SLOVENSKI STANDARD
oSIST prEN IEC 80601-2-52:2024

01-maj-2024

Medicinska električna oprema - 2-52. del: Posebne zahteve za osnovno varnost in bistvene lastnosti medicinskih postelj

Medical electrical equipment - Part 2-52: Particular requirements for the basic safety and essential performance of medical beds

Appareil électromédicaux - Partie 2-52: Exigences particulières de sécurité de base et de performances essentielles des lits médicaux

Ta slovenski standard je istoveten z: **prEN IEC 80601-2-52:2024**

ICS:

11.140	Oprema bolnišnic	Hospital equipment

oSIST prEN IEC 80601-2-52:2024 **en**

62D/2114/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER: **IEC 80601-2-52 ED1**	
DATE OF CIRCULATION: **2024-03-01**	CLOSING DATE FOR VOTING: **2024-05-24**
SUPERSEDES DOCUMENTS: **62D/1759A/CD, 62D/1782A/CC**	

IEC SC 62D : PARTICULAR MEDICAL EQUIPMENT, SOFTWARE, AND SYSTEMS

SECRETARIAT: United States of America	SECRETARY: Ms Ladan Bulookbashi
OF INTEREST TO THE FOLLOWING COMMITTEES:	PROPOSED HORIZONTAL STANDARD: ☐ Other TC/SCs are requested to indicate their interest, if any, in this CDV to the secretary.

FUNCTIONS CONCERNED:

☐ EMC ☐ ENVIRONMENT ☐ QUALITY ASSURANCE ☒ SAFETY

☒ SUBMITTED FOR CENELEC PARALLEL VOTING	☐ NOT SUBMITTED FOR CENELEC PARALLEL VOTING
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Recipients of this document are invited to submit, with their comments, notification of any relevant “In Some Countries” clauses to be included should this proposal proceed. Recipients are reminded that the CDV stage is the final stage for submitting ISC clauses. (SEE AC/22/2007 OR NEW GUIDANCE DOC).

TITLE:

Medical electrical equipment - Part 2-52: Particular requirements for the basic safety and essential performance of medical beds

PROPOSED STABILITY DATE: 2030

NOTE FROM TC/SC OFFICERS:

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113 ## FOREWORD

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International standard IEC 80601-2-52 has been prepared by IEC subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice, and by ISO technical committee 173: Assistive products for persons with disability.

It is published as double logo standard.

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 collateral 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.

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

187 • reconfirmed,

188 • withdrawn,

189 • replaced by a revised edition, or

190 • amended.

191

INTRODUCTION

In 1996, the IEC published the first edition of the particular standard for electrically operated hospital beds, IEC 60601-2-38. The publication was in response to demand in the field for a universal standard addressing HAZARDS specific to the safety of the hospital bed. Used in conjunction with a MANUFACTURER'S RISK ASSESSMENT, the standard was felt to be the current thinking on establishing a basic safety benchmark for industry.

An amendment of IEC 60601-2-38 issued in 1999 recognized the need to mitigate against a RISK of PATIENT entrapment in the SIDE RAILS, again combined with the use of the MANUFACTURER'S RISK ASSESSMENT. Although this improved the particular standard, it still was centered upon electrically operated hospital beds, and failed to take into account manually operated hospital beds and products in other medical environments.

In 2000, the EN 1970 standard (*Adjustable beds for DISABLED PERSONS – Requirements and test methods*) was published, which addressed beds used by PERSONS WITH DISABILITY to alleviate or compensate for a disability or handicap. This standard offered a broadened scope in conjunction with IEC 60601-2-38, but after the edition of Amendment 1 to IEC 60601-2-38, the opportunity presented itself to combine the two standards to a common, international standard.

As work began on the integration, the IEC adjusted its stance on BASIC SAFETY and ESSENTIAL PERFORMANCE, integrating them into the third edition of IEC 60601-1. It therefore became necessary to align the new standard with the third edition. The particular standard was given a new number, IEC 60601-2-52, and work began on alignment to third edition.

This particular standard, therefore, is the realization of much work in alignment, and scope adjustment between IEC 60601-2-38, EN 1970, and the third edition of IEC 60601-1. It represents the current thinking in BASIC SAFETY and ESSENTIAL PERFORMANCE of the MEDICAL BED as used to alleviate illness of PATIENTS and disability of PERSONS WITH DISABILITY. This is the effort of a joint working group of the IEC and the ISO.

