BS EN 60601-2-50:2009+A1:2016

BSI Standards Publication

Medical electrical equipment

Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment (IEC 60601-2-50:2009)

bsi.

National foreword

This British Standard is the UK implementation of EN 60601-2-50:2009+A1:2016. It is identical to IEC 60601-2-50:2009, incorporating amendment 1:2016. It supersedes BS EN 60601-2-50:2009+A11:2011, which will be withdrawn on 16 December 2019.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to IEC text carry the number of the IEC amendment. For example, text altered by IEC amendment 1 is indicated by [A1] 〈A1〉.

The UK participation in its preparation was entrusted by Technical Committee CH/62, Electrical Equipment in Medical Practice, to Subcommittee CH/62/4, Electromedical equipment.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 July 2009.

Amendments/corrigenda issued since publication

Date	Text affected
31 March 2012	Implementation of CENELEC amendment A11:2011: Annex ZZ replaced
31 January 2017	Implementation of IEC amendment 1:2016 with CENELEC endorsement A1:2016: Annex ZA updated

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 60601-2-50:2009+A1

December 2016

ICS 11.040.60

English version

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

(IEC 60601-2-50:2009)

Appareils électromédicaux -
Partie 2-50: Exigences particulières
pour la sécurité de base
et les performances essentielles
des appareils de photothérapie
pour nouveau-nés
(CEI 60601-2-50:2009)

Medizinische elektrische Geräte -
Teil 2-50: Besondere Festlegungen
für die Sicherheit einschließlich
der wesentlichen Leistungsmerkmale
von Säuglings-Phototherapiegeräten
(IEC 60601-2-50:2009)

This European Standard was approved by CENELEC on 2009-05-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Central Secretariat: Avenue Marnix 17, B - 1000 Brussels

Ref. No. EN 60601-2-50:2009 E

Foreword

The text of document 62D/736A/FDIS, future edition 2 of IEC 60601-2-50, prepared by SC 62D, Electromedical equipment, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-2-50 on 2009-05-01.

This European Standard supersedes EN 60601-2-50:2002.

Specific technical changes from EN 60601-2-50:2002 include:

– requiring graphical representation of the spectral irradiance in the instructions for use (this was previously optional; see 201.7.9.2.5 b));

– requirements for support and mounting brackets for ACCESSORIES (see 201.9.8.101);

– requiring restoration of any preset values upon interruption and restoration of the power supply, if applicable (see 201.11.8); and

– corrections to the first four exposure limits (ELs) listed in Table AA.1.

Minor changes from EN 60601-2-50:2002 include replacing the figure containing the eye protection symbol with a reference to this same symbol in IEC 60878 (see 201.7.2.101), defining an INFANT (see 201.3.202) and clarifying the titles for subclauses 201.5.4.102 and 201.5.4.103.

The main purpose, however, is to provide consistency with the general standard EN 60601-1:2006. This EN 60601-2-50:2009 further provides consistency with the four other particular standards related to pediatric equipment for which the committee is responsible.

The following dates were fixed:

– latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2010-02-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2012-05-01

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive MDD (93/42/EEC). See Annex ZZ.

In this standard, the following print types are used:

– Requirements and definitions: roman type.

– *Test specifications: italic type.*

– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

– “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

– “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

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

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

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

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

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

Annexes ZA and ZZ have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 60601-2-50:2009 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60335-2-27	NOTE	Harmonized as EN 60335-2-27:1997 (not modified).
IEC 60601-2-19	NOTE	Harmonized as EN 60601-2-19:2009 (not modified).
IEC 60601-2-21	NOTE	Harmonized as EN 60601-2-21:2009 (not modified).
ISO 3743-1	NOTE	Harmonized as EN ISO 3743-1:1995 (not modified).

Foreword to amendment A11

This document (EN 60601-2-50:2009/A11:2011) has been prepared by CLC/TC 62 “Electrical equipment in medical practice”.

The following dates are fixed:

• latest date by which this document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2012-10-01
• latest date by which the national standards conflicting with this document have to be withdrawn	(dow)	2014-10-01

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

Foreword to amendment A1

The text of document 62D/1327/FDIS, future IEC 60601-2-50:2009/A1, prepared by SC 62D "Electromedical equipment", of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 60601-2-50:2009/A1:2016.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2017-06-16
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2019-12-16

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive 93/42/EEC, see informative Annex ZZ, included in EN 60601-2-50:2009/A11:2011.

Endorsement notice

The text of the International Standard IEC 60601-2-50:2009/A1:2016 was approved by CENELEC as a European Standard without any modification.

