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International Standard

IEC/FDIS
80601-2-89

Medical electrical equipment —

Part 2-89: Particular requirements for the basic safety and essential performance of medical beds for children

ISO/TC **173**

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This draft is submitted to a parallel vote in ISO and in IEC.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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Medical electrical equipment - Part 2-89: Particular requirements for the basic safety and essential performance of medical beds for children

FOREWORD

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IEC 80601-2-89 has been prepared by a Joint Working Group of IEC subcommittee 62D: Particular medical equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems, and ISO technical committee 173: Assistive products. It is an International Standard.

This publication is published as a double logo standard.

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

Draft	Report on voting
62D/XX/FDIS	62D/XX/RVD

Full information on the voting for its approval can be found in the report on voting indicated in the above table. In ISO, the document was approved by XXX P members out of YYY having cast a vote.

The language used for the development of this International Standard 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.

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 IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 AND IEC 60601-1:2005/AMD2:2020, IN THIS DOCUMENT OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this document, 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 document are preceded by the term "Clause" followed by the clause number. References to subclauses within this document are by number only.

In this document, 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 document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this document;

– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document;

– "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 80601 series, published under the general title *Medical electrical equipment,* can be found on the IEC website.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn, or
- revised.

INTRODUCTION

IEC 80601-2-52[1][1] applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL BEDS for ADULTS, hence not covering requirement for beds for CHILDREN and ADULTS with atypical anatomy. This particular standard is based on EN 50637[2], which was created pursuant to Mandate M/467 Medical beds issued by the European Commission with the following background information:

It appears, from a first analysis undertaken by EU Competent Authorities, that the current set of standards is not adapted to the needs of CHILDREN or ADULTS with an atypical anatomy. IEC 80601-2-52 does not foresee a maximum distance for the bars that is small enough to prevent accidents.

According to the EU Competent Authorities' representatives, a part of the safety problem is due to the fact that MEDICAL BEDS for ADULTS are not appropriately labelled as being designed only for ADULTS with a normal anatomy. Users are therefore not always aware of the risk of MEDICAL BEDS for young PATIENTS or for ADULTS with an atypical anatomy. Hospital administrations do not always see a need to buy MEDICAL BEDS which are appropriate for CHILDREN or for ADULTS with an atypical anatomy. Therefore, clear labelling of the targeted PATIENT groups for MEDICAL BEDS complying with IEC 80601-2-52 could reduce the risk of inappropriate use of this kind of MEDICAL BEDS for CHILDREN or for ADULTS with an atypical anatomy.

EU Competent Authorities' representatives also stated that there is a need for the development of requirements for MEDICAL BEDS and COTS for CHILDREN and ADULTS with an atypical anatomy.

In order to prevent IEC 80601-2-52 from being extraordinarily complex to use, TC 62 decided to develop this particular standard rather than further amending IEC 80601-2-52 in relation to use for CHILDREN and ADULTS with an atypical anatomy.

This standard is based on EN 50637 and IEC 80601-2-52 with input from the following standards and reports:

- EN 716-1, *Furniture – V Children's cots and folding cots for dom estic use – Part 1: Safety requirements*
- EN 716-2, *Furniture – Children's cots and folding cots for domestic use – Part 2: Test methods*
- EN 1130, *Furniture – Children's furniture – Cribs – Safety requirements and test methods*
- EN 747-1, *Furniture – Bunk beds and high beds – Part 1: Safety, strength and durability requirements*
- EN 747-2, *Furniture – Bunk beds and high beds – Part 2: Test methods*
- CEN/TR 13387 (all parts), *Child use and care articles – General safety guidelines*
- DIN 32623, *Hospital children's cots made from metal and plastic – Safety requirements and testing*
- *Nordic Requirements specification for Adjustable beds for disabled children*

[1] Numbers in square brackets refer to the Bibliography.

