INTERNATIONAL STANDARD

IEC 60601-2-38

1996

AMENDMENT 1
1999-12

Amendment 1

Medical electrical equipment –

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

Amendement 1

Appareils électromédicaux –

Partie 2-38:
Règles particulières de sécurité
des lits d'hôpital électriques

International Electrotechnical Commission 3, rue de Varembé Geneva, Switzerland
Telefax: +41 22 919 0300 e-mail: inmail@iec.ch IEC web site http://www.iec.ch

Commission Electrotechnique Internationale
International Electrotechnical Commission
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FOREWORD

This amendment has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice.

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

FDIS	Report on voting
62D/336/FDIS	62D/346/RVD

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

_____

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CONTENTS

Add the title of clause 23, as follows:

23 Surface, corners and edges

Add, on page 5, the titles of the new figures:

Figure 113 – Application of forces for test of SIDE RAILS

Figure 114 – Examples (only) of BEDS with segmented SIDE RAILS and single-piece SIDE RAILS

Figure 115 – Test cone

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2.1.109 SQUEEZING and SHEARING POINTS

Modify the title of the defined term to read:

SQUEEZING and SHEARING POINTS (FOR FINGERS)

Add, after 2.1.109, the following new definition:

***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)**

Replace the text of the definition by the following text and note:

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.

Add, after 2.2.101, the following new definition:

***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

3.101

Add, on page 15, the following new text at the end of this subclause:

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.

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6.1 Marking on the outside of EQUIPMENT or EQUIPMENT PARTS

**u) Mechanical stability*

Replace the text of this item by the following:

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

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6.8.2 Instructions for use

a) General information

Replace the second dashed item by the following:

– 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.

Add the following new dashed items:

– 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).

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18 Protective earthing, functional earthing and potential equalization

**e) Addition:*

Replace the first dashed item by the following:

– 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.

21 Mechanical strength

21. 3 *Replace the text of this subclause of the General Standard by the following:*

***21.3** BED parts used for the support and/or immobilisation of the PATIENT or for the support of masses which could be hazardous to the PATIENT shall be designed and manufactured so as to minimise 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 minimised.

Add, after 21.3.101, the following new subclause:

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

Add the following new subclause:

21.4 *Replace the text of this subclause of the General Standard by the following:*

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.

*21.6.102 Threshold test

Replace, on page 21, the text of the third paragraph of this subclause by the following:

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 ± 0,1 m/s, without loss of function, and without unlocking/unlatching of the SIDE RAILS.

Page 21

22 Moving parts

22.2.101 *Replace the text of this subclause by the following:*

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.

Add, after clause 22, the following text:

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 shown 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

24.3 *Addition:*

Add the following new item:

**bb)* The BED shall not become unstable when the LIFTING POLE is loaded as in NORMAL USE.

Compliance is checked by the following test:

Without the SAFE WORKING LOAD of the BED in place, the LIFTING POLE in its worst case position of NORMAL USE shall be loaded with its SAFE WORKING LOAD. The BED and LIFTING POLE shall not overbalance.

Page 23

28 Suspended masses

Add the following three new subclauses:

***28.4.101** ACCESSORIES, and their attachment points and fixings shall be designed with the following SAFETY FACTORS:

– two times the SAFE WORKING LOAD for all ACCESSORIES.

Compliance is checked by the following test:

With the ACCESSORY in its worst case NORMAL USE position, attach a static load equal to two times its SAFE WORKING LOAD for 1 h. There shall be no SAFETY HAZARD or loss of function. For LIFTING POLES, a sudden movement of the POLE or its handle shall be considered a SAFETY HAZARD.

28.4.102 SIDE RAIL latches/locks shall remain secure when subjected to the forces of NORMAL USE.

Compliance is checked by the following test:

A force (as specified in figure 113) shall be applied to the worst case position for locking/ latching of the SIDE RAIL in the direction of unlatching/unlocking, without the SIDE RAIL becoming unlatched/unlocked or creating any other SAFETY HAZARD.

28.4.103 SIDE RAILS shall be designed to withstand the forces applied during NORMAL USE without creating a SAFETY HAZARD.

