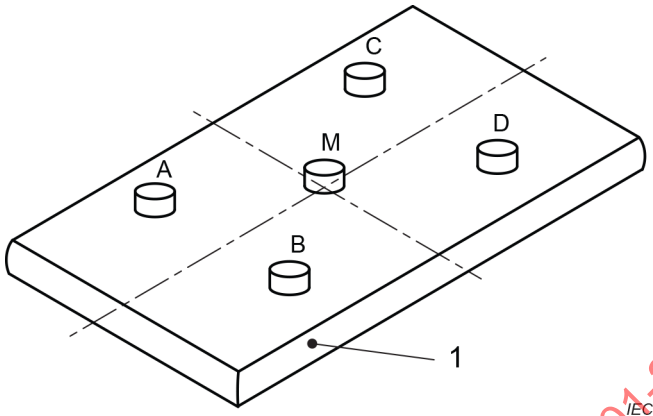
If a weighing scale is supplied as an integral part of the ME EQUIPMENT or as an ACCESSORY specifically for use with the ME EQUIPMENT, the scale-displayed value shall not differ from the test load by more than the MANUFACTURER'S specifications in the ACCOMPANYING DOCUMENTS when operating the ME EQUIPMENT with horizontal MATTRESS orientation. Each value measured shall remain latched on the scale display at the conclusion of any individual measurement cycle and be retained until discarded by the OPERATOR. If the scale may be exposed to an OXYGEN RICH ENVIRONMENT in use, it shall comply with the requirements of 6.5 of the general standard.

NOTE Device calibration can be able to be both verified and updated by the OPERATOR during usage.

Compliance is checked by the following test:

Test measurements shall be demonstrated using values of (500 ± 1) g and (2 000 ± 1) g. Tests shall be conducted with the ME EQUIPMENT operating at maximum settings.

The accuracy of measurement test shall be verified with the test loads positioned in locations M and A through D in Figure 201.102.



Key

1 MATTRESS

Figure 201.102 – Layout of weight test devices

201.12.4 Protection against hazardous output

Subclause 12.4 of the general standard does not apply.

201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT

Clause 13 of the general standard applies, except as follows:

201.13.2 SINGLE FAULT CONDITIONS

Additional subclause:

201.13.2.101 Power supply fluctuation

If the output of the INFANT PHOTOTHERAPY EQUIPMENT increases to a level greater than that stated in 201.10.5, 201.10.6 and 201.10.7 for more than 30 s in a SINGLE FAULT CONDITION, the INFANT PHOTOTHERAPY EQUIPMENT shall switch off automatically.

Compliance with this requirement is checked by inspection.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of the general standard applies.

201.15 Construction of ME EQUIPMENT

Clause 15 of the general standard applies, except as follows:

201.15.3.1 General

Addition:

The lamps of the INFANT PHOTOTHERAPY EQUIPMENT shall be protected against shock and impacts by means of guards (see 201.9.5.1).

201.15.4.4 Indicators

Addition:

201.15.4.4.101 Examination of the lifetime

The INFANT PHOTOTHERAPY EQUIPMENT shall be equipped with a supplementary device that indicates operating hours or how much of the lifetime of the lamp has elapsed.

Compliance with this requirement is checked by inspection.

201.16 ME SYSTEMS

Clause 16 of the general standard applies.

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

Clause 17 of the general standard applies.

202 Electromagnetic disturbances – Requirements and tests

IEC 60601-1-2:2014 applies, except as follows:

202.8.9 IMMUNITY TEST LEVELS

Addition:

For radiated radio-frequency electromagnetic fields, the INFANT PHOTOTHERAPY EQUIPMENT and/or system shall

– continue to perform its intended function as specified by the MANUFACTURER at a level up to 3 V/m for the frequency range of the collateral standard for EMC.

NOTE INFANT PHOTOTHERAPY EQUIPMENT is not considered suitable for use in a HOME HEALTHCARE ENVIRONMENT.

Annexes

The annexes of the general standard apply.

Annex AA
(informative)

Particular guidance and rationale

The following are rationales for specific clauses and subclause in this particular standard, with clause and subclause numbers parallel to those in the body of the document. The numbering is, therefore, not consecutive.

The terms and definitions for the photobiological effects of optical radiation have been specified on the assumption of the additive theorems formula of the Bunsen-Roscow law of linear behaviour (see literature in physics), i.e. the sum of the partial irradiations of the different wave ranges is independent of the type of partial radiation.

Subclause 201.1.1 – Scope

Indirect bilirubin is unconjugated bilirubin that is present in the blood. Phototherapy treatment of indirect hyperbilirubinemia decreases bilirubin levels in the bloodstream, thereby reducing the RISK of bilirubin deposition in the brain. By contrast, direct bilirubin is bilirubin that is conjugated by the liver cells. Phototherapy treatment should not be administered for direct hyperbilirubinemia because skin bronzing may occur and this condition may be permanent.

Subclause 201.3.203 – INFANT PHOTOTHERAPY EQUIPMENT

The lower limit was based on the limitation from 201.10.7. The upper limit was based on the *in vitro* bilirubin absorption curve [5].

The spectral content and bandwidth of the bilirubin response curve are a source of controversy; no accepted “standard” curve is available [6].

Subclause 201.4.3 – ESSENTIAL PERFORMANCE

The experts of the working group have determined that there are no ESSENTIAL PERFORMANCE requirements, as defined by the general standard, because there is no HAZARDOUS SITUATION for the PATIENT under any NORMAL or SINGLE FAULT CONDITION. Unlike baby incubators and transport incubators for which THERMAL STABILITY and accuracy of temperature measurements are essential performance requirements with immediate impact on the INFANT if the ESSENTIAL PERFORMANCE is not achieved, blood bilirubin levels change slowly and all requirements addressed in this document for INFANT PHOTOTHERAPY EQUIPMENT are BASIC SAFETY requirements.

