BRITISH STANDARD

BS EN 60601-2-50:2002
IEC 60601-2-50:2000

Medical electrical equipment —

Part 2-50: Particular requirements for the safety of infant phototherapy equipment

The European Standard EN 60601-2-50:2002 has the status of a British Standard

ICS 11.040.50

EUROPEAN STANDARD

NORME EUROPÉENNE

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EN 60601-2-50

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English version

Medical electrical equipment
Part 2-50: Particular requirements for the safety of infant phototherapy equipment
(IEC 60601-2-50:2000 + corrigendum March 2001)

Appareils électromédicaux
Partie 2-50: Prescriptions particulières de sécurité des appareils de photothérapie infantile
(CEI 60601-2-50:2000 + corrigendum mars 2001)

Medizinische elektrische Geräte
Teil 2-50: Besondere Festlegungen für die Sicherheit von Säuglings-Phototherapiegeräten
(IEC 60601-2-50:2000 + Corrigendum März 2001)

CENELEC

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

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

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6.8.2 Instructions for use

Additions:

*aa) The mean TOTAL IRRADIANCE FOR BILIRUBIN between all points $E_{bi\ min}$ and $E_{bi\ max}$ measured on the EFFECTIVE SURFACE AREA and its dependance on the distance between the PHOTOTHERAPY EQUIPMENT and the EFFECTIVE SURFACE AREA shall be indicated.

If necessary, a notice shall give information about the filter and the protective barrier required for normal use.

The instructions for use shall

- inform the OPERATOR about the necessity of temperature measurements on the PATIENT, if the PHOTOTHERAPY EQUIPMENT will influence the body temperature of the PATIENT;
- contain information about the distance between the PHOTOTHERAPY EQUIPMENT and the EFFECTIVE SURFACE AREA. If the distance between the PHOTOTHERAPY EQUIPMENT and the EFFECTIVE SURFACE AREA is adjustable, the manufacturer has to describe how the operator can keep to the permissible distances;
- inform the OPERATOR about the impact of PHOTOTHERAPY EQUIPMENT on the heat supply in thermotherapy devices (incubators, radiant heaters, heated mattresses) and on the PATIENT's body temperature;
- inform the OPERATOR that the use of the skin-controlled mode of the incubator, an infant radiant warmer or heated mattresses is recommended, otherwise the set air temperature of the incubator or the heater output of the radiant warmer or heated mattress has to be reduced according to body temperature measurements;
- contain details informing the USER or the OPERATOR about the limited lifetime of the radiation source;
- contain information about the maintenance intervals to make sure the radiation source will be changed after a decrease of 25 % of its TOTAL IRRADIANCE FOR BILIRUBIN E_{bi} stated in the documents;
- contain the notice that if there are several lamps in a PHOTOTHERAPY EQUIPMENT, all lamps have to be changed when the expected lifetime has been exceeded;
- contain 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 effectivity of the phototherapy;
- contain a graphical representation including figures of the size of the EFFECTIVE SURFACE AREA and its position with respect to the PHOTOTHERAPY EQUIPMENT;
- indicate the total spectral irradiance E_{bi} emitted by the PHOTOTHERAPY EQUIPMENT and averaged over a wavelength interval of 5 nm for the wavelength range between 320 nm and 550 nm. A graphical representation is desirable;
- include the calibration curve of the measurement device in the integral TOTAL IRRADIANCE FOR BILIRUBIN E_{bi} emitted by the PHOTOTHERAPY EQUIPMENT measured under the condition of 50.103;
- contain the notice that photoisomers of the bilirubin may cause toxic effects;
- contain the notice that some PATIENTS' water balance may be disturbed;
- contain the notice that PATIENTS adjacent to the PHOTOTHERAPY EQUIPMENT may need to be protected, and contain a notice and details about additional protective measures (e.g. shields, protective glasses);
- contain information about the radiation intensity if different types of lamps are recommended by the manufacturer;
- contain the notice that the PATIENT's bilirubin values shall be measured regularly;

Foreword

The text of document 62D/363/FDIS, future edition 1 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 2000-09-01.

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)	2002-08-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2003-09-01

Annexes designated "normative" are part of the body of the standard.
Annexes designated "informative" are given for information only.
In this standard, annex ZA is normative and annexes AA and ZB are informative.
Annexes ZA and ZB have been added by CENELEC.

In this standard, the following print types are used:
- requirements, compliance with which can be tested, and definitions: roman type;
- notes, explanations, advice, introductions, general statements, exceptions and references: smaller roman type;
- *test specifications: italic type;*
- TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD EN 60601-1 OR THIS PARTICULAR STANDARD: SMALL CAPITALS.

Endorsement notice

The text of the International Standard IEC 60601-2-50:2000 was approved by CENELEC as a European Standard without any modification.

