IEC 80601-2-35

Edition 1.0 2016-04

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

Medical electrical equipment –
Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads or mattresses and intended for heating in medical use

Appareils électromédicaux –
Partie 2-35: Exigences particulières pour la sécurité de base et les performances essentielles des dispositifs de réchauffage utilisant des couvertures, des coussins ou des matelas chauffants et destinés au réchauffage des patients en usage médical

IEC 80601-2-35:2009-10/AMD1:2016-04(en-fr)

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FOREWORD

This amendment has been prepared by a joint working group of IEC subcommittee 62D: Electromedical equipment of IEC technical committee 62: Electrical equipment in medical practice and ISO subcommittee TC121/SC1: Breathing attachments and anaesthetic machines, of ISO technical committee 121: Anaesthetic and respiratory equipment.

It is published as a double logo standard.

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

FDIS	Report on voting
62D/1328/FDIS	62D/1355/RVD

Full information on the voting for the approval of this amendment can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by 15 P-members out of 15 having cast a vote.

The committee has decided that the contents of this amendment and the base publication will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

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- withdrawn,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

INTRODUCTION

Replace, in the second paragraph, “IEC 60601-1 (third edition, 2005)” *by* “IEC 60601-1”.

201.1 Scope, object and related standards

Replace, in footnote 1), “IEC 60601-1:2005” *by* “IEC 60601-1”.

201.2 Normative references

Replace “IEC 60601-1-2:2007” *by* “IEC 60601-1-2”.

Replace “IEC 60601-1-8:2006” *by* “IEC 60601-1-8”.

Replace “IEC 60601-1-10:2007” *by* “IEC 60601-1-10”.

Delete the following reference:

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*

201.3 Terms and definitions

Replace, in the first paragraph, "IEC 60601-1:2005*" by* "IEC 60601-1".

201.7.2.1.101.2 CONTROLLERS

Replace the text in item a) by the following new text:

a) The HOSE shall be marked within 15 cm of the NOZZLE to caution that the NOZZLE needs to be connected to a BLANKET. The following statement and the safety sign ISO 7010-M002 (see IEC 60601-1, Table D.2, safety sign 10) shall accompany the "NO FREE HOSING" safety sign of IEC 60878, shown in Annex D of this particular standard:

201.8.5.1.2.101 * Additional requirements for MEANS OF PATIENT PROTECTION (MOPP)

Replace the first two paragraphs by the following:

The electrical circuit within the APPLIED PART shall be isolated from earth by at least one MOPP and from MAINS by at least two MOPP. Where a transformer is used to achieve this isolation, it need not meet 15.5.3.

201.12.3.104 Disconnection or short-circuiting of sensors ALARM CONDITION

Replace the second paragraph by the following:

The HEATING DEVICE shall be equipped with an ALARM SYSTEM that includes at least a MEDIUM PRIORITY TECHNICAL ALARM CONDITION for HIGH HEAT TRANSFER DEVICES and at least a LOW PRIORITY ALARM for LOW HEAT TRANSFER DEVICES and FORCED AIR DEVICES that indicates when leads to either the temperature control sensors or the THERMAL CUT-OUT sensors are damaged or otherwise disconnected from the control unit.

202 Electromagnetic compatibility – Requirements and tests

Replace, in the first paragraph, "IEC 60601-1-2:2007" *by* "IEC 60601-1-2".

202.6.2.3 Radiated RF electromagnetic fields

Replace the number, title and entire text by the following new subclause number, title and text:

202.8.9 IMMUNITY TEST LEVELS

Addition:

For radiated radio-frequency electromagnetic fields, the HEATING DEVICE and/or system shall

– continue to perform its intended function as specified by the MANUFACTURER at the level up to 3 V/m for the frequency range of the collateral standard of EMC.

NOTE A HEATING DEVICE is not considered to be used in a HOME HEALTHCARE ENVIRONMENT.

208 General requirements, tests and guidance for ALARM SYSTEMS IN MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS

Replace, in the first paragraph, "IEC 60601-1-8:2006" *by* "IEC 60601-1-8".

210 Requirements for the development of physiologic closed-loop controllers

Replace both instances of "IEC 60601-1-10:2007" *by* "IEC 60601-1-10".

Annex AA
(informative)

Particular guidance and rationale

Add, immediately after the annex title, the following new text and figure:

AA.1 Requirements and the safety concept of this standard

Compliance with the minimum safety requirements specified in this particular standard is predominantly checked by measurement of physical quantities such as the temperature. In most cases the spatial location of the measuring site or the temporal development of the quantity is of interest. Therefore, the expert group of this standard considered it helpful to provide a synopsis of the requirements of this standard. Hence, Figure AA.1 illustrates the requirements and their schematic measuring sites or expected temporal development. The requirements as given by their clauses are set in brackets.