Subclause 201.5.4.101 – Pre-ageing

A 5 h ± 15 min pre-ageing time for fluorescent tube lamps and 1 h ± 15 min for high-pressure lamps is required in the standard for solar light (see IEC 60335-2-27).

It is necessary to take into account this pre-ageing time for performances assessment. But it has little matter for the actual condition of use and performances in hospital.

Subclause 201.5.4.104 – Arrangement in space

Knowing that other than flat surfaces of the EFFECTIVE IRRADIATED AREA and the INFANT PHOTOTHERAPY EQUIPMENT are possible, the MANUFACTURER can describe the position and surface of his INFANT PHOTOTHERAPY EQUIPMENT in the ACCOMPANYING DOCUMENTS if necessary and if it is different from the requirement of this subclause (see also 201.7.9.2.5 a)).

Subclause 201.7.2.101 – Safety sign for PATIENT eye shield

Some information regarding sheltering parts of the body other than just the eyes are under discussion, but, at the moment, no approved clinical data are available.

Subclause 201.7.9.2.2 i) – Warning and safety notices

“The blue light of overhead phototherapy lamps can hinder clinical observations by masking skin colour changes, such as cyanosis. In addition, blue light may cause discomfort to caregivers, such as eye irritation, nausea, and headaches.” [7]

Subclause 201.7.9.2.13 b) – Maintenance

At this time, there is no evidence justifying a maximum irradiance level (see rationale given for subclause 201.10.5); however, it is necessary for the clinician to be aware of the actual irradiance level produced by the INFANT PHOTOTHERAPY EQUIPMENT so that the clinician can adjust the phototherapy treatment protocol (i.e. treatment time) as a function of lamp aging.

Subclause 201.9.6.2 – Acoustic energy

The maximum level of noise cannot be limited by the results of clinical data for safety reasons. The incubator standard (IEC 60601-2-19:2020) requires 60 dB(A). In some countries, the allowable noise level in sleeping rooms is limited to 35 dB(A).

Subclause 201.9.8.3.1 – General

The load has been reduced because 9.8.1 of the general standard shall be met.

Subclause 201.10.5 – Other visible electromagnetic radiation

It has been demonstrated that the effectiveness of phototherapy is dependent upon the spectral distribution and intensity of light used in treatment. Light in the 400 nm to 550 nm spectral range is most effective for photoisomerization of bilirubin [8].

Present clinical research has not demonstrated a need for a maximum limit on the irradiance level in the spectral range from 400 nm to 550 nm delivered during phototherapy, but blue-light HAZARDS have been described (retinal damage, photosensitization and mutagenesis). The American Conference of Governmental Industrial Hygiene gives advice on radiance limits applicable during phototherapy (ACGIH, 1993). Research has demonstrated RISK associated with the amount of infrared irradiation (see 201.10.6) and ultraviolet irradiation (see 201.10.7) which often accompany phototherapy treatment. Consequently, both IR and UV irradiation have been limited in this document [9].

The publication, Maisels, M. Jeffrey [10] shows that there is a decrease of serum bilirubin when the spectral irradiance has been increased. However, it has not been established that a saturation point exists. Given that the conversion of bilirubin to excretable photoproducts is partly irreversible and follows first-order kinetics, there may not be a saturation point. At this time, there is no evidence justifying a maximum irradiance level.

Subclause 201.10.6 – Infrared radiation

The limits proposed in this document are based upon a review of literature regarding the effect of infrared radiation upon the eyes and skin of humans.

Infrared measurements can be made for λ > 780 nm wavelength (IR-A region) as well as for λ > 1 400 nm (IR-B and IR-C regions).

The IR-A region is associated with potential for damage to the crystalline lens of the eye which may lead to cataract. The IR-B and IR-C regions are almost completely absorbed by the cornea (the outermost layer of the eye) with a resulting potential for burn.

Subclause 201.10.7 – Ultraviolet radiation

The definitions are given in IEC 60050-845. The values comply with the limits given in IEC 60335-2-27:2019. Further information regarding limitation and measuring principles are given in reference [11].

In 1985, the International Radiation Protection Association (IRPA) published limits for UV exposure in adults [12]. This listed limits of 0,1 μW/cm^2 for wavelengths up to 320 nm and 1 000 μW/cm^2 for wavelengths of 320 nm to 400 nm. It should be recognized that these limits are for an eight-hour exposure of adults, whereas phototherapy is used on INFANTS for much longer periods.

See also IRPA Guidelines on protection against non-ionizing radiation [13]. In this publication, the exposure limits (EL) were given for the near-ultraviolet UV-A spectral region (315 nm to 400 nm). The total radiant exposure incident on the unprotected skin should not exceed the values given in Table AA.1.

Values for the relative spectral effectiveness, S_λ, are given up to 400 nm to expand the action spectrum into the UV-A for determining the EL for skin exposure.

To determine the effective irradiance of a broadband source weighted against the peak of the spectral effectiveness curve (peak at 270 nm), to take into account the wavelength dependence of UV radiation upon the eyes and skin, the following weighting formula should be used:

$$E_{\text{eff}} = \sum_{\lambda} E_\lambda \times S_\lambda \times \Delta_\lambda$$

where

E_{eff} is the effective irradiance in W/m^2 normalized to a monochromatic source at 270 nm;

E_λ is the spectral irradiance from measurements in W/m^2;

S_λ is the relative spectral effectiveness of UV radiation on the eyes and skin (unitless);

Δ_λ is the bandwidth in nanometres of the calculation or measurement intervals.

These ELs should be used as guides in the control of exposure to UV sources and as such are intended as upper limits for non-therapeutic and non-elective exposure. The ELs were developed by considering lightly pigmented populations (i.e. Caucasian) with greatest sensitivity and genetic predisposition.