In the Bibliography of EN 60601-2-50:2009, replace the existing reference to ISO 3743-1 by the following:

IEC 61672-1	NOTE	Harmonized as EN 61672-1.

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE 1 When an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

Annex ZA of EN 60601-1:2006 applies, except as follows:

Publication	Year	Title	EN/HD	Year
***Replace** the reference to IEC 60601-1-2 by:*				
IEC 60601-1-2	–	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic compatibility - Requirements and tests	EN 60601-1-2	2015

Annex ZZ
(informative)

Coverage of Essential Requirements of EC Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex I of the EC Directive 93/42/EEC except as follows:

– Essential Requirement 6a
– Essential Requirement 7.1
– Essential Requirement 7.4
– Essential Requirement 7.5 paragraph 2 & 3
– Essential Requirement 13.6 (q)

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.

CONTENTS

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 ⟦A1⟩ IEC 60601-1 ⟨A1⟧, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*, hereinafter referred to as the general standard.

The requirements are followed by specifications for the relevant tests.

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

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

MEDICAL ELECTRICAL EQUIPMENT –

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

201.1 Scope, object and related standards

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

201.1.1 * Scope

Replacement:

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

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

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

NOTE See also 4.2 of the general standard.

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

This particular standard does not apply to:

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

201.1.2 Object

Replacement:

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

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

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 2 of this particular standard.

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

201.1.4 Particular standards

Replacement:

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

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

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

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

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

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

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

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

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

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2) [A1] IEC 60601-1-10 [A1], *Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers*

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

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

201.2 Normative references

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

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

Amendment:

〖A1〗 IEC 60601-1-2 〖A1〗, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in 〖A1〗 IEC 60601-1 〖A1〗, apply, except as follows:

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

Replacement:

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

Addition:

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

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

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

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

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

Table 201.101 – List of symbols, abbreviations and acronyms

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

201.4 General requirements

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

201.4.3 * ESSENTIAL PERFORMANCE

Replacement:

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

201.5 General requirements for testing of ME EQUIPMENT

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

201.5.4 Other conditions

Additional subclauses:

201.5.4.101 * Pre-ageing

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

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

201.5.4.102 Position of measurements

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

201.5.4.103 Stabilization period

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

201.5.4.104 * Arrangement in space

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

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

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

201.6.3 Protection against harmful ingress of water or particular matter

Additional subclause:

201.6.3.101 INFANT PHOTOTHERAPY EQUIPMENT located under the PATIENT

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

201.7 ME EQUIPMENT identification, marking and documents

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

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

Additional subclause:

201.7.2.101 * Safety sign for PATIENT eye shield

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

201.7.3.1 Heating elements or lamp holders

Addition:

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

201.7.9.2.2 Warning and safety notices

Addition:

The instructions for use shall also include the following:

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

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

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

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

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

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

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

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

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

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

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

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

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

201.7.9.2.5 ME EQUIPMENT description

Additions:

The instructions for use shall also contain:

a) a graphical representation, including figures, of the size of the EFFECTIVE SURFACE 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 SURFACE AREA;

b) The instructions for use shall contain information about the distance between the INFANT PHOTOTHERAPY EQUIPMENT and the EFFECTIVE SURFACE AREA. If the distance between the INFANT PHOTOTHERAPY EQUIPMENT and the EFFECTIVE SURFACE AREA is adjustable, the MANUFACTURER has to describe how the OPERATOR can keep to the permissible distances;

c) The instructions for use shall inform the OPERATOR about the necessity of temperature measurements on the PATIENT, if the INFANT PHOTOTHERAPY EQUIPMENT will influence the body temperature of the PATIENT;

d) The instructions for use shall inform the OPERATOR about the impact of INFANT PHOTOTHERAPY EQUIPMENT on the heat supply in thermotherapy devices (INFANT INCUBATORS, INFANT TRANSPORT INCUBATORS, INFANT RADIANT WARMERS, devices supplying heat via BLANKETS, PADS or MATTRESSES) and on the PATIENT'S body temperature when the INFANT PHOTOTHERAPY is used in combination with one of these warming therapy devices;

e) The instructions for use shall inform the OPERATOR that the use of the baby controlled mode of the INFANT INCUBATOR, INFANT TRANSPORT INCUBATORS an INFANT RADIANT WARMER or devices supplying heat via BLANKETS, PADS or MATTRESSES is recommended when the INFANT PHOTOTHERAPY is used in combination with one of these warming therapy devices, otherwise the set air temperature of the incubator or the heater output of the INFANT RADIANT WARMER or HEATED MATTRESS has to be reduced according to the body temperature measurements.