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Clause Page

SECTION SEVEN – PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

SECTION EIGHT – ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT

SECTION NINE – ABNORMAL OPERATION AND FAULT CONDITIONS – ENVIRONMENTAL TESTS

SECTION TEN – CONSTRUCTIONAL REQUIREMENTS

INTRODUCTION

This Particular Standard concerns the safety of INFANT PHOTOTHERAPY EQUIPMENT. The minimum requirements specified in this Particular Standard shall ensure a reasonable degree of safety during operation. This Particular Standard amends and supplements IEC 60601-1 (second edition 1988): *Medical electrical equipment – Part 1: General requirements for safety,* as amended by its amendment 1 (1991) and its amendment 2 (1995), hereinafter referred to as the General Standard. The requirements of this Particular Standard take priority over those of the General Standard.

A guidance and rationale for the requirements of this Particular Standard is included in annex AA.

It is considered that a knowledge of the reasons for these requirements will not only facilitate the proper application of the 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.

An asterisk (*) by a clause or subclause number indicates that some explanatory notes are given in the guidance and rationale section at the end of this Particular Standard.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-50: Particular requirements for the safety of infant phototherapy equipment

SECTION ONE – GENERAL

The clauses and subclauses of this section of the General Standard apply, except as follows:

1 Scope and object

This clause of the General Standard applies except as follows:

1.1 Scope

Addition:

This Particular Standard specifies requirements applicable to INFANT PHOTOTHERAPY EQUIPMENT (as defined in 2.1.101) which by means of visible radiation serve to reduce bilirubin in the body of infants suffering from icterus in the first months of life.

1.2 Object

Replacement:

The object of this Particular Standard is to establish requirements for INFANT PHOTOTHERAPY EQUIPMENT which reduce the safety hazards to PATIENTS and operators as much as possible and to specify tests for demonstrating compliance with these requirements.

1.3 Particular Standards

Addition:

This Particular Standard refers to IEC 60601-1 (1988): *Medical electrical equipment – Part 1: General requirements for safety*, as amended by its amendment 1 (1991) and its amendment 2 (1995).

For brevity, IEC 60601-1 is referred to in this Particular Standard either as the General Standard or as the General Requirement(s).

The numbering of sections, clauses and subclauses of this Particular Standard corresponds to that of the General Standard. 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 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.

"Amendment" means that the clause or subclause of the General Standard is amended as indicated by the text of this Particular Standard.

Subclauses or figures which are additional to those of the General Standard are numbered starting from 101, additional annexes are lettered AA, BB, etc. and additional items aa), bb), etc.

The term "this Standard" is used to make reference to the General Standard and this Particular Standard taken together.

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard, although possibly not relevant, applies without modification; where it is intended that any part of the General Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this Particular Standard.

1.5 Collateral Standards

Addition:

IEC 60601-1-1:1992, *Medical electrical equipment – Part 1: General requirements for safety – 1. Collateral standard: Safety requirements for medical electrical systems*

IEC 60601-1-2:1993, *Medical electrical equipment – Part 1: General requirements for safety – 2. Collateral standard: Electromagnetic compatibility – Requirements and tests*

IEC 60601-1-3:1994, *Medical electrical equipment – Part 1: General requirements for safety – 3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment*

IEC 60601-1-4:1996 *Medical electrical equipment – Part 1: General requirements for safety – 4. Collateral standard: Programmable electrical medical systems*

*2 Terminology and definitions

This clause of the General Standard applies, except as follows:

2.1 EQUIPMENT parts, auxiliaries and ACCESSORIES

Additional definitions:

***2.1.101**
INFANT PHOTOTHERAPY EQUIPMENT (hereinafter referred to as **PHOTOTHERAPY EQUIPMENT**)
irradiation 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

2.1.102
EFFECTIVE SURFACE AREA
surface on which the PATIENT rests according to the intended position and which is radiated by the PHOTOTHERAPY EQUIPMENT

NOTE The EFFECTIVE SURFACE 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.

2.12 Miscellaneous

2.12.4 PATIENT

Replacement:

infant who is being treated by means of visible radiation from equipment as specified under 2.1.102.

Additional definitions:

2.12.101
RADIOMETRIC PARAMETERS

NOTE See IEC 60050(845).

2.12.102
TOTAL IRRADIANCE FOR BILIRUBIN E_{bi}
irradiance equal to the evaluated irradiance in the range between 400 nm and 550 nm, given by an integration

$$E_{bi} = \int_{400\,nm}^{550\,nm} E_{\lambda}(\lambda)\, d\lambda \qquad \text{unit: } W/m^2 \qquad (1)$$

where $E_{\lambda}(\lambda)$ is the measured irradiance at an individual wavelength (λ).