It has been considered that these limits can also be used for the phototherapy of INFANTS, when the above limits are calculated to a 3-day (72-hour) exposure (dividing the 30 J/m^2 by 72 h) and calculated to a constant power of irradiance in watts (W/m^2) (dividing by 3 600 s). This calculation results in a reduced limited spectrum for the UV-A irradiation and respects the uninterrupted phototherapy exposition time of between 24 h and 3 days.

Table AA.1 – UV radiation exposure limits and spectral weighting function

Wavelength	Exposure limit (EL)	Relative spectral effectiveness	Wavelength	Exposure limit (EL)	Relative spectral effectiveness
nm	J/m^2	S_λ	nm	J/m^2	S_λ
180	2 500	0,012	300	100	0,300
190	1 600	0,019	305	500	0,060
200	1 000	0,030	310	2 000	0,015
205	590	0,051	315	$1,0 \times 10^4$	0,003
210	400	0,075	320	$2,9 \times 10^4$	0,001 0
215	320	0,095	325	$6,0 \times 10^4$	0,000 50
220	250	0,120	330	$7,3 \times 10^4$	0,000 41
225	200	0,150	335	$8,8 \times 10^4$	0,000 34
230	160	0,190	340	$1,1 \times 10^5$	0,000 28
235	130	0,240	345	$1,3 \times 10^5$	0,000 24
240	100	0,300	350	$1,5 \times 10^5$	0,000 20
245	83	0,360	355	$1,9 \times 10^5$	0,000 16
250	70	0,430	360	$2,3 \times 10^5$	0,000 13
255	58	0,520	365	$2,7 \times 10^5$	0,000 11
260	46	0,650	370	$3,2 \times 10^5$	0,000 093
265	37	0,810	375	$3,9 \times 10^5$	0,000 077
270	30	1,000	380	$4,7 \times 10^5$	0,000 064
275	31	0,960	385	$5,7 \times 10^5$	0,000 053
280	34	0,880	390	$6,8 \times 10^5$	0,000 044
285	39	0,770	395	$8,3 \times 10^5$	0,000 036
290	47	0,640	400	$1,0 \times 10^6$	0,000 030
295	56	0,540			

Subclause 201.11.1 – Excessive temperatures in ME EQUIPMENT

The limitation of temperatures is given by the other relevant standards for INFANTS (see IEC 60601-2-19:2020, IEC 60601-2-20:2020, IEC 60601-2-21:2021 and IEC 60601-2-35:2020) for BABY INCUBATORS, TRANSPORT INCUBATORS, RADIANT WARMERS and heated MATTRESSES.

The temperatures in ME EQUIPMENT may rise when combined with other heat sources such as phototherapy BLANKETS or PADS. Hence, it is important to specifically consider the impact of such additional heat sources in the RISK MANAGEMENT.

Subclause 201.11.2 – Fire prevention

During the review of this document, the committee was requested to consider adding a flammability requirement to the INFANT MATTRESS. Because the committee could find no evidence to support an addition of this type, this brief rationale was added to the subclause.

MATTRESSES or PADS usually consist of two materials that serve two different functions. The filler functions to support or cradle the INFANT while the surface material acts as a barrier from the inner material. The primary requirement of the surface material is to present no HAZARD to the PATIENT which could contact the PATIENT under a system SINGLE FAULT CONDITION. In most clinical applications, the outer surface has been observed to be covered with additional coverings consisting of a natural fibre (cotton or materials supplied by PATIENT'S parent) based material which is not specifically flame retardant but functions to further reduce the low abrasion qualities of the PAD'S cover with the neonate's skin. The primary requirements of the filler material are to provide a comfortable surface for long term stay of the PATIENT.

Since there is no source of ignition inside the canopy of an incubator, the RISK of fire ignition in the area of the MATTRESS is limited since the requirements of 6.5 of the general standard for an OXYGEN RICH ENVIRONMENT has been complied with. No incident has been reported concerning fire ignition inside the canopy of an incubator for many years. Also, even with warming MATTRESSES, additional concerns were discussed around the toxicity of fumes that can be produced by materials that have been treated with flame retardant additives. Therefore, with the exception of elevating (accelerant) the RISK of fire from the cover material, no specific flammability rating is required of the PAD cover and the inner filler.

Subclause 201.12.1.103 – Spectral method

For the definition, see IEC 60050-845:1987, 845-01-16.

Subclause 201.12.1.105 – TOTAL IRRADIANCE FOR BILIRUBIN E_{bi} after pre-ageing

See rationale for 201.7.9.2.13 b).

Subclause 201.12.1.106 – Local distribution

Up to this time, no clinical results and recommendations are available. The value of 0,4 is accepted as an adequate and safe limitation.

Subclause 201.12.1.107 – Weighing scale

Weight scales used in paediatric ME EQUIPMENT have unique requirements that differ significantly from those of weight scales used in general commercial or domestic weighing applications. Absolute accuracy is important, however not to the degree of accuracy (1/1 000) required by commercial scales used for monetary transactions. More important from a clinical application is the information provided by weight trends, demonstrating an increase or decrease trend in the weight of the INFANT. Absolute accuracy is very difficult at best due to electrical leads, tubing, and other PATIENT care devices that cannot be completely eliminated from the measurement.

Because weighing an INFANT is a difficult process requiring both hands of the OPERATOR in the manipulation of the INFANT, it is necessary that the weight reading be held and displayed until such time as the OPERATOR has completed the PROCEDURE. The weight reading should be displayed until the OPERATOR has recorded it or stored it, if electronic storage is an option.

