

SLOVENSKI STANDARD

SIST EN IEC 80601-2-52:2026

01-september-2026

Nadomešča:

SIST EN 60601-2-52:2010

SIST EN 60601-2-52:2010/A1:2015

SIST EN 60601-2-52:2010/AC:2011

Medicinska električna oprema - 2-52. del: Posebne zahteve za osnovno varnost in bistvene lastnosti medicinskih postelj za odrasle (IEC 80601-2-52:2026)

Medical electrical equipment - Part 2-52: Particular requirements for the basic safety and essential performance of medical beds for adults (IEC 80601-2-52:2026)

Medizinische elektrische Geräte - Teil 2-52: Besondere Festlegungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von medizinischen Betten für Erwachsene (IEC 80601-2-52:2026)

Appareil électromédicaux - Partie 2-52: Exigences particulières de sécurité de base et de performances essentielles des lits médicaux (IEC 80601-2-52:2026)

Ta slovenski standard je istoveten z: EN IEC 80601-2-52:2026

ICS:

11.140

Oprema bolnišnic

Hospital equipment

SIST EN IEC 80601-2-52:2026

en

Sample Document

get full document from standards.iteh.ai

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN IEC 80601-2-52

July 2026

ICS 11.140

Supersedes EN 60601-2-52:2010; EN 60601-2-52:2010/AC:2011; EN 60601-2-52:2010/A1:2015

English Version

**Medical electrical equipment - Part 2-52: Particular requirements
for the basic safety and essential performance of medical beds
for adults
(IEC 80601-2-52:2026)**

Appareil électromédicaux - Partie 2-52: Exigences
particulières de sécurité de base et de performances
essentielles des lits médicaux pour adultes
(IEC 80601-2-52:2026)

Medizinische elektrische Geräte - Teil 2-52: Besondere
Festlegungen für die Sicherheit einschließlich der
wesentlichen Leistungsmerkmale von medizinischen Betten
für Erwachsene
(IEC 80601-2-52:2026)

This European Standard was approved by CENELEC on 2026-06-09. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.



European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

EN IEC 80601-2-52:2026 (E)**European foreword**

The text of document 62D/2271/FDIS, future edition 1 of IEC 80601-2-52, prepared by SC 62D "Particular medical equipment, software, and systems" of IEC/TC 62 "Medical equipment, software, and systems" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 80601-2-52:2026.

The following dates are fixed:

- latest date by which the document has to be implemented at national (dop) 2027-07-31 level by publication of an identical national standard or by endorsement
- latest date by which the national standards conflicting with the (dow) 2029-07-31 document have to be withdrawn

This document supersedes EN 60601-2-52:2010 and all of its amendments and corrigenda (if any).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC shall not be held responsible for identifying any or all such patent rights.

Any feedback and questions on this document should be directed to the users' national committee. A complete listing of these bodies can be found on the CENELEC website.

Sample Document

Endorsement notice

The text of the International Standard IEC 80601-2-52:2026 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standard indicated:

IEC 80601-2-89:2025	NOTE Approved as EN IEC 80601-2-89:2026 (not modified)
ISO 20342 (series)	NOTE Approved as EN ISO 20342 (series)
ISO 9999:2022	NOTE Approved as EN ISO 9999:2022 (not modified)
IEC 60068-2-31	NOTE Approved as EN 60068-2-31
IEC 60601-1-10	NOTE Approved as EN 60601-1-10
ISO/IEC Guide 71:2014	NOTE Approved as CEN/CLC Guide 6:2014 (not modified)

Annex ZA (normative)

Normative references to international publications with their corresponding European publications

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 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

Annex ZA of EN 60601-1:2006 and all of its amendments and corrigenda applies except as follows:

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
<i>Replacement:</i>				
IEC 60529	1989	Degrees of protection provided by enclosures (IP Code)	EN 60529	1991
-	-		+ corrigendum May	1993
+ A1	1999		+ A1	2000
+ A2	2013		+ A2	2013
			+ AC	2016-12
			+ A2:2013/AC	2019-02
<i>Addition:</i>				
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
-	-		+ corrigendum Mar.	2010
+ A1	2012		+ A1	2013
			+ A1:2013/AC	2014
-	-		+ A12	2014
+ A2	2020		+ A2	2021
			+ AC	2022-12
-	-		+ A13	2024
ISO 3746	-	Acoustics - Determination of sound power levels and sound energy levels of noise sources using sound pressure - Survey method using an enveloping measurement surface over a reflecting plane	EN ISO 3746	-