2.12.103
UNIFORMITY G_2 OF THE TOTAL IRRADIANCE FOR BILIRUBIN
ratio of the lowest TOTAL IRRADIANCE FOR BILIRUBIN $E_{bi\ min}$ to the highest TOTAL IRRADIANCE FOR BILIRUBIN $E_{bi\ max}$ on the EFFECTIVE SURFACE AREA, given by the expression

$$G_2 = E_{bi\ min} / E_{bi\ max} \qquad (2)$$

4 General requirements for tests

This clause of the General Standard applies, except as follows:

4.6 Other conditions

Additions:

*4.6.101 Pre-ageing

The following general operating conditions shall be taken into account for radiation measurements of therapeutical PHOTOTHERAPY EQUIPMENT for the human body.

After 5 h of pre-ageing of the radiator source, or after operating 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 the PHOTOTHERAPY EQUIPMENT shall be measured at normal load without exceeding the given tolerances for the temperature rise.

4.6.102 Position of burning

The measurements shall be taken in the operating position of the lamp of the PHOTOTHERAPY EQUIPMENT.

4.6.103 Burn-in period

The PHOTOTHERAPY EQUIPMENT shall be operated until all parameters which are important for the measurement have reached stable conditions. Therefore, it is necessary to wait for the state of thermal equilibrium. The burn-in period shall be at least 0,5 h, or longer, unless the manufacturer states a different time in the ACCOMPANYING DOCUMENTS

*4.6.104 Arrangement in space

The PHOTOTHERAPY EQUIPMENT shall be orientated such that the centre of THE EFFECTIVE SURFACE AREA and the radiant output area are parallel and the centres are in the same line and at the distance(s) specified by the manufacturer.

5 Classification

This clause of the General Standard applies, except as follows:

Addition:

5.3.101 If PHOTOTHERAPY EQUIPMENT is located under the PATIENT it shall at least comply with IPX4 specified in IEC 60529.

6 Identification, marking and documents

This clause of the General Standard applies, except as follows:

6.1 Marking on the outside of EQUIPMENT or EQUIPMENT parts

Addition:

***6.1.101** A symbol for requiring eye shields for the PATIENT shall be used if the PATIENT's eyes can be exposed to the PHOTOTHERAPY EQUIPMENT's radiation. See figure 101.

6.2 Marking on the inside of EQUIPMENT or EQUIPMENT parts

6.2. b)

Addition:

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

6.8 ACCOMPANYING DOCUMENTS

This clause of the General Standard applies, except as follows:

6.8.2 Instructions for use

Additions:

*aa) The mean TOTAL IRRADIANCE FOR BILIRUBIN between all points $E_{bi\ min}$ and $E_{bi\ max}$ measured on the EFFECTIVE SURFACE AREA and its dependance on the distance between the PHOTOTHERAPY EQUIPMENT and the EFFECTIVE SURFACE AREA shall be indicated.

If necessary, a notice shall give information about the filter and the protective barrier required for normal use.

The instructions for use shall

- inform the OPERATOR about the necessity of temperature measurements on the PATIENT, if the PHOTOTHERAPY EQUIPMENT will influence the body temperature of the PATIENT;
- contain information about the distance between the PHOTOTHERAPY EQUIPMENT and the EFFECTIVE SURFACE AREA. If the distance between the PHOTOTHERAPY EQUIPMENT and the EFFECTIVE SURFACE AREA is adjustable, the manufacturer has to describe how the operator can keep to the permissible distances;
- inform the OPERATOR about the impact of PHOTOTHERAPY EQUIPMENT on the heat supply in thermotherapy devices (incubators, radiant heaters, heated mattresses) and on the PATIENT's body temperature;
- inform the OPERATOR that the use of the skin-controlled mode of the incubator, an infant radiant warmer or heated mattresses is recommended, otherwise the set air temperature of the incubator or the heater output of the radiant warmer or heated mattress has to be reduced according to body temperature measurements;
- contain details informing the USER or the OPERATOR about the limited lifetime of the radiation source;
- contain information about the maintenance intervals to make sure the radiation source will be changed after a decrease of 25 % of its TOTAL IRRADIANCE FOR BILIRUBIN E_{bi} stated in the documents;
- contain the notice that if there are several lamps in a PHOTOTHERAPY EQUIPMENT, all lamps have to be changed when the expected lifetime has been exceeded;
- contain 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 effectivity of the phototherapy;
- contain a graphical representation including figures of the size of the EFFECTIVE SURFACE AREA and its position with respect to the PHOTOTHERAPY EQUIPMENT;
- indicate the total spectral irradiance E_{bi} emitted by the PHOTOTHERAPY EQUIPMENT and averaged over a wavelength interval of 5 nm for the wavelength range between 320 nm and 550 nm. A graphical representation is desirable;
- include the calibration curve of the measurement device in the integral TOTAL IRRADIANCE FOR BILIRUBIN E_{bi} emitted by the PHOTOTHERAPY EQUIPMENT measured under the condition of 50.103;
- contain the notice that photoisomers of the bilirubin may cause toxic effects;
- contain the notice that some PATIENTS' water balance may be disturbed;
- contain the notice that PATIENTS adjacent to the PHOTOTHERAPY EQUIPMENT may need to be protected, and contain a notice and details about additional protective measures (e.g. shields, protective glasses);
- contain information about the radiation intensity if different types of lamps are recommended by the manufacturer;
- contain the notice that the PATIENT's bilirubin values shall be measured regularly;