201.1 Scope, object and related standards

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, Clause 1, applies, except as follows:

201.1.1 * Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL BEDS, hereafter referred to as MEDICAL BEDS as defined in 201.3.219, intended for CHILDREN as defined in 201.3.207, and ADULTS with atypical anatomy (ADULTS ranging outside the definition for ADULTS in 201.3.201).

This document applies to both electrical and non-electrical(manual) MEDICAL BEDS with or without adjustable functions. This document applies to MEDICAL BEDS with an INTERNAL LENGTH of up to 180 cm suitable to a body length of 155 cm.

NOTE 1 The limitation of 180 cm is in order to minimize the foreseeable misuse, of a parent sharing the bed with the CHILD or that the bed will be used by an ADULT.

If a MANUFACTURER wishes to make a bed that can be used by both a CHILD and an ADULT, e.g. INTERNAL LENGTH of 180 cm or more, then IEC 80601-2-52 and this document apply.

This document does not apply to:

- ADULT *only* beds covered by IEC 80601-2-52;
- SPECIALITY MATTRESS covered by the ISO 20342 series[5];
- incubators covered by IEC 60601-2-19;
- devices for which the INTENDED USE is mainly for examination or transportation under medical supervision (e.g. stretcher, examination table).

If a clause or subclause is specifically intended to be applicable to a MEDICAL BED 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 MEDICAL BEDS and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of MEDICAL BEDS or ME SYSTEMS within the scope of this document are not covered by specific requirements in this document except in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 7.2.13 and 8.4.1.

NOTE 2 See also IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, 4.2.

NOTE 3 Whenever the term MEDICAL ELECTRICAL EQUIPMENT (MEE, ME Equipment) is used within the series of IEC 60601 standards, it refers to MEDICAL BEDS, both electrical and non-electrical.

201.1.2 Object

Replacement:

The object of this document is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements and test methods for MEDICAL BEDS as defined in 201.3.219 intended for CHILDREN as defined in 201.3.207 and ADULTS with atypical anatomy, i.e. ADULTS ranging outside the definition for ADULTS in 202.3.201.

201.1.3 Collateral standards

Addition:

This document refers to those applicable collateral standards that are listed in Clause 2 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 and Clause 201.2 of this document.

IEC 60601-1-3 and IEC 60601-1-10 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

NOTE Some IEC 60601-1-8 requirements can be excluded if they do not affect PATIENT safety, could lead to user confusion, or are inappropriate to MEDICAL BED usage.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, including the collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

Requirements of this document takes priority over IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

The numbering of clauses and subclauses of this particular standard corresponds to that of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 with the prefix "201" (e.g. 201.1 in this document addresses the content of Clause 1 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020) or applicable collateral standard with the prefix "20x" where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this document addresses the content of Clause 4 of the IEC 60601-1-2:2015 collateral standard, 203.4 in this document addresses the content of Clause 4 of the IEC 60601-1-3:2008 collateral standard, etc.). The changes to the text of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are specified by the use of the following words:

"*Replacement*" means that the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard is replaced completely by the text of this document.

"*Addition*" means that the text of this document is additional to the requirements of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard.

"*Amendment*" means that the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard is amended as indicated by the text of this document.

Subclauses, figures or tables which are additional to those of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered starting from 201.101. However, due to the fact that definitions in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 are numbered 3.1 through 3.154, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where "x" is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this document.

201.2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE Informative references are listed in the Bibliography.

IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, Clause 2, applies except as follows:

Addition:

IEC 60068-2-31, *Environmental testing - Part 2-31: Tests - Test Ec: Rough handling shocks, primarily for equipment-type specimens*

IEC 60529, *Degrees of protection provided by enclosures (IP Code)*

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

ISO 48-5:2018, *Rubber, vulcanized or thermoplastic - Determination of hardness - Part 5: Indentation hardness by IRHD pocket meter method*

ISO 3746*, Acoustics - Determination of sound power levels of noise sources using sound pressure - Survey method using an enveloping measurement surface over a reflecting plane*

