IEC 60601-2-50

Edition 3.0 2023-10

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

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

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

IEC 60601-2-50:2020-09/AMD1:2023-10(en-fr)

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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

ICS 11.040.60

ISBN 978-2-8322-7664-8

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

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

AMENDMENT 1

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Amendment 1 to IEC 60601-2-50:2020 has been prepared by subcommittee 62D: Particular medical equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems.

The text of this Amendment is based on the following documents:

Draft	Report on voting
62D/2069/FDIS	62D/2087/RVD

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

The language used for the development of this Amendment is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications/.

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- reconfirmed,
- withdrawn, or
- revised.

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

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INTRODUCTION to Amendment 1

At the October 2019 meeting of IEC SC 62D in Shanghai, China, the subcommittee discussed the need for administrative/technical changes to most 62D standards after completion of the amendment projects within the IEC 60601-1 series. Those projects were all completed and the amendments published in 2020.

The full list of IEC SC 62D documents that will be amended or revised can be found within the IEC document 62D/1792/DC. The results and comments on the DC can be found within 62D/1808/INF. The review report for this amendment is 62D/1814/RR.

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201.1 Scope, object and related standards

Replace the existing footnote 1 with the following new footnote:

The general standard is IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

201.1.3 Collateral standards

Add an asterisk (*) at the beginning of the subclause title.

*Replace, in the existing second paragraph, "*IEC 60601-1-2:2014 applies*" with "*IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 apply*".*

201.1.4 Particular standards

*Replace, in the existing third paragraph, "*IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012*" with "*IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020*".*

201.2 Normative references

Replace the existing references to IEC 60601-1 and IEC 60601-1-2 with the following new references:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012
IEC 60601-1:2005/AMD2:2020

IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests*
IEC 60601-1-2:2014/AMD1:2020

201.3 Terms and definitions

Replace, in the existing first paragraph, "IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012" *with* "IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020".

Delete the existing instruction "Replacement:", and the existing term and definition 201.3.76.

201.3.202
INFANT

Add, after the existing definition, the following note to entry:

Note 1 to entry: INFANT includes premature/pre-born baby and neonate baby/newborn baby.

Table 201.101 – List of symbols, abbreviations and acronyms

Replace the existing 16th row of this table with the following new row:

IR – C	C region of infrared radiation (with wavelengths between 3 μm and 1 mm)

201.4.3 * ESSENTIAL PERFORMANCE

Replace the existing instruction "Replacement:" with "Addition:".

201.12.1.102 Measuring principles

Add an asterisk (*) at the beginning of the subclause title.

202 Electromagnetic disturbances – Requirements and tests

Replace the existing text of this clause, including 202.8.9, with the following new text:

IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 apply.

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