- contain the notice that the use of reflective foils may cause hazardous body temperatures, if the type of PHOTOTHERAPY EQUIPMENT will influence the radiation;
- contain the advice to supply the PATIENT with an eye shield, whenever the PATIENT's eye can be exposed to the PHOTOTHERAPY EQUIPMENT's radiation;
- contain the warning notice that the OPERATOR may experience some effects if he stays longer in the area irradiated by the PHOTOTHERAPY EQUIPMENT;
- contain the pre-ageing time, if the time is different from 5 h;
- contain the burn-in time, if the time is different from 0,5 h;
- contain the maximum noise level measured under the condition of 26.101.

bb) Flammable solutions

The instructions for use shall contain a notice in case it is not allowed to treat the PHOTOTHERAPY EQUIPMENT with flammable solutions (antiseptics, cleaning agents, etc.).

cc) Regular inspection of the protective device

The instructions for use shall contain 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.

dd) Details about ambient effects

The manufacturer shall explain the effect of varying ambient conditions on the PATIENT, i.e. varying ambient temperatures, different radiation sources (insulation), etc.

ee) Auxiliary shelf loading

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

ff) Electric safety of auxiliary devices

The instructions for use shall contain the notice that the requirements for the safety of auxiliary devices shall comply with the general requirements for safety according to IEC 60601-1.

gg) Photo effects on drugs

The instructions for use shall contain the notice that drugs and infusion liquids shall not be stored in the radiation area.

hh) Presence of gases which can support combustion

The instructions for use shall contain the notice that the PHOTOTHERAPY EQUIPMENT shall not be used in the presence of gases which can support combustion (e.g. oxygen, nitrous oxide, anaesthetic agents), if the PHOTOTHERAPY EQUIPMENT is not designed for this use.

SECTION TWO – ENVIRONMENTAL CONDITIONS

The clauses and subclauses of the General Standard apply.

SECTION THREE – PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

The clauses and subclauses of the General Standard apply.

SECTION FOUR – PROTECTION AGAINST MECHANICAL HAZARDS

The clauses and subclauses of this section of the General Standard apply, except as follows:

21 Mechanical strength

This clause of the General Standard applies, except as follows:

***21.3**

Replacement:

All EQUIPMENT parts serving for support and/or immobilization of PATIENTS shall be so designed and manufactured that physical injuries are avoided and that these parts cannot become loose as a result of the PATIENT's movements. Supporting parts for PATIENTS shall be designed as regarding mechanical strength to carry a STATIC LOAD of 10 kg.

Additions:

21.101 For devices with an integral bed, suitable barriers shall prevent the PATIENT from falling off the EFFECTIVE SURFACE AREA. 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:

The barriers shall be in the closed position. A horizontal force of 20 N is applied to the centre of the barriers and maintained for 5 s. The barriers shall remain in the closed position.

21.102 The lamps of the PHOTOTHERAPY EQUIPMENT shall be protected against shock and impacts by means of guards (see 25.1).

24 Stability in NORMAL USE

This clause of the General Standard applies, except as follows:

Additions:

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

24.102 If the PHOTOTHERAPY EQUIPMENT is equipped with wheels, the manufacturer shall provide for suitable locking devices on the wheels to prevent its inadvertent movement.

Compliance with this requirement is checked when tilted through an angle of 5° in any position of NORMAL USE.

25 Expelled parts

This clause of the General Standard applies, except as follows:

25.1

Addition:

A protective device, referred to as guards, shall be removable only by means of TOOLS.

Compliance with this requirement is checked by visual inspection.

NOTE In general, if the PATIENT is lying directly under the PHOTOTHERAPY EQUIPMENT, a protection against falling glass splinters is absolutely necessary.

26 Vibration and noise

This clause of the General Standard applies, except as follows:

Addition:

***26.101** The noise caused by the 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 PHOTOTHERAPY EQUIPMENT. The measuring room shall comply with a reverberation test room (ISO 3743).

SECTION FIVE – PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

The clauses and subclauses of this section of the General Standard apply, except as follows:

*32 Light radiation (including lasers)

This clause of the General Standard applies.