Compliance is checked by the following test:

Static forces are applied for a duration of 30 s, 10 times in each indicated direction and at the worst case point, to each SIDE RAIL while it is in its raised/closed position, as shown in figure 113. The dimensional requirements of 23.101 shall be tested after the load is removed, and the SIDE RAILS shall not unlatch/unlock during the test.

36 Electromagnetic compatibility

Replace the text of this clause by the following:

The Collateral Standard IEC 60601-1-2 applies except as follows:

36.202 Immunity

Replace the text of the fourth paragraph by the following:

Failure conditions for all immunity tests for BEDS shall be the failure to comply with any requirement established in this Collateral Standard, or the creation of any hazard.

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52 Abnormal operation and fault conditions

Add, after 52.5.102, the following new subclause:

***52.5.103** Failure of PROGRAMMABLE SYSTEMS or subsystems which control the motion of the BED and which could cause an unintended movement of the BED or result in the creation of any hazard identified in this standard.

Compliance is checked by the following test:

The requirements of IEC 60601-1-4 shall be applied to the relevant (as described above) PROGRAMMABLE SYSTEMS.

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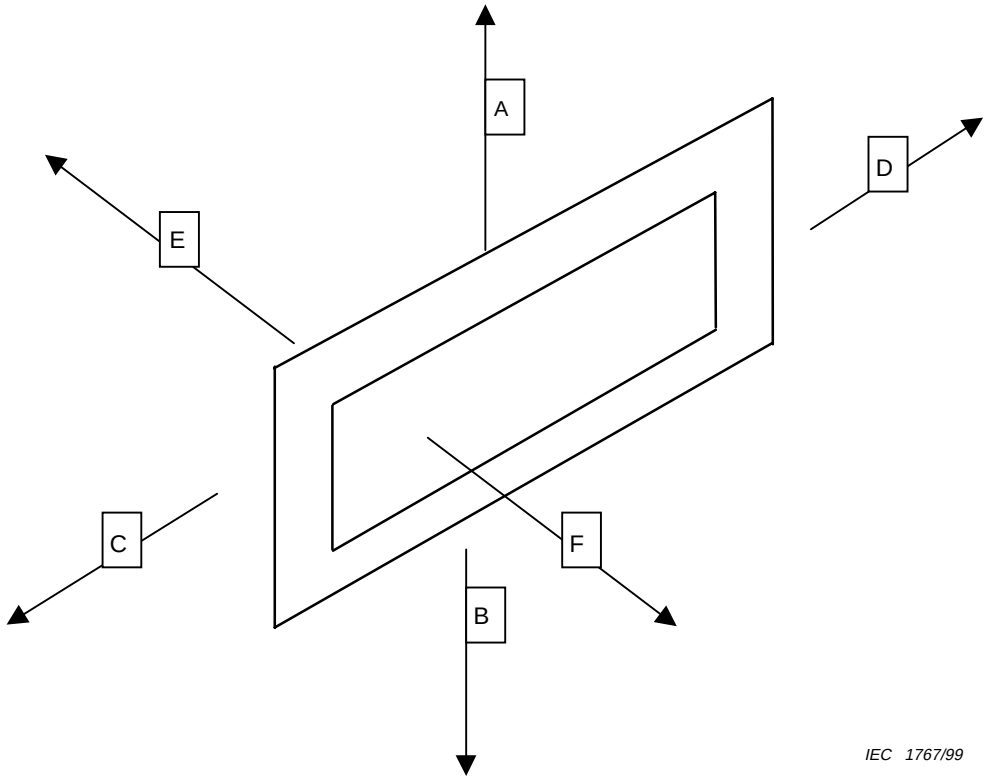
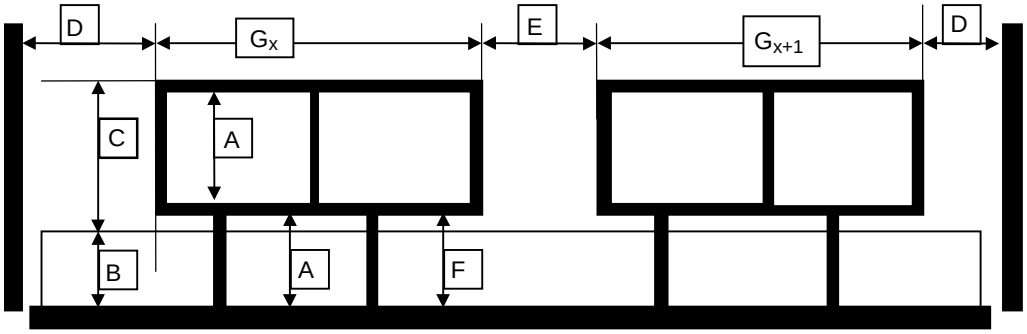
Add the following new figures:



