

# 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**

[IEC 80601-2-35:2009/Amd 1:2016](#)

**Appareils électromédicaux –  
Partie 2-35: Exigences particulières pour la sécurité de base et les performances  
essentiels 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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IEC Central Office  
3, rue de Varembe  
CH-1211 Geneva 20  
Switzerland

Tel.: +41 22 919 02 11  
Fax: +41 22 919 03 00  
[info@iec.ch](mailto:info@iec.ch)  
[www.iec.ch](http://www.iec.ch)

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#### **Glossaire IEC - [std.iec.ch/glossary](http://std.iec.ch/glossary)**

65 000 entrées terminologiques électrotechniques, en anglais et en français, extraites des articles Termes et Définitions des publications IEC parues depuis 2002. Plus certaines entrées antérieures extraites des publications des CE 37, 77, 86 et CISPR de l'IEC.

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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- withdrawn,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.

<https://standards.iteh.ai/catalog/standards/sist/f219ab8b-3c6e-47d8-ac8f-1d07873a43ce/iec-80601-2-35-2009-amd-1-2016>

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## 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”.*

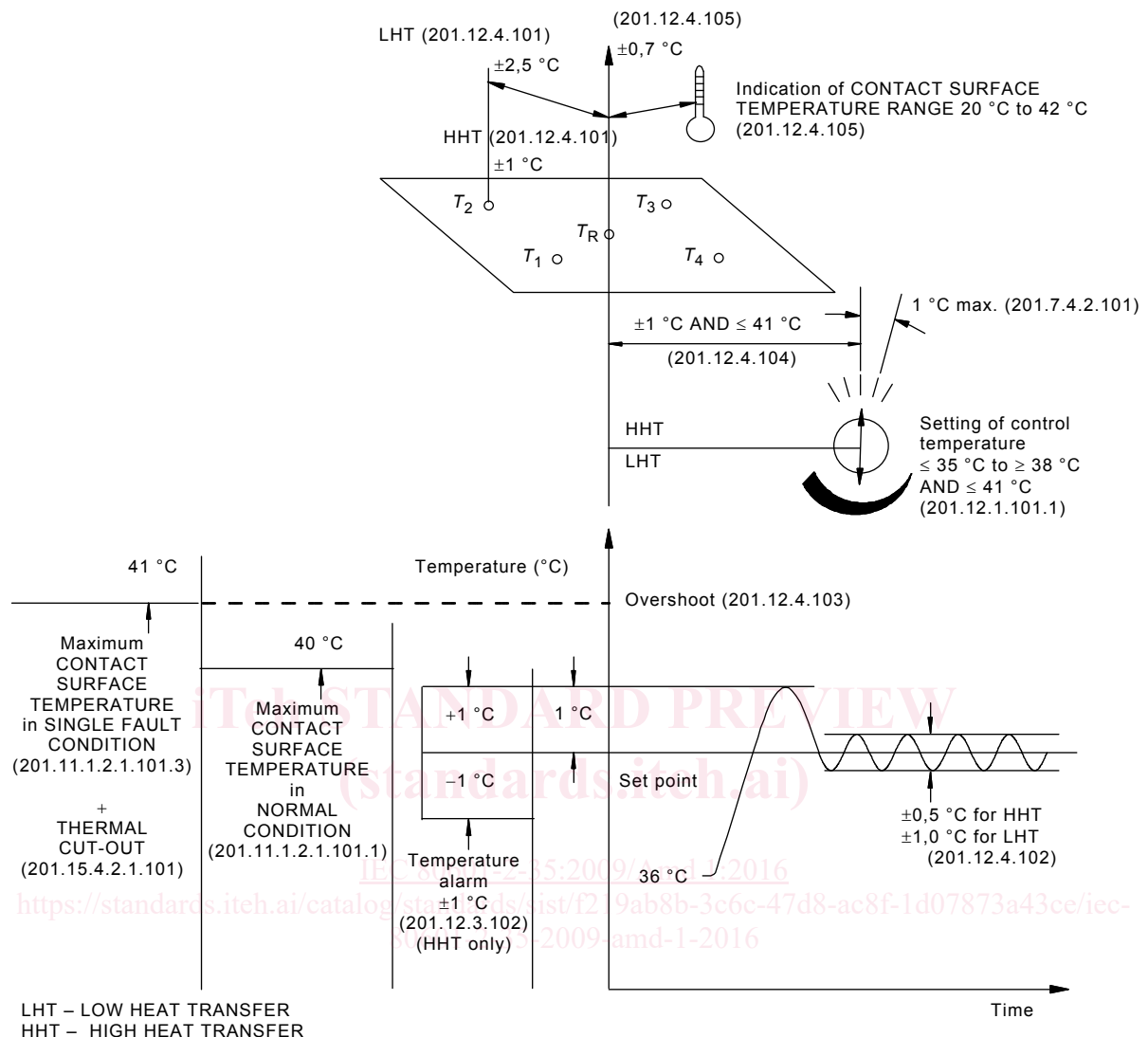
# **Annex AA** (informative)

## **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.



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NOTE Numbers in brackets indicate the relevant subclauses.