An INFANT needs to be contained in a heated, controlled environment for an extended period of time. Moving an INFANT for any reason can be harmful to the INFANT'S well being. INFANTS often remain in their controlled environment, incubator or radiant warmer, for two or more weeks. During this time it is necessary for the OPERATOR to assure the calibration of the weight scale. Additionally, it may be necessary for the OPERATOR to be able to adjust the calibration, should the weight scale be out of calibration, without the necessity to remove the scale or move the INFANT for calibration.

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Index of defined terms used in this document

SOMMAIRE

COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

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APPAREILS ÉLECTROMÉDICAUX –

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

AVANT-PROPOS

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8) L'attention est attirée sur les références normatives citées dans cette publication. L'utilisation de publications référencées est obligatoire pour une application correcte de la présente publication.
9) L'attention est attirée sur le fait que certains des éléments de la présente Publication de l'IEC peuvent faire l'objet de droits de brevet. L'IEC ne saurait être tenue pour responsable de ne pas avoir identifié de tels droits de brevets et de ne pas avoir signalé leur existence.

La Norme internationale IEC 60601-2-50 a été établie par le sous-comité 62D: Appareils électromédicaux, du comité d'études 62 de l'IEC: Équipements électriques dans la pratique médicale.

Cette troisième édition annule et remplace la deuxième édition parue en 2009 et son Amendement 1 (2016). Cette édition constitue une révision technique.

Cette édition inclut la modification technique majeure suivante par rapport à l'édition précédente: nouvelle datation des références normatives.

Le texte de cette Norme internationale est issu des documents suivants:

FDIS	Rapport de vote
62D/1767/FDIS	62D/1775/RVD

Le rapport de vote indiqué dans le tableau ci-dessus donne toute information sur le vote ayant abouti à l'approbation de cette Norme internationale.

La version française de la norme n'a pas été soumise au vote.

Ce document a été rédigé selon les Directives ISO/IEC, Partie 2.

Dans le présent document, les caractères d'imprimerie suivants sont utilisés:

– exigences et définitions: caractères romains;
– *modalités d'essais: caractères italiques;*
– indications de nature informative apparaissant hors des tableaux, comme les notes, les exemples et les références: petits caractères. Le texte normatif à l'intérieur des tableaux est également en petits caractères;
– TERMES DEFINIS A L'ARTICLE 3 DE LA NORME GENERALE, DE LA PRESENTE NORME PARTICULIERE OU COMME NOTES: PETITES MAJUSCULES.

Concernant la structure du présent document, le terme:

– «article» désigne l'une des dix-sept sections numérotées dans la table des matières, avec toutes ses subdivisions (par exemple, l'Article 7 inclut les paragraphes 7.1, 7.2, etc.);
– «paragraphe» désigne une subdivision numérotée d'un article (par exemple, 7.1, 7.2 et 7.2.1 sont tous des paragraphes appartenant à l'Article 7).

Dans le présent document, les références à des articles sont précédées du mot «Article» suivi du numéro de l'article concerné. Dans la présente norme particulière, les références aux paragraphes utilisent uniquement le numéro du paragraphe concerné.

Dans le présent document, la conjonction «ou» est utilisée avec la valeur d'un «ou inclusif», ainsi un énoncé est vrai si une combinaison des conditions, quelle qu'elle soit est vraie.

Les formes verbales utilisées dans la présente norme sont conformes à l'usage donné à l'Article 7 des Directives ISO/IEC, Partie 2. Pour les besoins du présent document:

– «devoir» mis au présent de l'indicatif signifie que la satisfaction à une exigence ou à un essai est impérative pour la conformité au présent document;
– «il convient/il est recommandé» signifie que la satisfaction à une exigence ou à un essai est recommandée, mais n'est pas obligatoire pour la conformité au présent document;
– «pouvoir» mis au présent de l'indicatif est utilisé pour décrire un moyen admissible pour satisfaire à une exigence ou à un essai.

Lorsqu'un astérisque (*) est utilisé comme premier caractère devant un titre, ou au début d'un titre d'alinéa ou de tableau, il indique l'existence d'une recommandation ou d'une justification à consulter à l'Annexe A.

Une liste de toutes les parties de la série IEC 60601, publiées sous le titre général: *Appareils électromédicaux*, peut être consultée sur le site web de l'IEC.

Le comité a décidé que le contenu de ce document ne sera pas modifié avant la date de stabilité indiquée sur le site web de l'IEC sous «http://webstore.iec.ch» dans les données relatives au document recherché. À cette date, le document sera

- reconduit,
- supprimé,
- remplacé par une édition révisée, ou
- amendé.

NOTE L'attention des utilisateurs du présent document est attirée sur le fait que les fabricants d'appareils et les organismes d'essai peuvent avoir besoin d'une période transitoire après la publication d'une nouvelle publication IEC, ou d'une publication amendée ou révisée, pour fabriquer des produits conformes aux nouvelles exigences et pour adapter leurs équipements aux nouveaux essais ou aux essais révisés. Le comité recommande que le contenu de cette publication soit entériné au niveau national au plus tôt 3 ans après la date de publication.

INTRODUCTION

Les exigences minimales de sécurité spécifiées dans la présente norme particulière sont considérées comme assurant un degré pratique de sécurité dans le fonctionnement des APPAREILS DE PHOTOTHERAPIE POUR NOUVEAU-NES.

APPAREILS ÉLECTROMÉDICAUX –

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

201.1 Domaine d'application, objet et normes connexes

L'Article 1 de la norme générale[1] s'applique avec les exceptions suivantes:

201.1.1 * Domaine d'application

Remplacement:

La présente partie de l'IEC 60601 s'applique à la SECURITE DE BASE et aux PERFORMANCES ESSENTIELLES des APPAREILS DE PHOTOTHERAPIE POUR NOUVEAU-NES, tels que définis au 201.3.203, également désignés sous le terme APPAREILS EM.

