SLOVENSKI STANDARD
SIST EN IEC 80601-2-52:2026

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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**

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11.140	Oprema bolnišnic	Hospital equipment

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EUROPEAN STANDARD

NORME EUROPÉENNE

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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)

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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

Ref. No. 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 level by publication of an identical national standard or by endorsement (dop) 2027-07-31
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2029-07-31

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.

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.cencenelec.eu.

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

Publication	Year	Title	EN/HD	Year
Replacement:				
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
Addition:				
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	-

IEC 80601-2-52

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INTERNATIONAL STANDARD

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

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CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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.
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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;

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;

– "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

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.

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1 Numbers in square brackets refer to the Bibliography.