INTERNATIONAL STANDARD

IEC 60601-2-50

First edition
2000-07

Medical electrical equipment –

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

Appareils électromédicaux –

Partie 2-50: Prescriptions particulières de sécurité des appareils de photothérapie infantile

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- **IEC web site***
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Terminology, graphical and letter symbols

For general terminology, readers are referred to IEC 60050: *International Electrotechnical Vocabulary* (IEV).

For graphical symbols, and letter symbols and signs approved by the IEC for general use, readers are referred to publications IEC 60027: *Letter symbols to be used in electrical technology*, IEC 60417: *Graphical symbols for use on equipment. Index, survey and compilation of the single sheets* and IEC 60617: *Graphical symbols for diagrams.*

* See web site address on title page.

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International Electrotechnical Commission
Международная Электротехническая Комиссия

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, the IEC publishes International Standards. Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
2) The formal decisions or agreements of the IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested National Committees.
3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical specifications, technical reports or guides and they are accepted by the National Committees in that sense.
4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.
5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.
6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 60601-2-50 has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

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

FDIS	Report on voting
62D/363/FDIS	62D/369/RVD

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

This publication has been drafted in accordance with the ISO/IEC Directives, Part 3.

Annex AA is for information only.

The contents of the corrigendum of March 2001 have been included in this copy.

In this Particular 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 type;

– *test specifications: in italic type*;

– TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD IEC 60601-1 OR IN THIS PARTICULAR STANDARD: SMALL CAPITALS.

The committee has decided that the contents of this publication will remain unchanged until 2005. At this date, the publication will be

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

A bilingual version of this publication may be issued at a later date.

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.