

# Medical electrical equipment —

## Part 2-38: Particular requirements for the safety of electrically operated hospital beds

The European Standard EN 60601-2-38:1996 with the incorporation of amendment A1:2000 has the status of a British Standard

ICS 11.140

# Committees responsible for this British Standard

The preparation of this British Standard was entrusted to Technical Committee CH/31, Hospital furniture, upon which the following bodies were represented:

- Association of British Paediatric Nurses
- British Lift Association
- British Surgical Trades' Association
- Buying Agency
- Chartered Society of Physiotherapy
- Consumer Policy Committee of BSI
- Department of Health
- Furniture Industry Research Association
- Health Service Supply Council
- Royal College of Nursing

This British Standard, having been prepared under the direction of the Health and Environment Sector Board, was published under the authority of the Standards Board and comes into effect on 15 May 1997

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The following BSI references relate to the work on this standard:  
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## National foreword

This Section of BS 60601 has been prepared by Technical Committee CH/31 and is the English language version of EN 60601-2-38:1996 *Medical electrical equipment Part 2-38: Particular requirements for the safety of electrically operated hospital beds*, including amendment A1:2000 published by the European Committee for Electrotechnical Standardization (CENELEC). It is identical with IEC 60601-2-38:1996 including amendment 1:1999, published by the International Electrotechnical Committee (IEC).

This Particular Standard amends and supplements BS EN 60601-1<sup>1)</sup> hereinafter called the General Standard. As stated in 1.3 of the General Standard, the requirements of the Particular Standard take precedence over those of the General Standard.

A rationale for the most important requirements is given in Annex AA. It is considered that a knowledge of the reasons for the requirements will not only facilitate the proper application of the standard but will expedite any subsequent revision. Annex AA does not form part of the requirements of the standard.

From 1 January 1997, all IEC publications have the number 60000 added to the old number. For instance, IEC 27-1 has been renumbered as IEC 60027-1. For a period of time during the change over from one numbering system to the other, publications may contain identifiers from both systems.

### Cross-references

The British Standards which implement international or European publications referred to in this document may be found in the BSI Standards Catalogue under the section entitled “International Standards Correspondence Index”, or by using the “Find” facility of the BSI Standards Electronic Catalogue.

NOTE There is no British Standard identical with ISO 2204:1979 which is obsolescent and is being withdrawn.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

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### Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, the EN title page, pages 2 to 37 and a back cover.

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Sidelining in this document indicates the most recent changes by amendment.

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<sup>1)</sup> Also numbered BS 5724-1

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Descriptors: Medical electrical equipment, hospital beds, safety requirements, protection against electric shock, protection against mechanical hazard, radiation protection, fire protection, environmental conditions

English version

Medical electrical equipment  
Part 2-38: Particular requirements for the safety of  
electrically operated hospital beds

(includes amendment A1:2000)  
(IEC 60601-2-38:1996 + A1:1999)

Appareils électromédicaux  
Partie 2-38: Règles particulières de sécurité des  
lits d'hôpital électriques  
(inclut l'amendement + A1:2000)  
(CEI 60601-2-38:1996 + A1:1999)

Medizinische elektrische Geräte  
Teil 2-38: Besondere Festlegungen für die  
Sicherheit von elektrisch betriebenen  
Krankenhausbetten  
(enthält Änderung + A1:2000)  
(IEC 60601-2-38:1996 + A1:1999)

This European Standard was approved by CENELEC on 1996-10-01. Amendment A1 was approved by CENELEC on 2000-01-01. 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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

## CENELEC

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

**Central Secretariat: rue de Stassart 35, B-1050 Brussels**

## Foreword

The text of document 62D/192/FDIS, future edition 1 of IEC 601-2-38, prepared by SC 62D, Electromedical equipment, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 60601-2-38 on 1996-10-01.

The following dates were fixed:

- latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 1997-07-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 1998-06-13

Annexes designated “normative” are part of the body of the standard.

Annexes designated “informative” are given for information only.

In this standard, Annex ZA is normative and Annex AA and Annex BB are informative.

Annex ZA has been added by CENELEC.

## Endorsement notice

The text of the International Standard IEC 601-2-38:1996 was approved by CENELEC as a European Standard without any modification.

## Foreword to amendment A1

The text of document 62D/336/FDIS, future amendment 1 to IEC 60601-2-38, prepared by SC 62D, Electromedical equipment, of IEC TC 62, Electrical equipment in medical practice, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as amendment A1 to EN 60601-2-38:1996 on 2000-01-01.