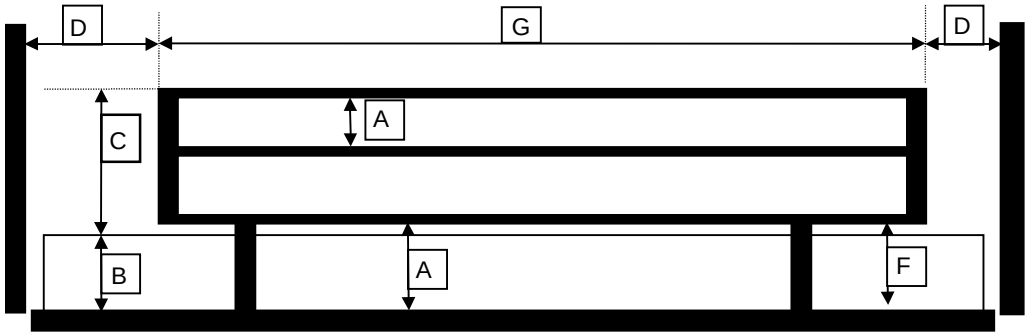
A: 500 N
B: 750 N
C: 500 N
D: 500 N
E: 500 N
F: 500 N

Figure 113 – Application of forces for test of SIDE RAILS



IEC 1768/99

Example (only) of a BED with segmented SIDE RAILS

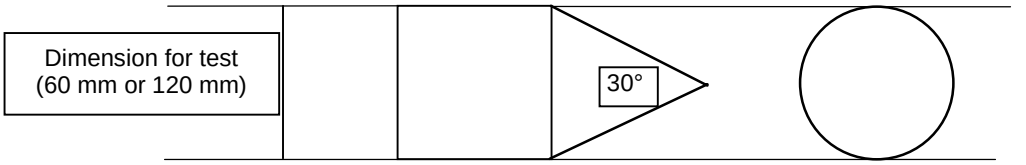


IEC 1769/99

Example (only) of a BED with single-piece SIDE RAILS

DESIGNATOR	DESCRIPTION	DIMENSION	
*A	Smallest dimension between elements inside the perimeter of the SIDE RAIL in its raised/locked positions *or* perimeters created between the SIDE RAIL and fixed parts of the BED	≤120 mm	
B	Thickness of NORMAL USE mattress	Specified by the manufacturer	
*C	Height of the top edge of the SIDE RAIL above the mattress (see B) without compression	≥220 mm	
*D	Distance between HEAD PANEL or FOOT PANEL and SIDE RAIL	≤60 mm or ≥235 mm	
*E	Distance between segmented SIDE RAIL with the MATTRESS SUPPORT PLATFORM in the flat position	≤60 mm or ≥235 mm	
*F	Smallest dimension of any accessible opening between the SIDE RAIL and the MATTRESS SUPPORT PLATFORM	If D or E ≥ 235 mm then F ≤ 60 mm	If D or E ≤ 60 mm then F ≤ 120 mm
*G	Total length of the SIDE RAIL or sum of the length of segmented SIDE RAILS on one side of the BED	$\sum G_X \geq$ half the length of the MATTRESS SUPPORT PLATFORM	

Figure 114 – Examples (only) of BEDS with segmented SIDE RAILS and single-piece SIDE RAILS



IEC 1770/99

Figure 115 – Test cone

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Appendix L – References – Publications mentioned in this standard

Add, to the existing list of IEC Standards, the title of the following standard:

IEC 60601-1-4:1996, *Medical electrical equipment – Part 1: General requirements for safety – 4. Collateral Standard: Programmable electrical medical systems*

Add, to the existing list of ISO Publications, the title of the following publication:

ISO 14971-1:1998, *Medical devices – Risk management – Application of risk management to medical devices*

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Annex AA – Guidance and rationale for particular subclauses

Add the following new subclauses:

2.1.110 Incidents have been reported in several countries where PATIENTS have been injured by having their heads, necks or chests caught in BED SIDE RAILS, causing contusions or, in the most severe conditions, partial or complete restriction of respiration. The definition of PATIENT ENTRAPMENT has been added to this Particular Standard with a view to addressing this hazard.

