

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

National foreword

This British Standard is the official English language version of EN 60601-2-50:2002. It is identical with IEC 60601-2-50:2000.

The UK participation in its preparation was entrusted to Technical Committee CH/91, Incubators, which has the responsibility to:

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- present to the responsible European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
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This British Standard, having been prepared under the direction of the Health and Environment Sector Policy and Strategy Committee, was published under the authority of the Standards Policy and Strategy Committee on 13 March 2002

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Medical electrical equipment
Part 2-50: Particular requirements for the safety
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(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 +
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Medizinische elektrische Geräte
Teil 2-50: Besondere Festlegungen
für die Sicherheit von Säuglings-
Phototherapiegeräten
(IEC 60601-2-50:2000 +
Corrigendum März 2001)

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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.

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CENELEC

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

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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.

INTRODUCTION	5
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SECTION ONE – GENERAL

Clause

1 Scope and object	6
1.1 Scope	6
1.2 Object	6
1.3 Particular Standards	6
1.5 Collateral Standards	7
*2 Terminology and definitions	7
2.1 EQUIPMENT parts, auxiliaries and ACCESSORIES	7
2.12 Miscellaneous	8
4 General requirements for tests	8
4.6 Other conditions	8
5 Classification	9
6 Identification, marking and documents	9
6.1 Marking on the outside of EQUIPMENT or EQUIPMENT parts	9
6.2 Marking on the inside of EQUIPMENT or EQUIPMENT parts	9
6.8 ACCOMPANYING DOCUMENTS	9

SECTION TWO – ENVIRONMENTAL CONDITIONS

SECTION THREE – PROTECTION AGAINST ELECTRIC SHOCK HAZARDS

SECTION FOUR – PROTECTION AGAINST MECHANICAL HAZARDS

21 Mechanical strength	12
24 Stability in NORMAL USE	12
25 Expelled parts	13
26 Vibration and noise	13

SECTION FIVE – PROTECTION AGAINST HAZARDS FROM UNWANTED OR EXCESSIVE RADIATION

*32 Light radiation (including lasers)	13
*33 Infrared radiation	13
*34 Ultraviolet radiation	14
36 ELECTROMAGNETIC COMPATIBILITY	14

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

SECTION SEVEN – PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

42 Excessive temperatures	14
43 Fire prevention	15

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

50 Accuracy of operating data	16
50.101 Measuring principles	16
*50.102 Spectral method	16
50.103 Integral method	17
50.104 Maximum TOTAL IRRADIANCE FOR BILIRUBIN $E_{bi\ max}$	17
*50.105 Distribution	17
51 Protection against hazardous output	17

SECTION NINE – ABNORMAL OPERATION AND FAULT CONDITIONS – ENVIRONMENTAL TESTS

52 Abnormal operation and fault conditions	17
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SECTION TEN – CONSTRUCTIONAL REQUIREMENTS

55 ENCLOSURES and covers	18
56 Components and general assembly	18
56.8 Indicators	18
Annex L References – Publications mentioned in this standard	20
Annex AA (informative) Guidance and rationale for particular subclauses	21
Annex ZA (normative) Normative references to international publications with their corresponding European publications	25
Annex ZB (informative) Other international publications mentioned in this standard with the references of the relevant European publications	26
Figure 101 Graphic symbol: Eye protection for the PATIENT (see 6.1)	18
Figure 102 Example of a measuring grid	19

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.