Sample Document

get full document from standards.iteh.ai



IEC 80601-2-52

Edition 1.0 2026-05

INTERNATIONAL STANDARD

Medical electrical equipment -

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

get full document from standards.iteh.ai

CONTENTS

FOREWORD	4
INTRODUCTION	7
201.1 Scope, object and related standards	8
201.2 Normative references	10
201.3 Terms and definitions	10
201.4 General requirements	15
201.5 General requirements for testing of ME EQUIPMENT	16
201.6 Classification of ME EQUIPMENT and ME SYSTEMS	19
201.7 ME EQUIPMENT identification, marking and documents	19
201.8 Protection against electrical HAZARDS from ME EQUIPMENT	25
201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS	26
201.10 Protection against unwanted and excessive radiation HAZARDS	53
201.11 Protection against excessive temperatures and other HAZARDS	53
201.12 Accuracy of controls and instruments and protection against hazardous outputs	57
201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT	57
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)	58
201.15 Construction of ME EQUIPMENT	58
201.16 ME SYSTEMS	63
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS	63
Annexes	64
Annex AA (informative) Particular guidance and rationale	65
Annex BB (normative) Additional design requirements and recommendations for MEDICAL BEDS	84
Annex CC (informative) Particular guidance for assessing RISK of entrapment in V- shaped openings	89
Annex DD (informative) Guidance and recommendations for periodic inspection	95
Bibliography	97
Index of defined terms	98
Figure 201.101 – MEDICAL BED, general arrangement (example, schematic presentation only)	13
Figure 201.102 – HEAD DOWN TILT, Example	15
Figure 201.103 – FOOT DOWN TILT, Example	15
Figure 201.104 – Entrapment test tools	17
Figure 201.105 – Loading pad	18
Figure 201.106 – Impactor	18
Figure 201.107 – Ball chain loop and spherical mass	19
Figure 201.108 – Graphic symbol for maximum PATIENT weight and SAFE WORKING LOAD	20
Figure 201.109 – Graphic symbol for mass; weight	20
Figure 201.110 – Graphic symbol for machine washable MEDICAL BED	20
Figure 201.111 – Graphic symbol for jet stream washable MEDICAL BED	21
Figure 201.112 – Graphic symbol for manual cleaning only	21

IEC 80601-2-52:2026 © IEC 2026

Figure 201.113 – Physical description of PATIENT	22
Figure 201.114 – MEDICAL BED function controls or actuators or both: guidelines for creating graphic symbols	23
Figure 201.115 – Example of MEDICAL BED with segmented or split SIDE RAIL	27
Figure 201.116 – Example of MEDICAL BED with single piece SIDE RAIL	28
Figure 201.117 – Allowable spacing for fingers in areas of normal reach around the perimeter of the MATTRESS SUPPORT PLATFORM	33
Figure 201.118 – Example using barriers for clearance measurement around the perimeter of the MATTRESS SUPPORT PLATFORM to mitigate PATIENT finger entrapment	34
Figure 201.119 – Clearance areas	35
Figure 201.120 – Retention of loop and mass	37
Figure 201.121 – Lateral stability test along the side of the MEDICAL BED	39
Figure 201.122 – Longitudinal stability test with removable FOOT BOARD	40
Figure 201.123 – Longitudinal stability test with fixed HEAD BOARD and FOOT BOARD	40
Figure 201.124 – Distribution of SAFE WORKING LOAD / maximum PATIENT weight for tests	44
Figure 201.125 – Positions of dynamic loading (see Figure 201.103 for loading pad and Figure 201.104 for impactor)	47
Figure 201.126 – Application of forces for test of SIDE RAIL	49
Figure 201.127 – Height of SIDE RAIL	52
Figure 201.128 – Direction of movement for rough handling test	59
Figure 201.129 – Configurations of the MATTRESS SUPPORT PLATFORM	61
Figure AA.1 – Example of marking to select recommended mattresses specified by the MANUFACTURER	68
Figure AA.2 – Example of marking for detachable SIDE RAILS specified by the MANUFACTURER	68
Figure AA.3 – Examples of marking on the MEDICAL BED of storage location for wired and wireless PENDANT CONTROLS	69
Figure AA.4 – Resultant forces without mattress	72
Figure AA.5 – Resultant forces with mattress	72
Figure AA.6 – Example of 60 mm gap measurement of B	73
Figure AA.7 – Angle measurement example of B	73
Figure AA.8 – Placement of measurement TOOL for measurement of D	74
Figure AA.9 – Example of area D measurement that passes	74
Figure AA.10 – Example of area D measurement that fails (on limit)	75
Figure AA.11 – Example of area D measurement that fails	75
Figure AA.12 – Example of potential PATIENT entrapment in area A within the SIDE RAIL	75
Figure AA.13 – Example of potential PATIENT entrapment in area A below the SIDE RAIL	76
Figure AA.14 – Example of potential PATIENT entrapment in area B	76
Figure AA.15 – Example of potential PATIENT entrapment in area C between split SIDE RAIL	76
Figure AA.16 – Example of potential PATIENT entrapment in area C between SIDE RAIL and HEAD BOARD	76
Figure AA.17 – Example of potential PATIENT entrapment in area D	77
Figure AA.18 – Example of potential PATIENT entrapment in area A below a single piece SIDE RAIL	77