2.2.101 In recent years, due to changes intended to reduce the cost of health care, the meaning of the phrase "under medical supervision" has been extended to include areas other than hospitals or clinics. These changes have been caused by the current reimbursement policies of private health care insurers as well as governmental agencies such as departments of health.

Persons under medical supervision in today's medical environment can include PATIENTS who are being cared for and clinically monitored in facilities such as nursing homes, rest homes, long term care facilities (the names of which may vary according to their geographic locations) or even in their own homes. It must be remembered that even PATIENTS within the conventional hospital or clinic environment are not under *continuous, direct* medical supervision. The key in determining if care is *medically supervised* is whether or not this care is given under the direction of medical personnel.

For this reason, the possible locations where a BED *may* be used should not be used in determining the applicability of this Particular Standard. NORMAL USE (as defined in the instructions for use) is the *only* factor which should be considered. If a BED is intended (by the manufacturer) to be used as a tool for *diagnosis* (determining the cause of an illness), *treatment* (action(s) taken to change the course of an illness) or *monitoring* (reading and/or recording physiological parameters), it falls within the definition of an ELECTRICALLY OPERATED HOSPITAL BED given in this standard.

These changes in the locations where healthcare is provided may require that modifications be made to the technical requirements of this Particular Standard, in order to ensure that an equivalent level of safety is provided when the equipment is transported, stored, installed, operated in NORMAL USE, and maintained according to the instructions of the manufacturer, as required in clause 3 of the General Standard. Any BED which is intended in NORMAL USE to be used outside the conventional hospital environment should be evaluated to determine any risks which might be created.

Examples of these modifications include the following:

- BEDS intended to be used in locations where a reliable connection to PROTECTIVE EARTH may not be available should have CLASS II protection against electrical shock.
- Where BEDS are intended for use in private homes, manufacturers should take into account the need to transport and assemble them easily in confined spaces.

- Due to the limited maintenance and service that are available in private homes, increased durability and reliability should be a primary consideration when designing BEDS for use in such locations. Provision should be made to guarantee the level of maintenance throughout the life of the BED. The design of BEDS which are likely to be "knocked down" or disassembled for transport should incorporate additional provision to ensure that disassembly and reassembly do not create potential hazards because of 'weak' linkages or parts.
- BEDS intended for use in private homes will typically be subject to more severe conditions with regard to stability and strength. This is due to the fact that the BED is likely to be treated as a piece of household furniture and therefore exposed to higher loads (both distributed and eccentric).
- When designing BEDS intended for use in private homes, significant consideration should be given to the fact that the USER is unlikely to be a trained professional (operation by trained professionals is a consideration when designing products for use inside hospitals). This means that increased attention should be given to modes of operation, ergonomics and performance characteristics. In addition, the lower level of surveillance (and any related issues of safety) of PATIENTS in a home environment should be considered.
- The electromagnetic (EMC) environment in private homes is typically less controlled than in hospitals and similar institutions. Acceptable levels for immunity and emissions in the home environment should be implemented if the BED is intended to be used there.
- Issues identified in standards which address related EQUIPMENT such as prEN 1970 (Technical aids for disabled persons. Adjustable beds) should also be consulted for additional safety concerns which are applicable to BEDS used outside the hospital environment.

Any limitations to NORMAL USE necessary for the safe use of the BED must be noted in the instructions for use and other appropriate ACCOMPANYING DOCUMENTS, as required in clause 6 of the General Standard and of this Particular Standard.