The following dates were fixed:

- latest date by which the amendment has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2000-10-01
- latest date by which the national standards conflicting with the amendment have to be withdrawn (dow) 2003-01-01

Annexes designated “normative” are part of the body of the standard.

Annexes designated “informative” are given for information only.

In this standard, Annex ZA is normative and Annex AA and Annex BB are informative.

Annex ZA has been added by CENELEC.

## Endorsement notice

The text of amendment 1:1999 to the International Standard IEC 60601-2-38:1996 was approved by CENELEC as an amendment to the European Standard without any modification.

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## Section 1. General

The clauses and subclauses of this section of the General Standard apply except as follows:

### 1 Scope and object

This clause of the General Standard applies, except as follows:

#### 1.1 Scope

*Addition:*

This Particular Standard specifies requirements for safety of ELECTRICALLY OPERATED HOSPITAL BEDS, hereinafter referred to as BED, as defined in **2.2.101**.

#### 1.2 Object

*Replacement:*

The object of this Particular Standard for BEDS is to keep the SAFETY HAZARDS to PATIENTS, OPERATORS, and the environment as low as possible, and to describe tests to verify that these requirements are attained.

#### 1.3 Particular Standards

*Addition:*

This Particular Standard amends and supplements a set of IEC publications, hereinafter referred to as “General Standard”, consisting of IEC 601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety*, amendment 1, amendment 2 and IEC 601-1-1:1992, *Medical electrical equipment — Part 1: General requirements for safety — 1. Collateral Standard: Safety requirements for medical electrical systems*.

For brevity, IEC 601-1 is referred to in this Particular Standard either as the “General Standard” or as the “General Requirement(s)”, and IEC 601-1-1 as the “Collateral Standard”.

The term “this Standard” covers the Particular Standard, used together with the General Standard and any Collateral Standards.

The numbering of sections, clauses and subclauses of this Particular Standard corresponds with that of the General Standard. 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 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.

“Amendment” means that the clause or subclause of the General Standard is amended as indicated by the text of this Particular Standard.

Subclauses or Figures which are additional to those of the General Standard are numbered starting from 101, additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Clauses and subclauses to which there is a rationale are marked with an asterisk \*. These rationales can be found in an informative Annex AA. Annex AA should be used in determining the relevance of the requirements addressed, but should never be used to establish additional test requirements.

Where there is no corresponding section, clause or subclause in this Particular Standard, the section, clause or subclause of the General Standard or the Collateral Standard applies without modification.

Where it is intended that any part of the General Standard or the Collateral Standard, although possibly relevant, is not to be applied, a statement to that effect is given in this Particular Standard.

A requirement of this Particular Standard replacing or modifying requirements of the General Standard or the Collateral Standard takes precedence over the corresponding General Requirement(s).

## 2 Terminology and definitions

This clause of the General Standard applies except as follows:

### 2.1.5

#### APPLIED PART

*Replacement:*

all parts of the BED which can intentionally or unintentionally come into contact with the PATIENT, are considered an APPLIED PART (See Figure 111)

*Additional definitions:*

#### 2.1.101

##### PENDANT CONTROL

means, used by either PATIENT or OPERATOR to control the drives that activate various BED functions

#### 2.1.102

##### SIDE RAIL

rail mounted to both sides of the BED which, when located in the “up” position, identifies the edge of the MATTRESS SUPPORT PLATFORM and by doing so, reduces the risk of the PATIENT accidentally slipping or rolling off the mattress

#### 2.1.103

##### CONTROL SIDE RAIL

SIDE RAIL which incorporates BED function controls for PATIENT activation

**2.1.104****INTEGRATED PATIENT  
MONITORING/COMMUNICATIONS SYSTEMS  
CONTROL SIDE RAIL**

see **2.1.103**. CONTROL SIDE RAIL with the addition of PATIENT/OPERATOR station communication control, and/or PATIENT television/radio entertainment control, and/or PATIENT room lighting control, and/or PATIENT egress detection system, etc.