**Figure AA.1 – Illustration of the main requirements of this standard**

## AA.2 Particular guidance

### Subclause 201.11.1.2.1.102.1 – Maximum CONTACT SURFACE TEMPERATURE in NORMAL CONDITION

Add, after the existing text, the following new text:

The CONTACT SURFACE TEMPERATURE of HEATING DEVICES may rise when combined with other heat sources such as heating BLANKETS or PADS. Hence, it is important to specifically consider the impact of such additional heat sources in the RISK MANAGEMENT.

### Subclause 202.6.2 – IMMUNITY

Delete the entire reference to subclause 202.6.2 and its rationale.

**Subclause 210 – Requirements for the development of physiologic closed-loop controllers**

*Replace, in the first paragraph, “IEC 60601-1-10-1” by “IEC 60601-1-10”.*

**Annex FF**  
(normative)

**Test procedure for maximum CONTACT SURFACE  
TEMPERATURE for FORCED AIR DEVICES**

*Replace the entire existing text of item a) by the following new text:*

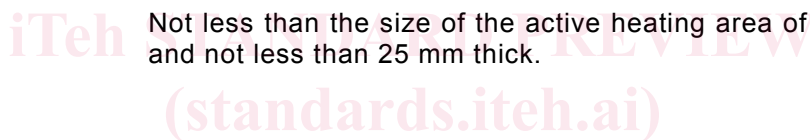
a) LAGGING MATERIAL

The LAGGING MATERIAL has the following characteristics:

Material: Polyurethane or polystyrene insulation material;

Thermal resistance: A minimum R-Value rating of 10 when tested in accordance with ASTM C578 [8];

Size: Not less than the size of the active heating area of the test blanket and not less than 25 mm thick.



**Bibliography**

[IEC 80601-2-35:2009/Amd 1:2016](#)

Delete “:2009” in references [10], [11] and [12]. [f219ab8b-3c6c-47d8-ac8f-1d07873a43ce/iec-80601-2-35-2009-amd-1-2016](#)

**Index of defined terms used in this particular standard**

*Replace all instances of “IEC 60601-1:2005” by “IEC 60601-1”.*

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

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

*Replace the term*

LIFE SUPPORTING ME EQUIPMENT OR ME SYSTEM ..... IEC 60601-1-2:2007, 3.18

*by the following new term:*

HOME HEALTHCARE ENVIRONMENT ..... IEC 60601-1-11, 3.2







## AVANT-PROPOS

Le présent amendement a été établi par le groupe de travail mixte du sous-comité 62D: Appareils électromédicaux du comité d'études 62 de l'IEC: Equipements électriques dans la pratique médicale, et du sous-comité SC1 de l'ISO: Raccords pour appareils d'anesthésie, du comité technique 121 de l'ISO: Matériel d'anesthésie et de réanimation respiratoire.

La présente publication est une norme double logo.

Le texte de cet amendement est issu des documents suivants:

FDIS	Rapport de vote
62D/1328/FDIS	62D/1355/RVD

Le rapport de vote indiqué dans le tableau ci-dessus donne toute information sur le vote ayant abouti à l'approbation de cet amendement. A l'ISO, la norme a été approuvée par 15 membres P sur 15 ayant voté.

Le comité a décidé que le contenu de cet amendement et de la publication de base ne sera pas modifié avant la date de stabilité indiquée sur le site web de l'IEC sous "http://webstore.iec.ch" dans les données relatives à la publication recherchée. A cette date, la publication sera

- reconduite,
- supprimée,
- remplacée par une édition révisée, ou
- amendée.

## INTRODUCTION

*Remplacer, dans le deuxième alinéa, "CEI 60601-1 (troisième édition, 2005)" par "IEC 60601-1".*

### 201.1 Domaine d'application, objet et normes connexes

*Remplacer, dans la note de bas de page 1), "CEI 60601-1:2005" par "IEC 60601-1".*

### 201.2 Références normatives

*Remplacer "CEI 60601-1-2:2007" par "IEC 60601-1-2".*

*Remplacer "CEI 60601-1-8:2006" par "IEC 60601-1-8".*

*Remplacer "CEI 60601-1-10:2007" par "IEC 60601-1-10".*