With regard to the term "adult", the working group recognises that the definitions of the terms "adult" and "child" are based on physical characteristics which vary from one country to another. If the highest level of safety is to be achieved for PATIENTS and USERS, caregivers must be relied upon to use their professional judgement to differentiate the needs of children from those of adults in relation to the EQUIPMENT, taking into consideration not only the physical, psychological and medical needs of the individual, but also the PATIENT's preference. The dimensional requirements of this Particular Standard are based on anthropometric data based on PATIENTS ranging in physical size from a 146 cm tall female to a 185 cm tall male. For BEDS intended for use with PATIENTS outside that range, all dimensional characteristics in this Particular Standard should be adjusted accordingly.

2.2.102 LIFTING POLES are not designed to support the entire weight of a PATIENT's body, but only that portion which the PATIENT himself/herself can lift using his/her arms.

6.1 *u)* It is important that USERS clearly understand the SAFE WORKING LOAD of the BED, and of each of its ACCESSORIES which is intended to support potentially hazardous masses, so that the BED and its accessories are not used in ways which could create SAFETY HAZARDS.

21.3 Many of the BED ACCESSORIES are intended to be used for the support/suspension of masses and, therefore, their mechanical failure or the failure of their fixings (attachments) could allow those masses to fall on the PATIENT or create some other hazard. The incorrect attachment of ACCESSORIES (e.g. using incorrect mounting holes) has been noted to create unstable/unsafe conditions. Although no specific requirements can be elaborated which would adequately address this issue, designers should always address the issue of incorrect attachment of ACCESSORIES which are intended to be attached by OPERATORS. The maximum weight which lighter PATIENTS will lift when using the LIFTING POLE does not exceed 75 kg of their body weight whilst heavier PATIENTS normally do not have the strength to lift more than 75 kg.

21.6.102 Since the test of 21.6.102 is intended to simulate rough handling of the BED, the SIDE RAIL latching/locking mechanism is evaluated for its immunity to vibration effects during this test.

23.101 The reference to "where danger of PATIENT ENTRAPMENT exists" is a recognition that the issue of entrapment may be addressed in other ways than the restriction of openings associated with SIDE RAILS. In addition, alerts published by medical device authorities in several countries recognise that the BED/SIDE RAIL design only partially addresses the issue and emphasize the importance of the caregiver's role in minimising the hazards associated with entrapment by evaluating the mental state/condition of the PATIENT.

The dimensional requirements listed in figure 114 are intended to restrict openings in and around SIDE RAILS so that parts of the anatomy cannot enter or to ensure that these openings are large enough to allow easy removal. Each requirement is based on commonly available anthropometric data. The 120 mm dimension represents the distance from the rear of the head to the tip of the nose (95 percentile). The 60 mm dimension is based on the minimum (5 percentile) width of an adult female neck. The 220 mm is based on the midpoint (centre of gravity) of an adult male torso (95 percentile) lying on the shoulder. The 235 mm dimension is based on the distance from the chin to the crown of an adult male (95 percentile). The requirement for SIDE RAILS to cover at least 50 % of the length of the MATTRESS SUPPORT PLATFORM is intended to ensure that SIDE RAILS "reduce the risk of the PATIENT accidentally slipping or rolling off the mattress", as stated in 2.1.102.

Due to the nature of the SIDE RAIL entrapment HAZARD, compliance with the listed dimensional requirements is *not* in itself considered adequate to address all possible dangers (including entrapment of legs and arms, or the risk of a PATIENT falling from attempts to climb over SIDE RAILS). For this reason, an additional requirement to perform a risk assessment (evaluating all issues pertaining to SIDE RAILS) has been included. A risk assessment is also considered the most effective way of proving equivalent safety as described in 3.4 of the General Standard.

24.3 *bb)* The SAFE WORKING LOAD (of the BED) is not applied (to the BED) during this test to simulate the use of the LIFTING POLE by a PATIENT getting into the BED from some other accommodation (such as a wheel chair).

28.4.101 The requirements of 28.4.101 do not apply to SIDE RAILS since specific loading tests for SIDE RAILS are contained in 28.4.102 and 23.101.

52.5.103 In certain circumstances (for example if the PATIENT is in traction or is receiving intravenous infusion), an unintended movement of the BED could present a SAFETY HAZARD to the PATIENT.