201.7.9.2.13 Maintenance

Addition:

The instructions for use shall also contain

a) details informing the OPERATOR about the limited lifetime of the radiation source;

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

c) the notice that if there are several lamps in the INFANT PHOTOTHERAPY EQUIPMENT, all lamps have to 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 SURFACE 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.

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:

〈A1〉 *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.* 〈A1〉

201.9.8 HAZARDS associated with support systems

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 SURFACE 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 SURFACE 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:

201.11.1.2.2 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:

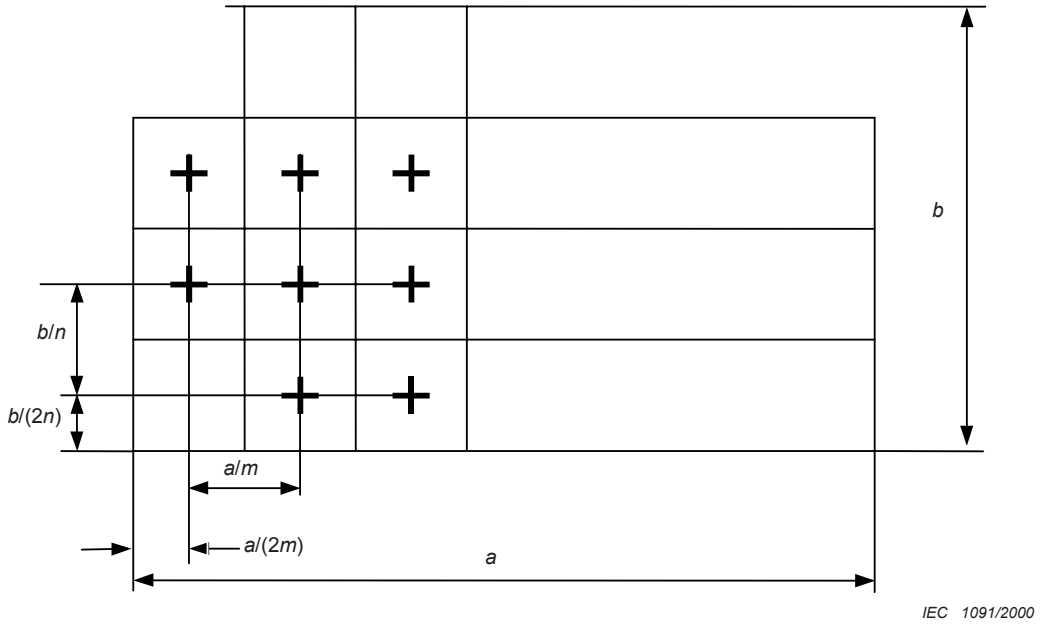
201.12.1 Accuracy of controls and instruments

Additional subclauses:

201.12.1.101 Irradiance distribution

The distribution of the TOTAL IRRADIANCE FOR BILIRUBIN E_{bi} on the EFFECTIVE SURFACE 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 centered to cover the whole EFFECTIVE SURFACE 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 SURFACE 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 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.

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 SURFACE 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

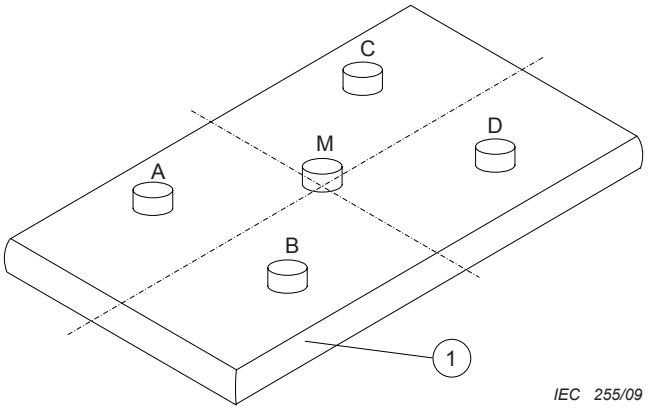
If a weighing scale is supplied as an integral part of the ME EQUIPMENT or as an accessory specifically for use with the ME EQUIPMENT, the scale-displayed value shall not differ from the test load by more than the MANUFACTURER'S specifications in the ACCOMPANYING DOCUMENTS when operating the ME EQUIPMENT 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 subclause 6.5 of the general standard.

NOTE Device calibration may 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 g (± 1 g) and 2 000 g (± 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

This subclause of the general standard does not apply.

201.13 HAZARDOUS SITUATIONS and fault conditions

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 subclauses 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

Additional subclause:

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

〚A1〛 IEC 60601-1-2 〈A1〉 applies, except as follows:

〚A1〛 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 to be used in a HOME HEALTHCARE ENVIRONMENT. 〈A1〉

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 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 subclause 201.10.7. The upper limit was based on the *in vitro* bilirubin absorption curve[9][3)].