*33 Infrared radiation

This clause of the General Standard applies, except as follows:

Replacement:

Infrared radiation shall be eliminated extensively in the PHOTOTHERAPY EQUIPMENT by suitable measures such as filtering. 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 testing.

*34 Ultraviolet radiation

This clause of the General Standard applies, except as follows:

Replacement:

Effective ultraviolet irradiance shall not exceed

for 180 nm < $\lambda \leq$ 400 nm $\leq 1{,}0 \times 10^{-5}$ mW/cm² ($1{,}0 \times 10^{-4}$ W/m²)

at any point of the EFFECTIVE SURFACE AREA.

Compliance with this requirement is checked by testing.

36 ELECTROMAGNETIC COMPATIBILITY

36.202 IMMUNITY (see IEC 60601-1-2)

36.202.1 ELECTROSTATIC DISCHARGE

36.202.2.1 Requirements

Item a) *Replace the text of this subclause by the following:*

For radiated radio-frequency electromagnetic fields, the 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 26 MHz to 1 GHz;
- continue to perform its intended function as specified by the manufacturer or fail without creating a SAFETY HAZARD at a level less than or equal to 10 V/m for the frequency range of 26 MHz to 1 GHz.

SECTION SIX – PROTECTION AGAINST HAZARDS OF IGNITION OR FLAMMABLE ANAESTHETIC MIXTURES

The clauses and subclauses of this section of the General Standard apply.

SECTION SEVEN – PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

The clauses and subclauses of this section of the General Standard apply, except as follows:

42 Excessive temperatures

This clause of the General Standard applies, except as follows:

*42.3

Amendment:

The temperature of those surfaces which are intended to come into contact with the PATIENT shall not exceed 40 °C. The temperature of other surfaces which 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 USE and in SINGLE FAULT CONDITION.

Compliance with this requirement is checked by testing.

43 Fire prevention

This clause of the General Standard applies, except as follows:

Additions:

***43.101** In order to eliminate the risk of oxygen fires caused by electrical components which can be a source of ignition in enclosed compartments of EQUIPMENT containing an oxygen system, at least one of the following requirements shall apply.

- Electrical components shall be separated from compartments in which accumulations of oxygen can occur by a barrier complying with the requirements of 43.102.
- Compartments containing electrical components shall be ventilated according to the requirements of 43.103.
- Electrical components which, in NORMAL USE or SINGLE FAULT CONDITION, can be a source of ignition shall comply with the requirements of 43.104.

43.102 Any barrier required under the provisions of 43.101 shall be sealed at all joints and at any holes for cables or for other purposes.

Compliance is checked by inspection and, if applicable, by the compliance test described in 40.5 of the General Standard, for enclosures with restricted breathing.

***43.103** The ventilation required under the provisions of 43.101 shall be such that the oxygen concentration in the compartment containing electrical components shall not exceed 4 vol % above the ambient level. If this requirement is met by forced ventilation, means for an alarm in the event of malfunction shall be provided.

Compliance is checked by the following test:

The oxygen concentration shall be measured under the following conditions and for such a period that the highest concentration of oxygen occurs:

- *SINGLE FAULT CONDITION including possible leakage of oxygen;*
- *selection of the most unfavourable control settings;*
- *mains supply voltage deviations of ±10 %.*

The measurements shall be repeated after 4 h during which time the supply voltage shall have been switched off and the gas supply shall have remained on.

The rate of air exchange in the test room shall be between 3 volumes and 10 volumes per hour.

***43.104** Electrical circuits which can produce sparks or generate increased surface temperatures and which might otherwise be a source of ignition shall be so designed that no ignition occurs. At least both of the following requirements shall be satisfied in NORMAL CONDITION and SINGLE FAULT CONDITION:

- *The product of the r.m.s. value of the no load voltage and the r.m.s. value of the short-circuit current shall not exceed 10 VA.*
- *The surface temperature of components shall not exceed 300 °C.*

Compliance is checked by the following test:

Voltages and currents shall be measured or calculated and surface temperatures shall be measured in NORMAL CONDITION and SINGLE FAULT CONDITIONS.

SECTION EIGHT – ACCURACY OF OPERATING DATA AND PROTECTION AGAINST HAZARDOUS OUTPUT

The clauses and subclauses of this section of the General Standard apply, except as follows:

50 Accuracy of operating data

This clause of the General Standard applies, except as follows:

Additions:

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 102. The grid is centered on the EFFECTIVE SURFACE AREA so that the measuring points are covered by the maximum of the TOTAL IRRADIANCE FOR BILIRUBIN. 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.

50.101 Measuring principles

The values of the TOTAL IRRADIANCE FOR BILIRUBIN E_{bi} and their distribution on the EFFECTIVE SURFACE AREA shall be measured.

