IEC 60601-2-52

Edition 1.0 2009-12

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

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

IEC 60601-2-52:2009

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

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

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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International standard IEC 60601-2-52 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 first edition cancels and replaces the first edition of IEC 60601-2-38, published in 1996, and its Amendment 1 (1999). This edition constitutes a technical revision.

The text of this particular standard is based on the following documents:

FDIS	Report on voting
62D/795/FDIS	62D/815/RVD

Full information on the voting for the approval of this particular standard can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by 20 P-members out of 20 having cast a vote.

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.

The committee has decided that the contents of this publication will remain unchanged until the maintenance result date indicated on the IEC web site 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.

The contents of the corrigendum of September 2010 have been included in this copy.

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 DISABLED PERSONS 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 DISABLED PERSONS. This is the effort of a joint working group of the IEC and the ISO.

MEDICAL ELECTRICAL EQUIPMENT –

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

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 intended for adults, hereafter referred to as MEDICAL BED as defined in 201.3.212.

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:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for MEDICAL BEDS as defined in 201.3.212.

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, IEC 60601-1-8 and IEC 60601-1-10[2)] do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

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

2) IEC 60601-1-10:2007, *Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Collateral Standard: Requirements for the development of physiologic closed-loop controllers*

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 81.

Clause 2 of the general standard applies except as follows:

Addition:

IEC 60068-2-31:2008, *Environmental testing – Part 2-31: Tests – Test Ec: Rough handling shocks, primarily for equipment-type specimens*

201.3 Terms and definitions

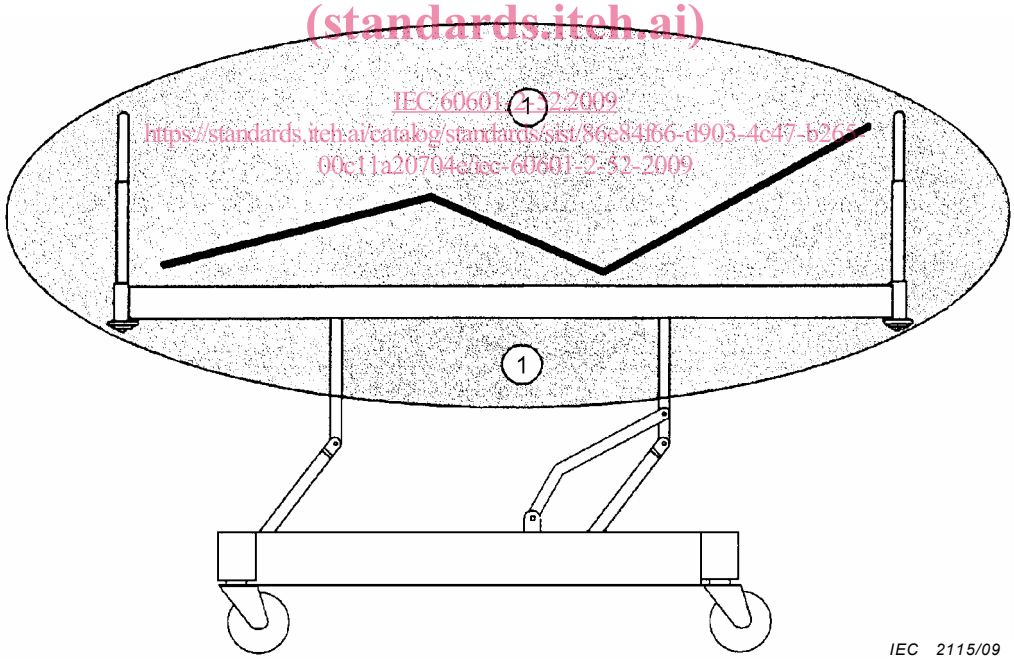
For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 apply, except as follows:

NOTE An index of defined terms is found beginning on page 82.

201.3.8
APPLIED PART

Addition:

The APPLIED PART includes all parts of the MEDICAL BED that are within reach of the PATIENT, even if they are underneath the MATTRESS SUPPORT SURFACE (see Figure 201.101)



Key

1 Region of APPLIED PART including ACCESSORIES

Figure 201.101 – APPLIED PART

201.3.76
PATIENT

Replacement:

person undergoing a medical procedure or DISABLED PERSON

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 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 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
BED-LIFT
height adjustable mechanism on which a MATTRESS SUPPORT PLATFORM can be mounted

NOTE The combination of a BED LIFT and a compatible non-MEDICAL BED as specified by the MANUFACTURER is considered to be a MEDICAL BED.