IEC 80601-2-52 is a continuation of the IEC 60601-2-52 standard. It will align with the CHILDREN version of the standard, IEC 80601-2-89. The standard number was changed from IEC 60601-2-52 to IEC 80601-2-52 to indicate joint work between the ISO and the IEC.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-52: Particular requirements for the basic safety and essential performance of medical beds for adults

201.1 Scope, object and related standards

Clause 1 of the general standard[1)] applies, except as follows:

201.1.1 * Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL BEDS as defined in 201.3.214, intended for ADULTS as defined in 201.3.222. Included in scope are both electrical and non-electrical (manual) MEDICAL BEDS with or without adjustable features.

This standard does not apply for MEDICAL BEDS intended for CHILDREN covered by IEC 80601-2-89 Medical electrical equipment – Particular requirements for the basic safety and essential performance of medical beds for children.

A BED-LIFT and/or a detachable MATTRESS SUPPORT PLATFORM in combination with a compatible non-MEDICAL BED as specified by the MANUFACTURER is also considered a MEDICAL BED.

Excluded are devices for which the intended use is mainly for examination or transportation under medical supervision (e.g. stretcher, examination table).

This standard does not apply in all requirements to MEDICAL BEDS with special functionality.

Beds that are intended to be used for ADULTS with atypical anatomy shall state what atypical anatomies are meant. Additional requirements for the stated atypical anatomies shall be determined in the product RISK MANAGEMENT process and implemented as appropriate in the bed design.

EXAMPLE A bed intended for bariatric PATIENTS would require consideration of the differences in anthropomorphic ranges, and having implemented those ranges would label appropriately for the intended PATIENT population.

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 BED and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of MEDICAL BED 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.

201.1.2 Object

Replacement:

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

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for MEDICAL BEDS as defined in 201.3.214, intended for ADULTS as defined in 201.3.222.

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 2 of this particular standard.

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.

Some IEC 60601-1-8 requirements may be excluded if they don't affect PATIENT safety, could lead to user confusion, or are inappropriate to MEDICAL BED usage.

Compliance is checked by inspection of the RISK MANAGEMENT FILE and USABILITY ENGINEERING FILE.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix "201" (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) 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 particular standard addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

"Addition" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard 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.

The term "this standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

NOTE Informative references are listed in the bibliography on page 86.

Clause 2 of the general standard applies except as follows:

Replacement:

Change IEC 60529 reference from Amendment 1 to Amendment 2:

IEC 60529:1989+AMD1:1999+AMD2:2013 CSV*, Degrees of protection provided by enclosures (IP Code)*

Additions:

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*

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

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in the general standard apply, except as follows:

NOTE An index of defined terms is found beginning on page *89*.

201.3.76
PATIENT

Replacement:

person undergoing a medical procedure or PERSON WITH DISABILITY

201.3.109
SAFE WORKING LOAD
SWL

Replacement:

The SAFE WORKING LOAD is the 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**

Addition:

locations where the body of a MEDICAL BED occupant 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

Addition:

201.3.201
*** APPLICATION ENVIRONMENT 1**
intensive/critical care provided in a hospital where 24 h medical supervision and constant monitoring is required and provision of life support system/equipment used in medical procedures is essential to maintain or improve the vital functions of the PATIENT

201.3.202
*** APPLICATION ENVIRONMENT 2**
acute care provided in a hospital or other medical facility where medical supervision and monitoring is required and ME EQUIPMENT used in medical procedures is often provided to help maintain or improve the condition of the PATIENT

201.3.203
*** APPLICATION ENVIRONMENT 3**
long-term care in a medical area where medical supervision is required and monitoring is provided if necessary and ME EQUIPMENT 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 nursing homes and in rehabilitation and geriatric facilities.

201.3.204
*** APPLICATION ENVIRONMENT 4**
care provided in a domestic area where ME EQUIPMENT 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. nursing homes, rehabilitation and geriatric facilities) when a MEDICAL BED is purely designed for APPLICATION ENVIRONMENT 4.

201.3.205
*** APPLICATION ENVIRONMENT 5**
outpatient (ambulatory) care, which is provided in a hospital or other medical facility, under medical supervision where ME EQUIPMENT, is provided for the need of persons with illness, injury or disability for treatment, diagnosis or monitoring

201.3.206
*** APPLICATION ENVIRONMENT 6**
Psychiatric (mental health) care environment where medical supervision is required, and monitoring is provided. ME EQUIPMENT used in medical procedures may be provided to help maintain, improve condition and protect the PATIENT. Environment where a PATIENT may be a harm to themselves or others.

NOTE 1 to entry: Includes prisons, jails, correctional facilities.