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 PHOTOTHERAPY EQUIPMENT (see 2.1.101). The spectral method shall be used if absolute values for the evaluation of the PHOTOTHERAPY EQUIPMENT are required.

*50.102 Spectral method

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

The TOTAL IRRADIANCE FOR BILIRUBIN is a result of the equation (1) with the numeric integration of the measured values between the wavelength of 400 nm and 550 nm.

50.103 Integral method

With the integral method the TOTAL IRRADIANCE FOR BILIRUBIN 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.

50.104 Maximum TOTAL IRRADIANCE FOR BILIRUBIN $E_{bi\ max}$

The maximum TOTAL IRRADIANCE FOR BILIRUBIN $E_{bi\ max}$ shall comply with the manufacturer's instructions with a maximum tolerance of ±25 %.

Compliance with this requirement is checked by using the tests from 50.101 to 50.103.

*50.105 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 $E_{bi\ max}$, G_2 shall be greater than 0,4 (see also 2.12.103).

Compliance with this requirement is checked by the following test:

Measurements shall be carried out with the distance specified by the manufacturer (according to 50.101).

51 Protection against hazardous output

This clause of the General Standard does not apply.

SECTION NINE – ABNORMAL OPERATION AND FAULT CONDITIONS – ENVIRONMENTAL TESTS

The clauses and subclauses of this section of the General Standard apply, except as follows:

52 Abnormal operation and fault conditions

This clause of the General Standard applies, except as follows:

Addition:

52.101 If the supply to the output of the radiator source increases the output of the radiator source to greater than the level stated in clauses 32 and 33 for more than 30 s in a SINGLE FAULT CONDITION, the PHOTOTHERAPY EQUIPMENT shall switch off automatically.

Compliance with this requirement is checked by inspection.

SECTION TEN – CONSTRUCTIONAL REQUIREMENTS

55 ENCLOSURES and covers

This clause of the General Standard applies.

56 Components and general assembly

This clause of the General Standard applies, except as follows:

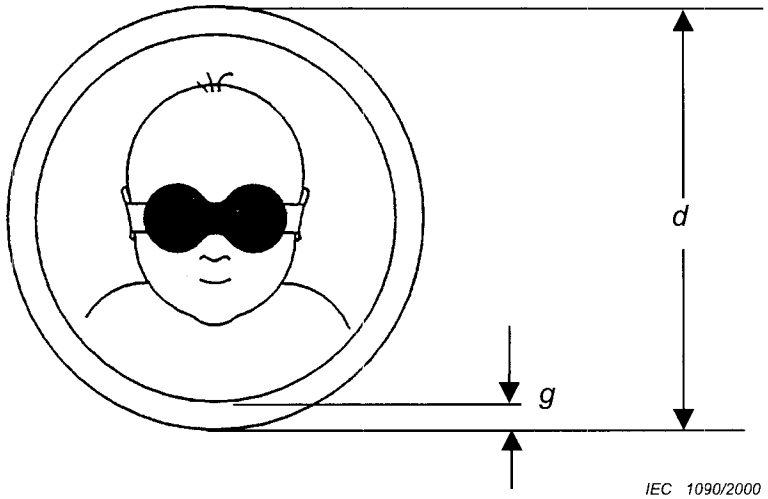
56.8 Indicators

Addition:

56.8.101 Examination of the lifetime

The PHOTOTHERAPY EQUIPMENT shall be equipped with a supplementary device which indicates operating hours and/or the lifetime of the lamp.

Compliance with this requirement is checked by inspection.