201.3.207
DISABLED PERSON
person with one or more impairments, one or more activity limitations, one or more participation restrictions or a combination thereof

[ISO 9999:2007]

201.3.208
HEAD/FOOT BOARD
assembly/assemblies mounted to MEDICAL BED, which identifies for the PATIENT the edge of the head or foot end of the MEDICAL BED and/or MATTRESS SUPPORT PLATFORM

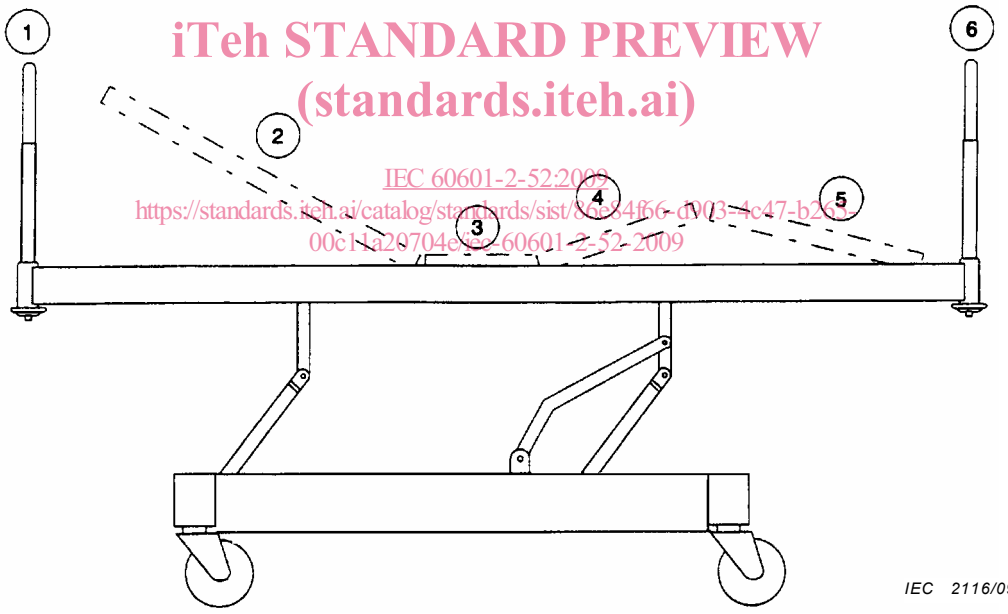
NOTE It may be used as handles to push a MEDICAL BED intended to transport PATIENTS.

201.3.209
LIFTING POLE
ACCESSORY attached to a MEDICAL BED and intended to assist support of a PATIENT when changing position by providing a gripping support above the PATIENT

201.3.210
MATTRESS OVERLAY
supplementary mattress (support surface), which is intended to be placed on an existing mattress, and generally used for prophylactic or therapeutic effect

201.3.211
MATTRESS SUPPORT PLATFORM
structure which supports a PATIENT surface (for example mattress)

NOTE It can articulate or change positions to facilitate various therapeutic, diagnostic and convenience positions (See Figures 201.102 and 201.119 a) to 201.119 d)).



Key

1 HEAD BOARD
2 Back section
3 Seat section
4 Upper leg section
5 Lower leg section
6 FOOT BOARD

Figure 201.102 – MEDICAL BED, general arrangement (example, schematic presentation only)

201.3.212
*** MEDICAL BED**
device for which the INTENDED USE is sleeping/resting that contains a MATTRESS SUPPORT PLATFORM and intended to assist in diagnosis, monitoring, prevention, treatment, alleviation of disease or compensation for an injury or handicap

NOTE 1 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.

NOTE 2 Excluded are devices for which the INTENDED USE is mainly for examination or transportation under medical supervision (e.g. stretcher, examination table).

201.3.213
MOTION LOCKOUT CONTROL
auxiliary subsystem that deactivates motion controls

201.3.214
PENDANT CONTROL
handheld device, which has a FUNCTIONAL CONNECTION to the MEDICAL BED, controlling at least MEDICAL BED articulations and/or movements

NOTE PENDANT CONTROLS may be wired, or wireless, and may integrate other functions, (e.g. communications, radio/tv, etc.).

201.3.215
SIDE RAIL
physical barrier, which may be a detachable ACCESSORY or integral to the overall construction of a MEDICAL BED and is mounted to the side(s) of the MEDICAL BED

NOTE When a SIDE RAIL is located in the "up" position it provides a physical barrier, which is intended to reduce the RISK of the PATIENT accidentally slipping or rolling off the mattress.

201.3.216
SPECIALTY MATTRESS
mattress intended for prophylactic or therapeutic effect

201.3.217
TEST BED BOARD
flat, rigid loading board of dimensions as specified by the MANUFACTURER representing the dimensions of the MEDICAL BED

201.3.218
UNDERCARRIAGE
all components of the MEDICAL BED or BED-LIFT below the MATTRESS SUPPORT PLATFORM

201.4 General requirements

Clause 4 of the general standard applies.

201.5 General requirements for testing of ME EQUIPMENT

Clause 5 of the general standard applies, except as follows:

Additional subclauses:

201.5.101 * Entrapment test tools

Figures 201.103a and 201.103b illustrate entrapment test tools (a cone tool and a cylinder tool respectively).