Si un article ou un paragraphe est spécifiquement destiné à être applicable uniquement aux APPAREILS EM ou uniquement aux SYSTEMES EM, le titre et le contenu de cet article ou de ce paragraphe l'indiquent. Si cela n'est pas le cas, l'article ou le paragraphe s'applique à la fois aux APPAREILS EM et aux SYSTEMES EM, selon le cas.

Les DANGERS inhérents à la fonction physiologique prévue des APPAREILS EM ou des SYSTEMES EM dans le cadre du domaine d'application du présent document ne sont pas couverts par des exigences spécifiques contenues dans le présent document, à l'exception de 7.2.13 et de 8.4.1 de la norme générale.

NOTE Voir aussi 4.2 de la norme générale.

La présente norme particulière spécifie les exigences de sécurité relatives aux APPAREILS DE PHOTOTHERAPIE POUR NOUVEAU-NES, mais des méthodes alternatives de conformité à un article spécifique, en démontrant un niveau équivalent de sécurité, ne sont pas considérées comme non conformes, si le FABRICANT a démontré dans son DOSSIER DE GESTION DES RISQUES que le RISQUE présenté par le DANGER s'est révélé avoir un niveau acceptable, lorsqu'il a été évalué par rapport aux avantages du traitement présentés par le dispositif.

Le présent document ne s'applique pas aux:

– dispositifs délivrant de la chaleur par l'intermédiaire de COUVERTURES, COUSSINS ou MATELAS en usage médical; voir l'IEC 60601-2-35 [1][2] à titre informatif;
– INCUBATEURS POUR NOUVEAU-NES, voir l'IEC 60601-2-19 [2] à titre informatif;
– INCUBATEURS DE TRANSPORT POUR NOUVEAU-NES; voir l'IEC 60601-2-20 [3] à titre informatif;
– INCUBATEURS RADIANTS POUR NOUVEAU-NES, voir l'IEC 60601-2-21 [4] à titre informatif.

1) La norme générale est constituée de l'IEC 60601-1:2005 et de l'IEC 60601-1:2005/AMD1:2012, *Appareils électromédicaux – Partie 1: Exigences générales pour la sécurité de base et les performances essentielles.*

2 Les chiffres entre crochets se réfèrent à la Bibliographie.

201.1.2 Objet

Remplacement:

L'objet de la présente norme particulière est d'établir des exigences particulières pour la SECURITE DE BASE et les PERFORMANCES ESSENTIELLES des APPAREILS DE PHOTOTHERAPIE POUR NOUVEAU-NES (définis au 201.3.203), qui réduisent le plus possible les DANGERS liés à la sécurité pour les PATIENTS et les OPERATEURS, et de spécifier des essais pour démontrer la conformité à ces exigences.

201.1.3 Normes collatérales

Addition:

La présente norme particulière se rapporte aux normes collatérales applicables répertoriées à l'Article 2 de la norme générale et à l'Article 201.2 de la présente norme particulière.

L'IEC 60601-1-2:2014 s'applique telle que modifiée dans l'Article 202. L'IEC 60601-1-3 et l'IEC 60601-1-10 ne s'appliquent pas. Toutes les autres normes collatérales publiées dans la série IEC 60601-1 s'appliquent telles que publiées.

201.1.4 Normes particulières

Remplacement:

Dans la série IEC 60601, des normes particulières peuvent modifier, remplacer ou supprimer des exigences contenues dans la norme générale et dans les normes collatérales en fonction de ce qui est approprié à l'APPAREIL EM particulier à l'étude, et elles peuvent ajouter d'autres exigences de SECURITE DE BASE et de PERFORMANCES ESSENTIELLES.

Une exigence d'une norme particulière prévaut sur l'exigence correspondante de la norme générale.

Par souci de concision, dans la présente norme particulière, l'IEC 60601-1:2005 et l'IEC 60601-1:2005/AMD1:2012 sont désignées par le terme «norme générale». Les normes collatérales sont désignées par leur numéro de document.

La numérotation des articles et paragraphes de la présente norme particulière correspond à celle de la norme générale avec le préfixe «201» (par exemple 201.1 dans le présent document aborde le contenu de l'Article 1 de la norme générale) ou à celle de la norme collatérale applicable avec le préfixe «20x», où x est le ou les derniers chiffres du numéro de document de la norme collatérale (par exemple 202.4 dans la présente norme particulière aborde le contenu de l'Article 4 de la norme collatérale IEC 60601-1-2, 203.4 dans la présente norme particulière aborde le contenu de l'Article 4 de la norme collatérale IEC 60601-1-3, etc.). Les modifications apportées au texte de la norme générale et des normes collatérales applicables sont spécifiées en utilisant les termes suivants:

«*Remplacement*» signifie que l'article ou le paragraphe de la norme générale ou de la norme collatérale applicable est remplacé complètement par le texte de la présente norme particulière.

«*Addition*» signifie que le texte de la présente norme particulière vient s'ajouter aux exigences de la norme générale ou de la norme collatérale applicable.

«*Modification*» signifie que l'article ou le paragraphe de la norme générale ou de la norme collatérale applicable est modifié comme indiqué par le texte de la présente norme particulière.

Les paragraphes, figures ou tableaux ajoutés à la norme générale sont numérotés à partir de 201.101. Toutefois, en raison du fait que les définitions dans la norme générale sont numérotées 3.1 à 3.147, les définitions complémentaires dans le présent document sont numérotées à partir de 201.3.201. Les annexes complémentaires sont nommées AA, BB, etc., et les points complémentaires aa), bb), etc.

Les paragraphes, figures ou tableaux ajoutés à une norme collatérale sont numérotés à partir de 20x, où «x» est le chiffre de la norme collatérale, par exemple 202 pour l'IEC 60601-1-2, 203 pour l'IEC 60601-1-3, etc.