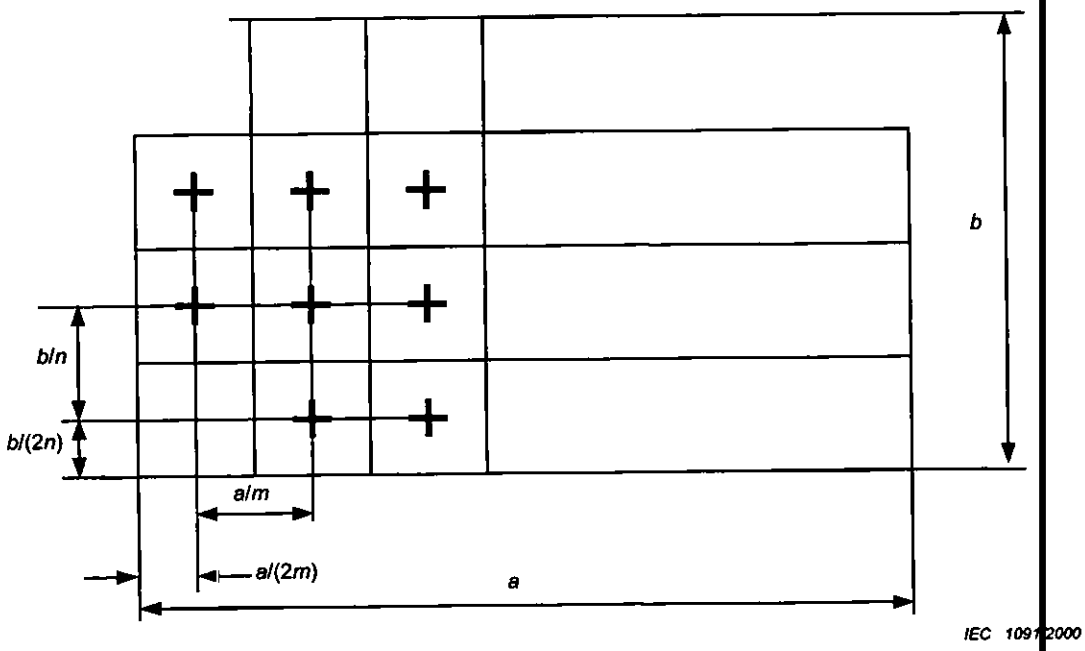


Sign size and required dimension for prohibition sign	
d	***g***
12,5	a)
25	0,6
50	1,3
100	2,5

a) The dimensions of the edge of light are specified in accordance with the technical manufacturing requirements.

Dimensions in millimetres

Figure 101 – Graphical symbol: Eye protection for the PATIENT (see 6.1)



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

Figure 102 – Example of a measuring grid

Annexes

The appendices A to K of the General Standard apply.

Annex L

References – Publications mentioned in this standard

Appendix L of the General Standard applies, except as follows:

Additions:

IEC 60050(845):1987, *International Electrotechnical Vocabulary – Lighting*

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

IEC 60601-2-19:1990, *Medical electrical equipment – Part 2: Particular requirements for the safety of baby incubators*
Amendment 1:1996

IEC 60601-2-20:1990, *Medical electrical equipment – Part 2: Particular requirements for the safety of transport incubators*
Amendment 1:1996

IEC 60601-2-21:1994, *Medical electrical equipment – Part 2: Particular requirements for the safety of infant radiant warmers*
Amendment 1:1996

IEC 60601-2-35:1996, *Medical electrical equipment – Part 2: Particular requirements for the safety of blankets, pads and mattresses intended for heating in medical use*

IEC 60651:1979, *Sound level meters*
Amendment 1:1993

ISO 3743-1:1994, *Acoustics – Determination of sound power levels of noise sources – Engineering methods for small, movable sources in reverberant fields – Part 1: Comparison method for hard-walled test rooms*

Annex AA
(informative)

Guidance and rationale for particular subclauses

2 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-Roscoe 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.

2.1.101 The lower limit was based on the limitation from clause 34. The upper limit was based on the *in vitro* bilirubin absorption curve (Cremer, Perryman, and Richards, *Lancet,* 1958, Vol.1, p. 1094-1097; and Ballowitz et al., Phototherapy in Gunn Rats, *Biology of the Neonate,* 1977, Vol. 31, p. 229-244.

The spectral content and bandwidth of the bilirubin response curve are a source of controversy; no accepted "standard" curve is available (*Health Devices*, April 1995, Vol. 24, No. 4, Fiberoptic Phototherapy Systems – Section: Uses and Limitation of Radiometers, p. 141-143).

4.6.101 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.

4.6.104 Knowing that other than flat surfaces of the EFFECTIVE SURFACE AREA and the PHOTOTHERAPY EQUIPMENT are possible, the manufacturer can describe the position and surface of his equipment in the ACCOMPANYING DOCUMENTS if necessary, and if it is different from the requirement of this subclause (see also 6.8.2 aa) dash 9).

6.1.101 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.

6.8.2 aa) dash 19 "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 (AAP recommends a mix of blue and white lamps to help reduce such discomfort)" quoted from: *Health Devices*, April 1995, Vol. 24, No. 4, Fiberoptic Phototherapy Systems – Section: Clinical and Technical Overview of Phototherapy, p. 134-136.

21.3 The load has been reduced because 28.4 of the General Standard shall be met.

26.101 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).

32 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 (see Ballowitz et al., Phototherapy in Gunn Rats, *Biology of the Neonate*, 1977, Vol. 31, p. 229-244 and DIN 5031-10, 1996.01, p. 17).

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 clause 33) and ultra-violet irradiation (see clause 34) which often accompany phototherapy treatment. Consequently, both IR and UV irradiation have been limited in this standard (see Brian Diffey and Graham Hart, Ultraviolet and Blue-light Phototherapy: Principles, Sources, Dosimetry and Safety, Report No. 76, The Institute of Physics and Engineering in Medicine, PO Box 303, York Y01 2WR, England ISBN 0 904181 86 3).

