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Tračni nosilci za pritrditev medicinske opreme

Rail systems for supporting medical equipment

Schienensysteme zum Halten medizinischer Geräte

Systemes de rails de support pour appareils médicaux

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English version

Rail systems for supporting medical equipment

Systèmes de rails de support pour appareils médicaux

Schienensysteme zum Halten medizinischer Geräte

This European Standard was approved by CEN on 2 October 1998.

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Foreword

This European Standard has been prepared by Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment", the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 1999, and conflicting national standards shall be withdrawn at the latest by April 1999.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this standard.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Annexes A, B, C, D and ZA are given for information.

Introduction

This European Standard specifies basic requirements and dimensions for rail systems used for supporting medical equipment.

Rail systems have been developed which allow medical equipment such as flowmeters, suction devices and luminaries to be placed near the patient. A rail system consists of rail supports, rail, rail clamps, equipment mount holders, equipment mounts and equipment pin holders and equipment mount pins. Rail systems can be mounted in many different locations: in hospitals, in ambulances and other means of transportation and on medical equipment such as medical supply units, ceiling pendants, trolleys, beds, ventilators and anaesthetic workstations. Patients with accompanying medical equipment are frequently moved either to or within hospitals. The lack of standardisation of rail systems in different locations can create hazardous situations in the transfer of the patient from one location to another. Rail systems have to be fitted to different kinds of loadbearing structures. These can vary from solid concrete walls or thin plasterboard partitions to the covers of medical equipment. The manufacturer is required to supply appropriate rail supports and mounting instructions to allow the mounted rail system to fulfil the requirements described in this European Standard.

Annex D contains rationale statements for this European Standard. The clauses and subclauses which have corresponding rationale statements are marked with ***R*** after their number.

1 Scope

This European Standard specifies basic requirements which ensure compatibility between rail systems complying with this Standard and medical equipment in order to permit the interchangeability of medical equipment from one rail system to another.

Medical equipment can be attached to a rail by rail clamps directly or via other components of dimensions which are specified in this Standard. Rail clamps are required to be compatible with rails which are within a range of dimensions specified in this Standard. The specifications for rail systems include dimensions, strength and information to be supplied by the manufacturer. Some medical equipment can be attached to the rail by means which are outside the scope of this Standard.

This Standard only applies to rail systems intended to be mounted horizontally. It specifies neither the structures nor the types of medical equipment that are to be supported. It does not apply to overhead rail systems for supporting curtains and infusion devices.

NOTE: It is expected that particular Standards will be prepared to cover applications for which the rail system specified in this European Standard is unsuitable, and particular device standards will specify whether or not the rail system specified in this Standard is to be fitted to the device.

2 Normative references

This European Standard incorporates, by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revision of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN 1441	Medical devices - Risk analysis
EN 980	Graphical symbols for use in the labelling of medical devices
HD 384	Electrical installations of buildings
ISO 468: 1982	Surface roughness - Parameters, their values and general rules for specifying requirements

3 Definitions

For the purpose of this Standard, the following definitions apply:

3.1 equipment mount: Means to attach medical equipment to an equipment mount holder.

3.2 equipment mount holder: Means to which an equipment mount can be attached and removed without the use of tools.

3.3 equipment mount pin: Means to attach medical equipment to an equipment pin holder.

3.4 equipment pin holder: Means to which an equipment mount pin can be attached and removed without the use of tools.

3.5 locking mechanism: That part of the rail clamp used to lock and unlock the rail clamp to the rail contact areas without the use of tools.

3.6 rail: Bar onto which, by use of a rail clamp, medical equipment can be attached and removed without the use of tools.

3.7 rail clamp: Means to attach and remove medical equipment or an equipment mount holder or an equipment pin holder to or from a rail without the use of tools.

3.8 rail clamp contact areas: Those areas of a rail clamp which are intended for direct contact with the rail.

3.9 rail contact areas: Those areas of a rail which are intended for direct contact with the rail clamp contact areas and the locking mechanism.

3.10 rail support: Means to attach a rail to a structure.

3.11 rail system: System which consists of rail supports, rail and rail clamps, with or without equipment mount holders and equipment mounts and equipment pin holders and equipment mount pins.

3.12 single fault condition: Condition in which a single means of protection against a safety hazard in equipment is defective or a single external abnormal condition is present.

4 Terminology

Typical components of a rail system are shown in figure 1.

5 General requirements

5.1 Safety

Rail systems shall, when installed, operated in normal use and maintained according to the instructions of the manufacturer, cause no safety hazard which could be foreseen using risk analysis procedures in accordance with EN 1441 and which is connected with their intended application, in normal condition and in single fault condition.

5.2 *R* Alternative construction

Rail systems using materials or having forms of construction different from those detailed in this Standard shall be accepted if it can be demonstrated that an equivalent degree of safety is obtained.

Evidence shall be provided by the manufacturer.

NOTE: It should be recognised that the components which ensure compatibility between rail system and medical equipment can be provided by different manufacturers.

5.3 Materials

5.3.1 ***R*** The materials shall be corrosion resistant and compatible with the cleaning and disinfecting products recommended by the manufacturer.

Evidence shall be provided by the manufacturer.

5.3.2 The materials shall allow the rail system to comply with the requirements described in clause 6.

5.4 Electrical requirements

In some countries it is required that in special medical locations the rail system has to be connected to the equipotential bonding installation.

The relevant parts of HD 384 or of national standards apply.

6 Rail system requirements

6.1 Rail supports

6.1.1 The rail supports shall leave a clearance of at least 15 mm between the contact areas of the rail and the loadbearing surface (see figure 2).