The spectral content and bandwidth of the bilirubin response curve are a source of controversy; no accepted “standard” curve is available [10].

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 particular standard 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, 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.

3) Figures in square brackets refer to the Bibliography.

Subclause 201.5.4.104 – Arrangement in space

Knowing that other than flat surfaces of the EFFECTIVE SURFACE 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 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 color changes, such as cyanosis. In addition, blue light may cause discomfort to caregivers, such as eye irritation, nausea, and headaches.” [11]

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) 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 [12].

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 subclause 201.10.6) and ultraviolet irradiation (see subclause 10.7) which often accompany phototherapy treatment. Consequently, both IR and UV irradiation have been limited in this standard [13].

The publication, Maisels, M. Jeffrey, Why Use Homeopathic Doses of Phototherapy, Pediatrics, August 1996, Vol. 98, No. 2, p. 283-287 [14], 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 standard 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. Further information regarding limitation and measuring principles are given in: Ultraviolet and Blue-Light Phototherapy – Principles, Sources, Dosimetry and Safety, Report [15].

In 1985, the International Radiation Protection Association (IRPA) published limits for UV exposure in adults [16]. 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 [17]. 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 (270 nm), the following weighting formula should be used:

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

where:

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

E_λ = spectral irradiance from measurements in W/m^2

S_λ = relative spectral effectiveness (unitless)

Δ_λ = bandwidth in nanometers 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 nm	Exposure limit (EL) J/m^2	Relative spectral effectiveness S_λ	Wavelength nm	Exposure limit (EL) J/m^2	Relative spectral effectiveness S_λ
180	2500	0,012	300	100	0,300
190	1600	0,019	305	500	0,060
200	1000	0,030	310	2 000	0,015
205	590	0,051	315	$1,0 \times 10^4$	0,003
210	400	0,075	320	$2,9 \times 10^4$	0,0010
215	320	0,095	325	$6,0 \times 10^4$	0,00050
220	250	0,120	330	$7,3 \times 10^4$	0,00041
225	200	0,150	335	$8,8 \times 10^4$	0,00034
230	160	0,190	340	$1,1 \times 10^5$	0,00028
235	130	0,240	345	$1,3 \times 10^5$	0,00024
240	100	0,300	350	$1,5 \times 10^5$	0,00020
245	83	0,360	355	$1,9 \times 10^5$	0,00016
250	70	0,430	360	$2,3 \times 10^5$	0,00013
255	58	0,520	365	$2,7 \times 10^5$	0,00011
260	46	0,650	370	$3,2 \times 10^5$	0,000093
265	37	0,810	375	$3,9 \times 10^5$	0,000077
270	30	1,000	380	$4,7 \times 10^5$	0,000064
275	31	0,960	385	$5,7 \times 10^5$	0,000053
280	34	0,880	390	$6,8 \times 10^5$	0,000044
285	39	0,770	395	$8,3 \times 10^5$	0,000036
290	47	0,640	400	$1,0 \times 10^6$	0,000030
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, IEC 60601-2-20, IEC 60601-2-21 and IEC 80601-2-35) for BABY INCUBATORS, TRANSPORT INCUBATORS, RADIANT WARMERS and heated MATTRESSES. [A1] 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. [A1]

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 clause.

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 fiber (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.

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

See rationale for subclause 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 pediatric 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 (1/1000) 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.

〚A1〛 *Text deleted* 〚A1〛

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[1] IEC 60050-845:1987, *International Electrotechnical Vocabulary – Chapter 845: Lighting*

[2] IEC 60335-2-27:1995, *Household and similar appliances – Safety – Part 2: Particular requirements for appliances for skin exposure to ultraviolet and infrared radiation*

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

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

[5] IEC 60601-2-21, *Medical electrical equipment – Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers*

[6] IEC 80601-2-35, *Medical electrical equipment – Part 2-35: Particular requirements for the basic safety and essential performance of blankets, pads and mattresses intended for heating in medical use*[4)]

[7] IEC 60878:2003, *Graphical symbols for electrical equipment in medical practice*

[8] [A1] IEC 61672-1, *Electroacoustics – Sound level meters – Part 1: Specifications* [A1]

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4) To be published.

[16] International Radiation Protection Association (IRPA): Guidelines on limits of exposure to ultraviolet radiation of wavelengths between 180 nm and 400 nm (incoherent optical radiation). *Health Physics*, 1985, Aug, 49(2), p. 331-40.

[17] *IRPA 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), pages 42-52.

Index of defined terms used in this particular standard

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