IEC 80601-2-52:2026 © IEC 2026

Figure AA.19 – Concept of potential PATIENT foot-first entrapment tool for area A below a SIDE RAIL	78
Figure BB.1 – Schematic presentation of under MEDICAL BED clearance.....	86
Figure BB.2 – Recommendations and requirements regarding angles for different sections of the MATTRESS SUPPORT PLATFORM	88
Figure CC.1 – Wedge tool.....	90
Figure CC.2 – V-shaped opening in relation to B.....	91
Figure CC.3 – Acceptance criteria in relation to area B	92
Figure CC.4 – Positioning of wedge TOOL.....	93
Figure CC.5 – Acceptance criteria in relation to area C between HEAD BOARD and FOOT BOARD	93
Figure CC.6 – Acceptance criteria in relation to area C between split SIDE RAILS	94
Table 201.101 – Protection against PATIENT entrapment	29
Table 201.102 – Minimum SAFE WORKING LOADS	43
Table 201.103 – Protection against inadvertent PATIENT falls	53
Table 24 – Allowable maximum temperatures for skin contact with MEDICAL BED APPLIED PARTS.....	53
Table 201.104 – Machine washable compliance PROCEDURE	55

Sample Document

get full document from standards.iteh.ai

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

FOREWORD

- 1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
- 2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 9) IEC and ISO draw attention to the possibility that the implementation of this document may involve the use of (a) patent(s). IEC and ISO take no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, IEC and ISO had not received notice of (a) patent(s), which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at <https://patents.iec.ch>. IEC and ISO shall not be held responsible for identifying any or all such patent rights.

IEC 80601-2-52 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 first edition cancels and replaces the first edition of IEC 60601-2-52 published in 2009 and its Amendment 1:2015. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

- a) scope updated to state standard applies to both electrical and non-electrical MEDICAL BEDS;
- b) updates to scope to explain the potential overlap with the IEC 80601-2-89;
- c) introduction of APPLICATION ENVIRONMENT 6 (psychiatric care or mental health care environment) and multiple requirements for APPLICATION ENVIRONMENT;

IEC 80601-2-52:2026 © IEC 2026

- d) alignment of requirements with IEC 60601-1:2005/AMD2:2020;
- e) new test to address snagging (201.9.3.101);
- f) moved required tests applicable to most application environments from Annex BB to 201.9.8.3.3, so the durability testing is in one subclause;
- g) new rating of jet stream washing and updated requirements in 201.11.6.5;
- h) updated the machine washing test (201.11.6.6.101) to define cycles by application environment and clarified evaluation after cycles;
- i) updated test tools to ensure tolerances and drawings.

It is published as double logo standard.

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

Draft	Report on voting
62D/2271/FDIS	62D/2291/RVD

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

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 document, 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 particular standard 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;

IEC 80601-2-52:2026 © IEC 2026

- "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.

Sample Document

get full document from standards.iteh.ai

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 published in 2005. 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 IEC 60601-1:2005. 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.

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 as defined in 201.3.214, intended for ADULTS as defined in 201.3.222. Included in the scope are both electrical and non-electrical (manual) MEDICAL BEDS with or without adjustable functions.

This document is applicable to either a BED-LIFT or a detachable MATTRESS SUPPORT PLATFORM or both. The combination of BED-LIFT or a detachable MATTRESS SUPPORT PLATFORM with a compatible non-MEDICAL BED as specified by the MANUFACTURER is also considered a MEDICAL BED.

This document does not apply to:

- MEDICAL BEDS for CHILDREN and ADULTS with atypical anatomies (ADULTS ranging outside the definition for ADULTS in 201.3.222) covered by IEC 80601-2-89[1]¹;
- SPECIALITY MATTRESS covered by ISO 20342 series[2];
- devices for which the INTENDED USE is mainly for examination or transportation under medical supervision (e.g. stretcher, examination table);
- all requirements for MEDICAL BEDS with special functionality.

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 document are not covered by specific requirements in this document except in 7.2.13 and 8.4.1 of IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020.

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

NOTE 2 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 for MEDICAL BEDS as defined in 201.3.214, intended for ADULTS as defined in 201.3.222.

¹ Numbers in square brackets refer to the Bibliography.