6.1.2 The rail support shall leave a clearance area behind the upper and lower rear edges of the rail with minimum dimensions of 8 mm x 4 mm (see figure 2).

6.1.3 Compliance with the requirements of 6.1.1 and 6.1.2 shall be checked by measurement.

6.2 Rail

6.2.1 *Shape*

The rail contact areas shall have a rectangular profile.

Except for the rear surface, all surfaces of the rail shall not extend outside the profile of the rail contact areas.

NOTE 1: The rear surface can be extended to function as the rail support within the profile shown in figure 2.

NOTE 2: For attaching the rail to the rail supports, special provisions can be required at intervals specified by the manufacturer.

6.2.2 *Dimensions*

Profile dimensions of the rail and of the rail contact areas shall comply with figure 3.

6.2.3 *Covering*

If a hollow rail is used, means shall be provided to cover the apertures.

6.2.4 Compliance with the requirements of 6.2.1, 6.2.2 and 6.2.3 shall be checked by measurement.

6.2.5 *R Surface roughness*

The rail shall have no sharp edges. The roughness of the rail contact areas shall be less than or equal to R_a 3,2 as defined in ISO 468: 1982.

Evidence shall be provided by the manufacturer.

6.2.6 *R Surface hardness*

The Brinell hardness of the rail contact area shall be not less than HB 80, 2.5/62.5.

Evidence shall be provided by the manufacturer.

6.2.7 *Bending*

6.2.7.1 When a force of 500 N is applied to the narrow side of a rail centrally between points 600 mm apart, the rail shall not deflect by more than 5 mm at the central point (see figure 4). When the test force is removed, the rail shall return to its original configuration without permanent deformation.

6.2.7.2 When a force of 500 N is applied to the wide side of a rail centrally between points 600 mm apart, the rail shall not deflect by more than 10 mm at the central point (see figure 5). When the test force is removed, the rail shall return to its original configuration without permanent deformation.

6.2.7.3 When the maximum load specified by the manufacturer is applied to the narrow side of a rail centrally between rigid supports at the maximum distance apart (L) specified by the manufacturer, the rail shall not deflect by more than 5 mm at the central point (see figure 6).

When the test load is removed, the rail shall return to its original configuration without permanent deformation.

The test method is given in 8.1.1.

6.2.8 *Torsion*

6.2.8.1 When a torque of 100 N·m is applied to a rail centrally between rigid supports 600 mm apart the angle of deflection α at the central point shall not exceed 5° (see figure 7). When the test torque is removed, the rail shall return to its original configuration without permanent deformation.

6.2.8.2 When the maximum torque specified by the manufacturer is applied to a rail centrally between rigid supports at the maximum distance apart (L) specified by the manufacturer, the angle of deflection α at the central point shall not exceed 5° (see figure 8).

When the test torque is removed, the rail shall return to its original configuration without permanent deformation.

The test method is given in 8.1.2.

6.3 Jointing

Means shall be provided so that, if a rail system is composed of more than one length of rail, the outer surfaces of the rail sections shall coincide and the requirements of 5.4, 6.2.7 and 6.2.8 shall be met.

6.4 Rail clamp

6.4.1 The rail clamp shall meet the requirements of this Standard when fitted to rails with all dimensions complying with 6.2.2 over the range specified for dimension B (see figure 3).

6.4.2 The rail clamp shall be provided with a locking mechanism which locks and unlocks the rail clamp to or from the rail contact areas without the use of tools. The locking mechanism shall be designed so as to prevent inadvertent removal of the clamp from the rail.

6.4.3 The rail clamp shall:

a) fit to and release from rails with all dimensions complying with 6.2.2 over the range specified for dimension B without the use of tools (see figure 3);

b) not overlap the rail support behind the rear of the rail (see figure 9);

c) be recessed 1 mm between the upper and lower contact area of the rail clamp which covers the front part of the rail (see figure 9);

d) not extend more than 14 mm from the rear contact area of the rail.

6.4.4 Compliance with the requirements of 6.4.1, 6.4.2 and 6.4.3 shall be checked by visual inspection.

6.4.5 The rail clamp, when secured to the rail by the locking mechanism in accordance with the manufacturer's instructions shall:

a) not move when a horizontal force of 50 N is applied in either direction parallel to the rail (see figure 10). The test is given in 8.1.3;

b) not deflect from the rail by an angle of more than 2° when a torque of 100 N·m is applied centrally to the clamp. The test is given in 8.1.4.

6.4.6 If the rail clamp is designed for acceptance of an equipment mount, it shall be fitted with an equipment mount holder.

NOTE: The rail clamp can be fitted with a means to prevent the equipment mount from being accidentally dislodged.

6.4.7 If the rail clamp is designed for acceptance of an equipment mount pin, it shall be fitted with an equipment pin holder.

NOTE: The rail clamp can be fitted with a means to prevent the pin from being accidentally dislodged. This means can be used to prevent free rotation of the attached equipment.

6.4.8 Compliance with 6.4.6 and 6.4.7 shall be checked by visual inspection.

6.5 Equipment mount holder

6.5.1 *R Dimensions*

The dimensions of the equipment mount holder shall comply with figure 11.

Compliance shall be verified by measurement.

6.5.2 *Mechanical characteristics*

The equipment mount holder shall accept and release the equipment mount without the use of tools.

The equipment mount holder shall withstand a vertical force of 500 N applied centrally without permanent deformation.

The equipment mount holder shall withstand a torque of 100 N·m without permanent deformation.

Both the force and the torque shall be applied using a test equipment mount made of metal (e.g. steel) and complying with 6.6.1.

The test is given in 8.1.5.

NOTE: The equipment mount holder can be fitted with one or more equipment pin holders.