**2.1.105****HEAD/FOOT PANEL ASSEMBLY**

assemblies mounted to BED end which may be used as handles to push the BED

**2.1.106****MOMENTARY CONTACT SWITCH**

control device which initiates and maintains operation of operating elements only as long as the control (actuator) is actuated. The manual control (actuator) returns automatically to the stop position when released. MOMENTARY CONTACT SWITCHES are also known as “hold-to-run control devices”

**2.1.107****MATTRESS SUPPORT PLATFORM**

structural surface on which the PATIENT sleeping surface (for example mattress) rests in NORMAL USE. The MATTRESS SUPPORT PLATFORM articulates or changes positions to facilitate various therapeutic, diagnostic and convenience positions (See Figure 101 and Figure 112)

**2.1.108****\* TRENDELENBURG**

with the MATTRESS SUPPORT PLATFORM in the flat position, tilting of the entire MATTRESS SUPPORT PLATFORM a minimum of 12° so that the PATIENT's head is lower than the circulatory centre point of the body

**2.1.109****SQUEEZING and SHEARING POINTS (FOR FINGERS)**

points where the spacing between moveable parts of the BED which in positions of NORMAL USE fail to maintain a clearance of less than or equal to 8 mm, or greater than or equal to 25 mm

**2.1.110****\*PATIENT ENTRAPMENT**

the ability for a PATIENT to insert his/her head, neck or chest cavity into a permanent opening in the BED and/or its ACCESSORIES or into a temporary opening created during NORMAL USE, from which the PATIENT cannot remove that portion of his/her anatomy

**2.2.101****\*ELECTRICALLY OPERATED HOSPITAL BED  
(hereinafter referred to as BED)**

BED and its accessories intended for use in the diagnosis, treatment or monitoring of an adult PATIENT whilst under medical supervision

NOTE For an explanation of the basis for the definition of “adult”, see Rationale in Annex AA.

**2.2.102****\*LIFTING POLE**

device suspended above the BED and intended to allow the PATIENT to change position by gripping it

**3 General requirements**

This clause of the General Standard applies except as follows:

*Addition:*

**3.101** \* If, in order to accomplish other specialized functions which provide benefit to the PATIENT, it is not technically feasible to meet specific requirements in this Particular Standard, the BED shall be accepted only if clear and specific instructions (in the INSTRUCTIONS FOR USE) restrict the NORMAL USE of the BED so that no SAFETY HAZARD exists.

BEDS with active therapeutic/prophylaxis MATTRESS SUPPORT PLATFORM, such as air fluidized, air mattress, or water surfaces and/or INTEGRATED PATIENT MONITORING/COMMUNICATION CONTROL SIDE RAIL are excluded from the requirements of **5.3**, **54.101** of this Particular Standard.

*Compliance with this requirement is checked by the following test:*

*If alternative means of construction have been employed or if a requirement of this Particular Standard has not been met, in order to provide benefit to the PATIENT, a risk assessment shall be performed (in accordance with ISO 14971-1) to demonstrate that the overall level of safety has not been compromised.*

**5 Classification**

This clause of the General Standard applies except as follows:

**5.2** \* *Replacement:*

BEDS shall be EQUIPMENT with TYPE B or BF APPLIED PART.

**5.3** \* *Replacement:*

BEDS shall be at least IPX4 in accordance with IEC 529.

## 6 Identification, marking and documents

This clause of the General Standard applies except as follows:

### 6.1 Marking on the outside of EQUIPMENT or EQUIPMENT PARTS

#### l) Classification

*Addition:*

— BEDS intended for use with “jet stream” washing machines, high pressure/steam cleaning, etc. shall be so marked.

#### u) \*Mechanical stability

*Replacement:*

The BED and its ACCESSORIES (intended to support and/or immobilize masses) shall be marked with their own SAFE WORKING LOAD. (See Figure 108.)

#### w) Warnings

*Replacement:*

When text is used for warning notices, they shall be in the official language of the country where the BED is placed on the market.

### 6.4 Symbols

*Addition:*

aa) Controls and/or indicators, when possible, should be marked using symbols which will convey the intended function of those controls or indicators without the need for additional text.

NOTE Figure 107 and Figure 108 are intended as guidelines when designing these symbols. In all cases where standard international symbols exist, they should be used.

#### 6.8.2 Instructions for use

##### a) General information

*Addition:*

— Complete instructions for use shall be provided which ensure the safe operation of the BED.

— The instructions for use shall indicate the SAFE WORKING LOAD of the BED and its ACCESSORIES intended to support masses and which can be removed during NORMAL USE.

— Mass of the BED.

— Recommended frequency of periodic inspection and maintenance of the BED. It is recommended that frequency of inspection be at least annually.

— If the BED or parts of the BED which can come into contact with the PATIENT are intended for use in jet stream and/or high pressure steam cleaning equipment the permissible range of temperature, spray pressure and allowable chemical application shall be given.

— For BEDS designed for “jet stream” washing machines, high pressure/steam cleaning, which require inspection after the cleaning procedure, the ACCOMPANYING DOCUMENTS shall contain instructions how to insure that NORMAL CONDITIONS are still valid.