L'expression «le présent document» est utilisée pour se référer à la norme générale, à toutes les normes collatérales applicables et à la présente norme particulière, considérées ensemble.

Lorsque la présente norme particulière ne comprend pas d'article ou de paragraphe correspondant, l'article ou le paragraphe de la norme générale ou de la norme collatérale applicable, qui peut être sans objet, s'applique sans modification; lorsqu'il est demandé qu'une partie quelconque de la norme générale ou de la norme collatérale applicable, bien que pertinente, ne s'applique pas, cela est expressément mentionné dans la présente norme particulière.

201.2 Références normatives

NOTE Une liste de références informatives est donnée dans la Bibliographie.

L'Article 2 de la norme générale s'applique avec les exceptions suivantes:

Addition:

IEC 60601-1:2005, *Appareils électromédicaux – Partie 1: Exigences générales pour la sécurité de base et les performances essentielles*
IEC 60601-1:2005/AMD1:2012

Remplacement:

IEC 60601-1-2:2014, *Appareils électromédicaux – Partie 1-2: Exigences générales pour la sécurité de base et les performances essentielles – Norme collatérale: Perturbations électromagnétiques – Exigences et essais*

201.3 Termes et définitions

Pour les besoins du présent document, les termes et définitions de l'IEC 60601-1:2005 et l'IEC 60601-1:2005/AMD1:2012, ainsi que les suivants s'appliquent.

L'ISO et l'IEC tiennent à jour des bases de données terminologiques destinées à être utilisées en normalisation, consultables aux adresses suivantes:

- IEC Electropedia: disponible à l'adresse http://www.electropedia.org/
- ISO Online browsing platform: disponible à l'adresse http://www.iso.org/obp

NOTE Un index des termes définis est donné à partir de la page 61. Une liste des symboles, abréviations et acronymes utilisés dans la présente norme particulière est donnée dans le Tableau 201.101.

Remplacement:

201.3.76
PATIENT
NOUVEAU-NE, tel que spécifié au 201.3.202, qui subit un traitement par rayonnements visibles à partir d'un APPAREIL DE PHOTOTHERAPIE POUR NOUVEAU-NES, tel que spécifié au 201.3.203

Addition:

201.3.201
SURFACE D'ECLAIREMENT EFFICACE
surface sur laquelle le PATIENT repose selon la position prévue et qui reçoit les rayonnements émis par l'APPAREIL DE PHOTOTHERAPIE POUR NOUVEAU-NES

Note 1 à l'article: La SURFACE D'ECLAIREMENT EFFICACE correspond à la surface de traitement prévue qui est éclairée par le rayonnement de photothérapie. La zone de 60 cm × 30 cm constitue la surface de taille de référence, sauf spécification différente dans les DOCUMENTS D'ACCOMPAGNEMENT.

201.3.202
NOUVEAU-NE
PATIENT âgé de trois mois au maximum et pesant moins de 10 kg

201.3.203
*** APPAREIL DE PHOTOTHERAPIE POUR NOUVEAU-NES**
APPAREIL EM qui émet dans le spectre du rayonnement principal dans la plage comprise entre 400 nm et 550 nm dans le but de réduire la concentration en bilirubine dans l'organisme des NOUVEAU-NES

201.3.204
ECLAIREMENT ENERGETIQUE TOTAL POUR LA BILIRUBINE
E_{bi}
éclairement énergétique égal au total de l'ensemble de l'éclairement énergétique dans la plage comprise entre 400 nm et 550 nm

Tableau 201.101 – Liste des symboles, abréviations et acronymes

Abréviation	Terme
AAP	American Academy of Pediatrics
°C	degrés Celsius (unité de température)
dB(A)	niveau sonore pondéré A en décibels par rapport à la réponse en fréquence chez l'homme (mesure logarithmique de l'intensité acoustique)
Δ_λ	largeur de bande (en nanomètres)
E	éclairement énergétique (incidence de la puissance rayonnante par unité de surface sur une surface)
E_{bi}	éclairement énergétique pour la bilirubine (éclairement énergétique total pour 400 nm à 550 nm)
E_{eff}	éclairement énergétique efficace
E_λ	éclairement énergétique spectral
EL	exposure limit (limite d'exposition)
G_2	uniformité de l'éclairement énergétique (sans unité)
GHz	gigahertz (unité de fréquence)
h	heure (unité de temps)
IR	infrared radiation (rayonnement infrarouge) (avec des longueurs d'onde comprises entre 700 nm et 1 mm)
IR – A	domaine A de rayonnement infrarouge (avec des longueurs d'onde comprises entre 700 nm et 1 400 nm)

Abréviation	Terme
IR – B	domaine B de rayonnement infrarouge (avec des longueurs d'onde comprises entre 1,4 μm et 3 μm)
IR – C	domaine C de rayonnement infrarouge (avec des longueurs d'onde comprises entre 3 μm et 8 μm)
kg	kilogrammes (unité de masse)
λ	lambda (unité de longueur d'onde)
m	mètre (unité de longueur)
MHz	mégahertz (unité de fréquence)
min	minute (unité de temps)
$\mu W/cm^2$	microwatts par centimètre carré (unité d'éclairement énergétique)
nm	nanomètre (unité de longueur)
N	newton (unité de force)
s	seconde (unité de temps)
S_λ	efficacité spectrale relative (sans unité)
UV	rayonnement ultraviolet (avec une longueur d'onde plus courte que la lumière visible)
UV-A	domaine de rayonnement ultraviolet proche (avec des longueurs d'onde comprises entre 315 nm et 400 nm)
V/m	volts par mètre (unité de l'intensité de champ électrique)
W/cm^2	watts par centimètre carré (unité d'éclairement énergétique)
W/m^2	watts par mètre carré (unité d'éclairement énergétique)

201.4 Exigences générales

L'Article 4 de la norme générale s'applique avec l'exception suivante:

201.4.3 * PERFORMANCE ESSENTIELLE

Remplacement:

Il n'y a pas d'exigences de PERFORMANCES ESSENTIELLES supplémentaires pour les APPAREILS DE PHOTOTHERAPIE POUR NOUVEAU-NES.