The publication, Maisels, M. Jeffrey, Why Use Homeopathic Doses of Phototherapy, *Pediatrics*, August 1996, Vol. 98, No. 2, p. 283-287, 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.

33 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 $\lambda > 780$ nm wavelength (IR-A region) as well as for $\lambda > 1400$ 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.

34 The definitions are given in IEC 60050-845. The values comply with the limits given in IEC 60335-2-27 (1997). Further information regarding limitation and measuring principles are given in: 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, PO Box 303, York Y01 2WR, ISBN 0 904181 86 3.

In 1985, the International Radiation Protection Association (IRPA) published limits for UV exposure in adults (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). 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, edited by A.S. Duchéne *et al*. Pergamon Press: Chapter 3: Guidelines on limits of exposure to ultraviolet radiation of wavelengths between 180 nm and 400 nm (incoherent optical radiation), pages 42-52.

In this publication the exposure limits (EL) were given for the near-ultraviolet UV-A spectral region (315 nm – 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:

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

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 babies, when the above limits are calculated to a 3-day (72-hour) exposure (dividing the 30 J/m² by 72 h) and calculated to a constant power of irradiance in watts (W/m²) (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[a]

Wavelength nm	Exposure limit (EL) J/m²	Relative spectral effectiveness S_λ	Wavelength nm	Exposure limit (EL) J/m²	Relative spectral effectiveness S_λ
180	2 500	0,012	300	65	0,300
190	1 600	0,019	305	100	0,060
200	1 000	0,030	310	500	0,015
205	590	0,051	315	2 000	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			

[a] IRPA/INIRC 1988 Revision (IR89)

42.3 The limitation of temperatures are given by the other relevant standards for infants (see IEC 60601-2-19, 60601-2-20, 60601-2-21 and 60601-2-35) for incubators, transport incubators, radiant warmers and heated mattresses.

43.101 A component may be a source of ignition only if materials which may ignite are present. However, materials which do not ignite in air may ignite and burn violently in oxygen.

43.103 When the concentration of oxygen in nitrogen exceeds 26 % to 28 %, the speed of combustion of flammable materials increases significantly above that in air. Allowing for experimental errors, it seems advisable that concentrations of 4 vol. % above that of ambient air should not cause a hazardous increase in speed of combustion.

43.104 The hazards of ignition caused by electrical sparks increase

- in purely resistive circuits by electrical power of the spark;
- in inductive and capacitive circuits with the stored energy which is transferred to the spark.

Because of the great variety of ignitable materials and designs of EQUIPMENT, it is not possible to specify uniquely the maximum power and/or energy of electrical circuits which will not cause fires in oxygen.

For guidance see: National Fire Protection Association (NFPA), USA, Publication 53M, "Fire hazards in oxygen enriched atmospheres."

The requirement that the product of open-circuit voltage and short-circuit current should not exceed the value 10 VA does not have complete experimental basis, but is specified in German standard VDE 0750, Teil 1, 1977 (see clause 43 of this standard). In EQUIPMENT made to this German standard, this requirement has proved to minimize the risk of oxygen fires without being too onerous for manufacturers.

The maximum surface temperature of 300 °C corresponds to the maximum surface temperatures specified in NFPA Publication 53M, Table 5-2.

50.102 For the definition, see IEC 60050(845).

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

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

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

Publication	Year	Title	EN/HD	Year
IEC 60050-845	1987	International Electrotechnical Vocabulary (IEV) Chapter 845: Lighting	-	-
IEC 60335-2-27	1995	Safety of household and similar electrical appliances Part 2-27: Particular requirements for appliances for skin exposure to ultraviolet and infrared radiation	EN 60335-2-27 + A11	1997 1997
IEC 60651 A1	1979 1993	Sound level meters	EN 60651 A1	1994 1994
ISO 3743-1	1994	Acoustics - Determination of sound power levels of noise sources using sound pressure - Engineering methods for small, movable sources in reverberant fields Part 1: Comparison method for hard-walled test rooms	-	-

Annex ZB
(informative)

Other international publications mentioned in this standard with the references of the relevant European publications

Publication	Year	Title	EN/HD	Year
IEC 60601-2-19	1990	Medical electrical equipment Part 2: Particular requirements for the safety of baby incubators	EN 60601-2-19	1996
A1	1996		A1	1996
IEC 60601-2-20	1990	Part 2: Particular requirements for the safety of transport incubators		
+ A1	1996		EN 60601-2-20	1996
IEC 60601-2-21	1994	Part 2: Particular requirements for the safety of infant radiant warmers	EN 60601-2-21	1994
A1	1996		A1	1996
IEC 60601-2-35	1996	Part 2: Particular requirements for the safety of blankets, pads and mattresses, intended for heating in medical use	EN 60601-2-35	1996