— Instructions for use shall identify the maximum angles which can be achieved in NORMAL USE by each part of the MATTRESS SUPPORT PLATFORM with reference to horizontal. They shall also identify the maximum and minimum heights from the floor which can be achieved by the MATTRESS SUPPORT PLATFORM in NORMAL USE.

— The instructions for use for the BED shall include a list of all ACCESSORIES which may be attached to or used with the BED.

— The instructions for use shall indicate any restriction with regard to the characteristics of the PATIENT (such as clinical condition, weight or size, etc.) necessary to insure safe operation of the bed.

— The instructions for use shall provide a warning that the BED should be left in its lowest position when unattended in order to reduce the risk of injury due to falls whilst getting into or out of the BED, or whilst lying on the BED.

— When the requirements of dimensions D and/or E of Figure 114 of this Particular Standard are met only when the MATTRESS SUPPORT PLATFORM is in the flat position, the instructions for use shall include a warning that, when a PATIENT'S condition (such as disorientation due to medication or clinical condition) could lead to PATIENT ENTRAPMENT, the MATTRESS SUPPORT PLATFORM should be left in the flat position whilst unattended (except when required otherwise by medical staff for special or particular circumstances).

— The instructions for use for ACCESSORIES shall list the BED type or model with which the ACCESSORIES may be used (except when required otherwise by medical staff for special or particular circumstances).

b) *Responsibility of the manufacturer**Addition:*

Instructions for use shall include a statement on SAFETY HAZARDS which may arise due to improper handling of POWER SUPPLY CORDS, e.g.: driving over cables or cords, crushing between HEAD/FOOT PANEL ASSEMBLY and movable parts.

*Additional item:*

aa) \*If a means to deactivate movement of the APPLIED PARTS (excluding non-energized ACCESSORIES) or MATTRESS SUPPORT PLATFORM is employed to prevent SAFETY HAZARDS created by SINGLE FAULT CONDITIONS, the instructions for use shall include clear directions on how to deactivate any BED function which might cause injury to the PATIENT if movement occurs.

**Section 2. Environmental conditions**

The clauses and subclauses of this section of the General Standard apply.

**Section 3. Protection against electrical shock hazards**

The clauses and subclauses of this section of the General Standard apply except as follows:

**17 Separation** (Previous title: Insulation and protective impedances)c) *\*Replacement:*

A type BF APPLIED PART shall have no CONDUCTIVE CONNECTION to ACCESSIBLE METAL PARTS.

**18 Protective earthing, functional earthing and potential equalization**e) *\*Addition:*

— The ACCESSIBLE METAL PARTS of APPLIED PARTS with conductive connections to parts which might become LIVE and which are intended for use together with MEDICAL ELECTRICAL EQUIPMENT connected intravascularly or intracardially to the PATIENT shall be provided with a means for potential equalization connection.

— ACCESSIBLE METAL PARTS of APPLIED PARTS shall have an impedance of less than  $0,2 \Omega$  with respect to the potential equalization connection.

*Compliance is checked by measurement.*

**Section 4. Protection against mechanical hazards**

The clauses and subclauses of this section of the General Standard apply except as follows:

**21 Mechanical strength****21.3 \*Replacement:**

BED parts used for the support and/or immobilization of the PATIENT or for the support of masses which could be hazardous to the PATIENT shall be designed and manufactured so as to minimize the risk of physical injuries and of accidental loosening of fixings. Fixings for ACCESSORIES shall be so designed that the risk of incorrect attachment which could create a SAFETY HAZARD is minimized.

This clause of the General Standard applies except as follows:

*Addition:*

**21.3.101** The SAFE WORKING LOAD of the BED shall be listed in the instructions for use and shall be at least 1 700 N. This 1 700 N load is considered to be the sum of the following:

- 1 350 N (PATIENT);
- 200 N (mattress);
- 150 N (ACCESSORIES).

(For testing purposes the load shall be distributed as shown in Figure 102.)

**21.3.102** \*The SAFE WORKING LOAD of a LIFTING POLE shall be at least 750 N.

**21.4 \*Replacement**

SIDE RAILS shall be equipped with a means to lock or latch them into the raised/closed position. The operation of the lock or latch mechanism shall be so designed that accidental unlocking or unlatching cannot occur in NORMAL USE and that SIDE RAILS will not remain raised/closed when they are not locked/latched.