201.5 Exigences générales relatives aux essais des APPAREILS EM

L'Article 5 de la norme générale s'applique avec les exceptions suivantes:

201.5.4 Autres conditions

Paragraphes complémentaires:

201.5.4.101 * Prévieillissement

Les conditions générales de fonctionnement suivantes doivent être prises en compte pour les mesurages des rayonnements des APPAREILS DE PHOTOTHERAPIE POUR NOUVEAU-NES.

Après 5 h de prévieillissement de la source rayonnante, ou après une durée de prévieillissement spécifiée par le FABRICANT, si ce dernier a spécifié une durée de prévieillissement différente dans les DOCUMENTS D'ACCOMPAGNEMENT, les valeurs initiales de l'ECLAIREMENT ENERGETIQUE TOTAL POUR LA BILIRUBINE E_{bi} de l'APPAREIL DE PHOTOTHERAPIE POUR NOUVEAU-NES doivent être mesurées dans les conditions normales de fonctionnement pour les différents réglages d'éclairement énergétique définis par le FABRICANT.

201.5.4.102 Emplacement des mesurages

Les mesurages des rayonnements doivent être effectués dans la position de fonctionnement de la lampe de l'APPAREIL DE PHOTOTHERAPIE POUR NOUVEAU-NES à une distance spécifiée par le FABRICANT, indiquée dans les instructions d'utilisation (voir 201.7.9.2.9).

201.5.4.103 Période de stabilisation

Les mesurages des rayonnements doivent être effectués lorsque tous les paramètres importants pour les mesurages ont atteint des conditions stables. La période de stabilisation doit être d'au moins 0,5 h, ou plus, sauf indication de temps différente par le FABRICANT dans les DOCUMENTS D'ACCOMPAGNEMENT.

201.5.4.104 * Disposition spatiale

L'APPAREIL DE PHOTOTHERAPIE POUR NOUVEAU-NES doit être orienté selon les spécifications du FABRICANT, comme indiqué dans les instructions d'utilisation (voir 201.7.9.2.9).

201.6 Classification des APPAREILS EM et des SYSTEMES EM

L'Article 6 de la norme générale s'applique avec les exceptions suivantes:

201.6.3 Protection contre les effets nuisibles de la pénétration d'eau ou de corps solides

Addition:

201.6.3.101 APPAREIL DE PHOTOTHERAPIE POUR NOUVEAU-NES situé sous le patient

Si l'APPAREIL DE PHOTOTHERAPIE POUR NOUVEAU-NES est situé sous le PATIENT, il doit être au moins conforme au niveau IPX3 spécifié dans l'IEC 60529.

201.7 Identification, marquage et documentation des APPAREILS EM

L'Article 7 de la norme générale s'applique avec les exceptions suivantes:

201.7.2 Marquage sur l'extérieur des APPAREILS EM ou PARTIES D'APPAREILS EM (voir aussi le Tableau C.1 de la norme générale)

Paragraphe complémentaire:

201.7.2.101 * Signe de sécurité pour l'écran oculaire du PATIENT

Un signe de sécurité qui indique l'exigence d'un écran oculaire pour le PATIENT doit être utilisé, si les yeux du PATIENT peuvent être exposés au rayonnement de l'APPAREIL DE PHOTOTHERAPIE POUR NOUVEAU-NES. Voir le symbole ISO 7010-M025 dans l'IEC TR 60878:2015.

201.7.3.1 Éléments chauffants ou douilles

Addition:

Les types de lampes spécifiés ou recommandés par le FABRICANT doivent être indiqués.

201.7.9.2.2 Avertissements et consignes de sécurité

Addition:

Les instructions d'utilisation doivent également contenir:

a) un énoncé stipulant qu'il convient qu'un APPAREIL DE PHOTOTHERAPIE POUR NOUVEAU-NES ne soit utilisé que par du personnel formé spécialement et sous la direction du personnel médical qualifié, qui connaît très bien les RISQUES et les avantages liés à l'utilisation d'un APPAREIL DE PHOTOTHERAPIE POUR NOUVEAU-NES;

b) une déclaration du FABRICANT expliquant l'effet des variations des conditions ambiantes sur le PATIENT, par exemple les variations des températures ambiantes, les différentes sources de rayonnement (lumière solaire), etc.;

c) si nécessaire, une indication donnant des informations sur le filtre et la barrière de protection exigée pour l'UTILISATION NORMALE;

d) une indication mentionnant que l'équilibre hydrique de certains PATIENTS peut être perturbé;

e) une indication mentionnant que les PATIENTS proches des APPAREILS DE PHOTOTHERAPIE POUR NOUVEAU-NES peuvent nécessiter une protection et une indication avec des informations détaillées concernant les mesures de protection complémentaires (par exemple, écrans, verres protecteurs);

f) une indication mentionnant que les valeurs de bilirubine des PATIENTS doivent être régulièrement mesurées;

g) une indication mentionnant que l'utilisation de feuilles réfléchissantes peut être à l'origine de températures corporelles dangereuses, si ceci concerne le type d'APPAREILS DE PHOTOTHERAPIE POUR NOUVEAU-NES;

h) un conseil pour équiper le PATIENT d'un écran oculaire, lorsque ce dernier peut être exposé aux rayonnements des APPAREILS DE PHOTOTHERAPIE POUR NOUVEAU-NES;

