

CONSOLIDATED VERSION

VERSION CONSOLIDÉE



**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
essentielle des dispositifs de réchauffage utilisant des couvertures, des
coussins ou des matelas chauffants et destinés au réchauffage des patients en
usage médical**



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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

FOREWORD

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This Consolidated version of IEC 80601-2-35 bears the edition number 2.1. It consists of the second edition (2009-10) [documents 62D/784A/FDIS and 62D/804/RVD], its corrigendum 1 (2012-03), its corrigendum 2 (2015-02) and its amendment 1 (2016-04) [documents 62D/1328/FDIS and 62D/1355/RVD]. The technical content is identical to the base edition and its amendment.

In this Redline version, a vertical line in the margin shows where the technical content is modified by amendment 1. Additions are in green text, deletions are in strikethrough red text. A separate Final version with all changes accepted is available in this publication.

International Standard IEC 80601-2-35 has been prepared by IEC technical committee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice, and subcommittee 1: Breathing attachments and anaesthetic machines, of ISO technical committee 121: Anaesthetic and respiratory equipment.

It is published as a double logo standard.

This second edition cancels and replaces the first edition published in 1996. This edition constitutes a technical revision.

This new edition provides consistency with the third edition of IEC 60601-1, as well as with the four other particular standards related to paediatric equipment for which the committee is responsible.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

- Requirements and definitions: roman type.
- *Test specifications: italic type.*
- Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

- “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
- “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 series, published under the general title: *Medical electrical equipment* can be found on the IEC website.

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

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INTRODUCTION

The minimum safety requirements specified in this particular standard are considered to provide for a practical degree of safety in the operation for heating devices using BLANKETS, PADS or MATTRESSES and intended for heating in medical use.

This particular standard amends and supplements IEC 60601-1 ~~(third edition, 2005)~~, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*, hereinafter referred to as the general standard. The text of this particular standard relating to forced air warmers is based on ASTM F2196-02, *Standard specification for circulating liquid and forced air patient temperature management devices*.

The requirements are followed by specifications for the relevant tests.

A "general guidance and rationale" section giving some explanatory notes, where appropriate, about the more important requirements is included in Annex AA.

While K (degree Kelvin) is the recognized unit and symbol for absolute temperature and temperature difference, °C has been used throughout this particular standard because all measurements are commonly made using equipment marked with the Celsius temperature scale.

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

201.1 Scope, object and related standards

Clause 1 of the general standard¹⁾ applies, except as follows:

201.1.1 * Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of HEATING DEVICES using BLANKETS, PADS or MATTRESSES in medical use, also referred to as ME EQUIPMENT. HEATING DEVICES intended to prewarm a bed are included in the scope of this International Standard.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

If a clause or subclause is specifically intended to apply to a specifically defined type of ME EQUIPMENT, as is the case with FORCED AIR DEVICES, then the clause or subclause is entitled as such. Clauses or subclauses that apply to all types of ME EQUIPMENT within the scope of this standard are not specifically entitled.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of the general standard.

NOTE See also 4.2 of the general standard.

This particular standard does not apply to:

- HEATING DEVICES intended for physiotherapy;
- radiant warmers; for information, see IEC 60601-2-21 [12]²⁾;
- incubators; for information, see IEC 60601-2-19 [10];
- transport incubators, for information, see IEC 60601-2-20 [11];
- cooling devices.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements, which minimize HAZARDS to PATIENTS, and OPERATORS for heating

¹⁾ The general standard is IEC 60601-1:~~2005~~, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

²⁾ Figures in square brackets refer to the Bibliography.