**21.6 Replacement:**

BEDS which are intended to be mobile while accommodating a PATIENT shall be subjected to the following:

**Impact test** — The BED, with HEAD/FOOT PANEL ASSEMBLIES mounted and SAFE WORKING LOAD in place, shall withstand, without permanent deformation or loss of NORMAL USE, three impacts to each end of the BED against a solid hardwood (e.g. oak) vertical wall with the BED moving at a speed of  $(0,4 \pm 0,1)$  m/s without loss of NORMAL USE.

**21.6.101** \* The HEAD/FOOT PANEL ASSEMBLIES shall withstand a static force of 450 N applied along the longitudinal axis of the BED and at the location(s) defined in the ACCOMPANYING DOCUMENTS as transport handholds/push points or, if these points are not defined, the force shall be applied horizontally and centrally at the highest extremity of the HEAD/FOOT PANEL. The load shall be applied over an area of 625 mm<sup>2</sup>. The test shall be applied for 30 s ten times, forwards and backwards, without material failure.

**21.6.102 \*Threshold test**

BEDS shall withstand the stresses caused by rough handling.

*Compliance with this requirement is checked by the following test:*

*The BED, with the SIDE RAILS in the closed/raised and locked/latched position, with all other ACCESSORIES intended for NORMAL USE during transport attached and with the SAFE WORKING LOAD in place, shall be moved ten times in the forward direction as in NORMAL USE. All castors shall impact a solid vertical plane obstruction which is fixed flat on the floor, with a rectangular cross-section, 20 mm high and 80 mm deep, at a speed of 0,4 m/s  $\pm$  0,1 m/s, without loss of function, and without unlocking/unlatching of the SIDE RAILS.*

## 22 Moving parts

This clause of the General Standard applies except as follows:

*Addition:*

**22.2.101** Exposed SQUEEZING and SHEARING POINTS which could constitute a SAFETY HAZARD are permissible for moveable parts below the MATTRESS SUPPORT PLATFORM if their distance from the outermost rigid edge of the MATTRESS SUPPORT PLATFORM (towards the inside) is 200 mm or greater. The 200 mm distance shall be measured around any barrier which separates the PATIENT from a SAFETY HAZARD. (See Figures 109 and 110).

Parts moved vertically which could create a SAFETY HAZARD shall maintain perpendicular clearances to the floor of at least 120 mm unless their distance from the outermost rigid edge of the MATTRESS SUPPORT PLATFORM (towards the inside) is 120 mm or greater.

**22.2.102** All BEDS shall incorporate means to deactivate BED function control (BED movement) available to the PATIENT.

The means to deactivate BED movement shall be located such that a PATIENT can not accidentally re-activate any functions.

**22.4.101** Electrically powered functional movements of the BED shall be possible only by means of MOMENTARY CONTACT SWITCHES.

*Replacement:*

**22.5** End stops or other means to limit movement shall be provided and their strength shall be adequate for the intended function. Compliance is checked by review of the manufacturer's design and test data.

## 23 Surfaces, corners and edges

*This clause of the General Standard applies except as follows:*

*Addition:*

### 23.101 \*Protection against PATIENT ENTRAPMENT

Openings within the perimeter of SIDE RAILS, and between SIDE RAILS and parts of the BED, shall meet the dimensional requirements of Figure 114 where a risk of PATIENT ENTRAPMENT exists.

*Compliance is checked by the following test:*

*After completion of the tests required in 28.4.103, the dimensional requirements of items A and F of Figure 114 are checked by inserting the test cone in Figure 115, with a force of 50 N, at the points indicated in Figure 114, without allowing the cone to pass through the opening. The tests are performed with the SIDE RAILS in the raised/closed position, and with the worst case NORMAL USE configuration and positions of ACCESSORIES.*

*A risk assessment shall also be performed (in accordance with ISO 14971-1) to evaluate the SIDE RAILS with regard to entrapment and all other safety issues. When SIDE RAILS cover less than the full length of the MATTRESS SUPPORT PLATFORM, they shall be positioned toward the head end.*

## 24 Stability in NORMAL USE

This clause of the General Standard applies except as follows:

**24.3 Addition:**

aa) \*With the BED, castors and side rails (if either are incorporated in the BED design) in their worst case position of NORMAL USE and the SAFE WORKING LOAD in place (as shown in Figure 102), the BED shall not overbalance when:

— *Lateral stability test:*

*A load of 2 250 N is located on the edge of the flat MATTRESS SUPPORT PLATFORM, centred at a distance 125 mm from the outer edge. (See Figure 103/Figure 105.)*