*i) un avertissement indiquant que l'OPERATEUR peut être victime de certains effets au cours d'une exposition prolongée dans la zone soumise au rayonnement des APPAREILS DE PHOTOTHERAPIE POUR NOUVEAU-NES;

j) une indication stipulant s'il convient de ne pas entretenir les APPAREILS DE PHOTOTHERAPIE POUR NOUVEAU-NES avec des solutions inflammables (antiseptiques, agents de nettoyage, etc.);

k) une indication mentionnant que la lumière bleue peut gêner les observations cliniques en masquant les variations de couleur de la peau, comme la cyanose;

l) une indication mentionnant qu'en raison des effets photochimiques, les médicaments et les liquides de perfusion ne doivent pas être stockés dans la zone de rayonnement;

m) un énoncé avertissant l'OPERATEUR des RISQUES éventuels associés au fonctionnement des APPAREILS DE PHOTOTHERAPIE POUR NOUVEAU-NES en présence de gaz combustibles (par exemple oxygène, protoxyde d'azote, produits anesthésiques), et sur la façon d'utiliser correctement les APPAREILS DE PHOTOTHERAPIE POUR NOUVEAU-NES en présence de ces gaz.

201.7.9.2.5 Description de l'APPAREIL EM

Addition:

Les instructions d'utilisation doivent contenir en plus:

a) une représentation graphique, incluant des figures, des dimensions de la SURFACE D'ECLAIREMENT EFFICACE et sa position par rapport à l'APPAREIL DE PHOTOTHERAPIE POUR NOUVEAU-NES;

b) une représentation graphique de la répartition d'intensité spectrale pour l'APPAREIL DE PHOTOTHERAPIE POUR NOUVEAU-NES dans la plage de longueurs d'onde définie au 201.3.203. L'ECLAIREMENT ENERGETIQUE TOTAL POUR LA BILIRUBINE E_{bi} émis par l'APPAREIL DE PHOTOTHERAPIE POUR NOUVEAU-NES doit être intégré sur des intervalles de longueurs d'onde de 5 nm ou moins pour la plage de longueurs d'onde définie au 201.3.203;

c) la courbe de la fonction de sensibilité spectrale du dispositif de mesure si la mesure par la méthode intégrale pour L'ECLAIREMENT ENERGETIQUE TOTAL POUR LA BILIRUBINE E_{bi} émis par l'APPAREIL DE PHOTOTHERAPIE POUR NOUVEAU-NES est effectuée dans les conditions décrites au 201.12.1.104;

d) la durée de prévieillissement, si elle est différente de 5 h;

e) la période de stabilisation, si elle est différente de 0,5 h; et

f) le niveau maximal de bruit mesuré dans les conditions du 201.9.6.2.

Si le FABRICANT recommande d'autres types de lampes, l'ensemble des exigences du présent paragraphe s'applique à chaque type de lampe.

201.7.9.2.9 Instructions de fonctionnement

Addition:

a) L'ECLAIREMENT ENERGETIQUE TOTAL POUR LA BILIRUBINE E_{bi} mesuré selon les instructions du FABRICANT doit être indiqué avec les informations sur la façon dont cet ECLAIREMENT ENERGETIQUE E_{bi} est affecté par la distance entre l'APPAREIL DE PHOTOTHERAPIE POUR NOUVEAU-NES et la SURFACE D'ECLAIREMENT EFFICACE;

b) Les instructions d'utilisation doivent contenir des informations sur la distance entre l'APPAREIL DE PHOTOTHERAPIE POUR NOUVEAU-NES et la SURFACE D'ECLAIREMENT EFFICACE. Si la distance entre l'APPAREIL DE PHOTOTHERAPIE POUR NOUVEAU-NES et la SURFACE D'ECLAIREMENT EFFICACE est réglable, le FABRICANT doit décrire comment l'OPERATEUR peut maintenir les distances autorisées;

c) Les instructions d'utilisation doivent informer l'OPERATEUR de la nécessité de mesurer la température du PATIENT, si l'APPAREIL DE PHOTOTHERAPIE POUR NOUVEAU-NES influence la température du corps du PATIENT;

d) Les instructions d'utilisation doivent informer l'OPERATEUR de l'impact des APPAREILS DE PHOTOTHERAPIE POUR NOUVEAU-NES sur la chaleur dégagée par les appareils de thermothérapie (INCUBATEURS POUR NOUVEAU-NES, INCUBATEURS DE TRANSPORT POUR NOUVEAU-NES, INCUBATEURS RADIANTS POUR NOUVEAU-NES, dispositifs délivrant de la chaleur par l'intermédiaire de COUVERTURES, COUSSINS ou MATELAS) et sur la température du corps du PATIENT lorsque la PHOTOTHERAPIE POUR NOUVEAU-NES est combinée avec l'un de ces dispositifs de thérapie par la chaleur;

e) Les instructions d'utilisation doivent informer l'OPERATEUR qu'il est recommandé d'utiliser le mode à régulation cutanée pour les INCUBATEURS POUR NOUVEAU-NES, les INCUBATEURS DE TRANSPORT POUR NOUVEAU-NES, un INCUBATEUR RADIANT POUR NOUVEAU-NES, ou des dispositifs délivrant de la chaleur par l'intermédiaire de COUVERTURES, COUSSINS ou MATELAS lorsque la PHOTOTHERAPIE POUR NOUVEAU-NES est combinée avec l'un de ces dispositifs de thérapie par la chaleur. Dans le cas contraire, la température réglée de l'air de l'incubateur, ou la chaleur émise par le corps chauffant de l'INCUBATEUR RADIANT POUR NOUVEAU-NES ou le MATELAS CHAUFFANT doit être réduit selon les mesurages de la température du corps.

201.7.9.2.13 Maintenance

Addition:

Les instructions d'utilisation doivent contenir en plus

a) le cas échéant, des informations détaillées pour l'OPERATEUR concernant la durée de vie limitée de la source de rayonnement;