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Annex BB – Possible considerations and tests for ELECTRICALLY OPERATED HOSPITAL BEDS

BB.1.3 Test method for determining the effects of loading on the edge of the MATTRESS SUPPORT PLATFORM

Add, on page 59, at the end of this subclause, the following text:

For ACCESSORIES which could be attached to more than one location on the BED, each location should be identified by labelling, whenever possible.

Add after BB.1.4, the following new subclause:

BB.1.5 *Test method for evaluating the durability OF LIFTING POLES*

The LIFTING POLE'S SAFE WORKING LOAD is applied to the handle 1 000 times. The deflection of the pole (at any point) should be less than 100 mm during the application of the load and any permanent deformation shall not exceed 20 mm.

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BB.2 Human factors (ergonomy) considerations in BED design

Add, on page 61, after BB.2.4.2, the following new subclause:

BB.2.5 Considerations for LIFTING POLES

Anthropometric data suggest that the length of the top arm of a LIFTING POLE (see figure BB.5) should be between 600 mm and 900 mm.

Page 69

Add the following new figure:

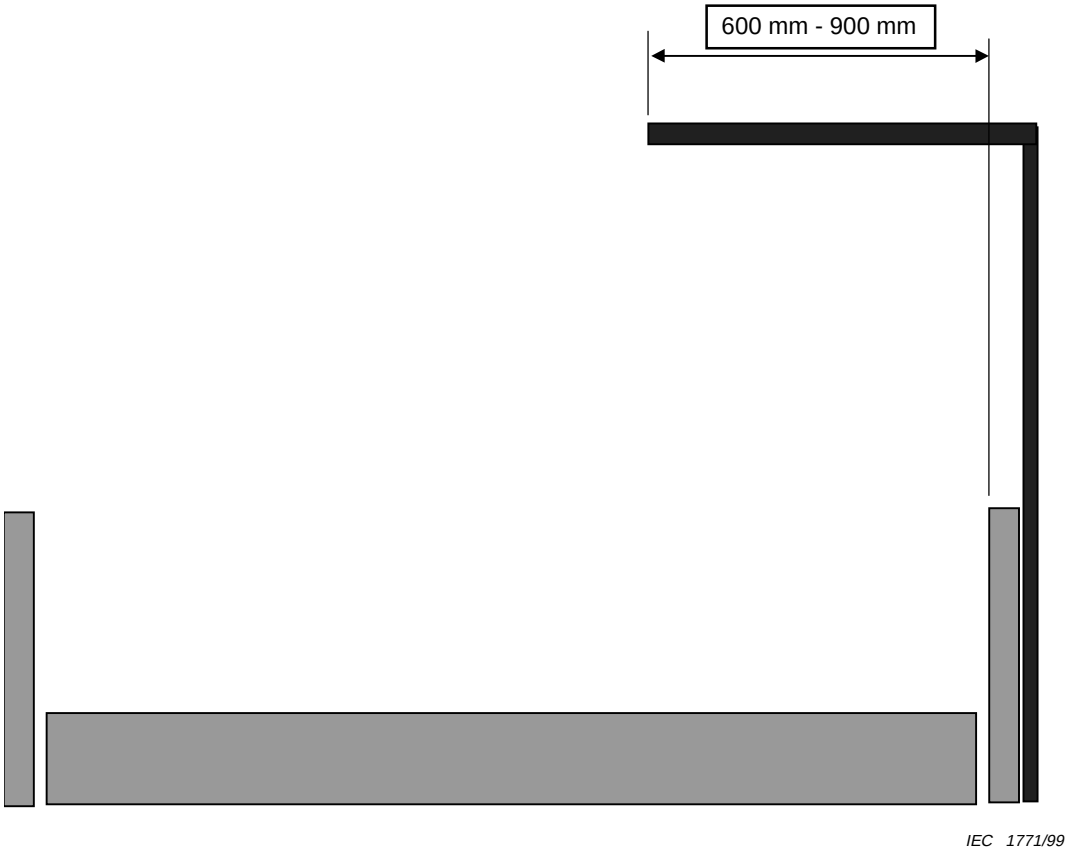

Figure BB.5 – Position of the LIFTING POLE handle

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