INTERNATIONAL STANDARD

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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

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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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Page 3

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

Page 13

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.

Page 15

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.)

Page 17

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).

Page 19

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.