EN 71-3, *Safety of toys - Part 3: Migration of certain elements*

EN 597-1, *Furniture - Assessment of the ignitability of mattresses and upholstered bed bases - Part 1: Ignition source : Smouldering cigarette*

EN 597-2, *Furniture - Assessment of the ignitability of mattresses and upholstered bed bases - Part 2: Ignition source: Match flame equivalent*

EN 716-2, *Furniture - Children's cots and folding cots for domestic use - Part 2: Test methods*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- IEC Electropedia: available at https://www.electropedia.org/
- ISO Online browsing platform: available at https://www.iso.org/obp

NOTE An index of defined terms is given after the Bibliography.

201.3.76
PATIENT

Replacement:

living person undergoing a medical PROCEDURE or PERSON WITH DISABILITY

Note 1 to entry: Whenever the term PATIENT is used, it comprises both ADULTS with an atypical anatomy and CHILDREN.

201.3.109
SAFE WORKING LOAD
SWL

Replacement:

sum of:

1) the PATIENT;
2) the mattress;
3) the ACCESSORIES of the MEDICAL BED, only if they are supported by the support system of the MEDICAL BED; and
4) the SAFE WORKING LOADS supported by those ACCESSORIES, excluding PATIENT weight

201.3.131
*** TRAPPING ZONE**

Replacement:

locations where the PATIENT or other persons can become entrapped, entangled, wedged, or stuck in or between parts of the MEDICAL BED, such as the SIDE RAILS, HEAD/FOOT BOARD, MATTRESS SUPPORT PLATFORM or mattress

Additional terms and definitions:

201.3.201
ADULT
PATIENT having a physical size equal to or more than 146 cm, a mass equal to or more than 40 kg and a body mass index (BMI) equal to or more than 17

[SOURCE: IEC 80601-2-52:20—, 201.3.222, modified – Deletion of “or having a physical size, mass, and body index as defined by the MANUFACTURER'S RISK MANAGEMENT FILE”.]

201.3.202
*** APPLICATION ENVIRONMENT 1**
Intensive care or critical care provided in a hospital where 24 h medical supervision and constant monitoring is required and provision of life support equipment used in medical PROCEDURES is essential to maintain or improve the vital functions of the PATIENT

201.3.203

*** APPLICATION ENVIRONMENT 2**

acute care provided in a hospital or other medical facility where medical supervision and monitoring is required and MEDICAL BED used in medical PROCEDURES is often provided to help maintain or improve the condition of the PATIENT

201.3.204

*** APPLICATION ENVIRONMENT 3**

long-term care in a medical area where medical supervision is required and monitoring is provided if necessary and MEDICAL BED used in medical PROCEDURES may be provided to help maintain or improve the condition of the PATIENT

Note 1 to entry: This includes use in CHILDREN'S nursing homes and in rehabilitation facilities.

201.3.205

*** APPLICATION ENVIRONMENT 4**

care provided in a domestic area where MEDICAL BED is used to alleviate or compensate for an injury, disability or disease

Note 1 to entry: This excludes use in all other application environments (e.g. CHILDREN'S nursing homes and rehabilitation facilities) when a MEDICAL BED is purely designed for APPLICATION ENVIRONMENT 4.

201.3.206

*** APPLICATION ENVIRONMENT 5**

outpatient care or ambulatory care, which is provided in a hospital or other medical facility, under medical supervision where MEDICAL BED, is provided for the need of persons with illness, injury or disability for treatment, diagnosis or monitoring

201.3.207

CHILD

PATIENT having a body length equal to or less than 155 cm and a mass equal to or less than 70 kg and may display cognitive immaturity, exploratory behaviours, risk taking tendencies or any combination.

Note 1 to entry: Body length is measured from crown to sole.

201.3.208

COT

MEDICAL BED with an INTERNAL LENGTH ≥90 cm and <140 cm provided with PROTECTION PANELS also intended for CHILDREN able to stand up in bed

Note 1 to entry: See Figure 201.101.