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Utgåva 1

**Skensystem för upphängning av medicinteknisk
utrustning (ISO 19054:2005)**

**Rail systems for supporting medical equipment
(ISO 19054:2005)**

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The European Standard EN ISO 19054:2006 has the status of a Swedish Standard. This document contains the official English version of EN ISO 19054:2006.

This standard supersedes the Swedish Standard SS-EN 12218, edition 1, SS-EN 12218/A1, edition 1.

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English Version

Rail systems for supporting medical equipment (ISO 19054:2005)

Systèmes de rails de support pour appareils médicaux (ISO
19054:2005)

Schienensysteme zum Halten medizinischer Geräte (ISO
19054:2005)

This European Standard was approved by CEN on 9 June 2006.

CEN 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 CEN 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 CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

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EN ISO 19054:2006(E)

Foreword

The text of ISO 19054:2005 has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 19054:2006 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of an identical text or by endorsement, at the latest by December 2006, and conflicting national standards shall be withdrawn at the latest by June 2008.

This document supersedes EN 12218:1998.

This document 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 document.

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

Endorsement notice

The text of ISO 19054:2005 has been approved by CEN as EN ISO 19054:2006 without any modifications.

Introduction

This International Standard specifies basic requirements and dimensions for rail systems used for supporting medical equipment. A rail system consists of a number of components that can be assembled into different configurations.

Rail systems allow medical equipment such as flowmeters, suction devices and luminaires to be placed near the patient. They can be mounted in many different locations in health care facilities and in ambulances and other means of transportation and on many different pieces of equipment such as medical supply units, ceiling pendants, trolleys, beds, ventilators and anaesthetic workstations.

Medical equipment can be attached to a rail by rail clamps directly or using other components of dimensions which are specified in this International Standard. Rail clamps are required to be compatible with rails which have dimensions specified in this International Standard.

Rail systems have to be fitted to different kinds of load-bearing structures which can vary from solid concrete walls or thin plasterboard partitions to the covers of medical equipment. This can create hazards to the equipment and to the patient. Patients with accompanying medical equipment are frequently moved either to or within health care facilities. Lack of standardization of rail systems in different locations can create hazardous situations in the transfer of the patient from one location to another.

Annex B contains rationale statements for some of the requirements of this International Standard. It is included to provide additional insight into the reasoning that led to the requirements and recommendations that have been incorporated in this International Standard. The clauses and subclauses marked with an asterisk (*) after their number have corresponding rationale contained in Annex B. It is considered that knowledge of the reasons for the requirements will not only facilitate the proper application of this International Standard, but will expedite any subsequent revisions.

Rail systems for supporting medical equipment

1 Scope

This International Standard specifies basic requirements to ensure compatibility between rail systems complying with this International Standard and medical equipment in order to facilitate the transfer of medical equipment from one rail system to another. The specifications for rail systems include dimensions, strength and information to be supplied by the manufacturer.

This International Standard applies only to rail systems intended to be mounted horizontally.

This International Standard does not specify either the structures to which a rail system can be attached or the types of medical equipment that can be supported.

This International Standard does not apply to overhead rail systems for supporting curtains and infusion devices.

NOTE 1 Some medical equipment can be attached to the rail by means that are outside the scope of this International Standard.

NOTE 2 It is expected that particular standards will be prepared to cover applications for which the rail systems specified in this International Standard are unsuitable.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 1302:2002, *Geometrical Product Specifications (GPS) — Indication of surface texture in technical product documentation*

ISO 4135:2001, *Anaesthetic and respiratory equipment — Vocabulary*

ISO 6506-1:1999, *Metallic materials — Brinell hardness test — Part 1: Test method*

ISO 14971:2000, *Medical devices — Application of risk management to medical devices*

EN 980, *Graphical symbols for use in the labelling of medical devices*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4135 and the following apply.

3.1

commissioning

proof of function to verify that the agreed system specification is met and is accepted by the user or the representative of the user

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- 3.2
equipment mount**
component of a rail system used to attach medical equipment to an equipment mount holder

(See Figure 1)
- 3.3
equipment mount holder**
component of a rail system to which an equipment mount can be attached and removed

(See Figure 1)
- 3.4
equipment mount pin**
component of a rail system used to attach medical equipment to an equipment mount pin holder

(See Figure 1)
- 3.5
equipment mount pin holder**
component of a rail system to which an equipment mount pin can be attached and removed

(See Figure 1)
- 3.6
installer**
person with legal responsibility for the installation of a device
- 3.7
locking mechanism**
part of the rail clamp used to lock and unlock the rail clamp to and from the rail contact area
- 3.8
manufacturer**
natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party
- 3.9
rail**
bar on which medical equipment can be attached or removed by use of a rail clamp
- 3.10
rail clamp**
means of attaching or removing medical equipment or an equipment mount holder or an equipment mount pin holder to or from a rail
- 3.11
rail clamp contact area**
part of a rail clamp intended for direct contact with the rail
- 3.12
rail contact area**
part of a rail intended for direct contact with the rail clamp contact area and the locking mechanism
- 3.13
rail end cap**
component that is attached to the end of the rail and is intended to stop a clamp from sliding off the rail

3.14

rail support

component of a rail system used to attach a rail to a structure or equipment

(See Figure 1)

3.15

rail system

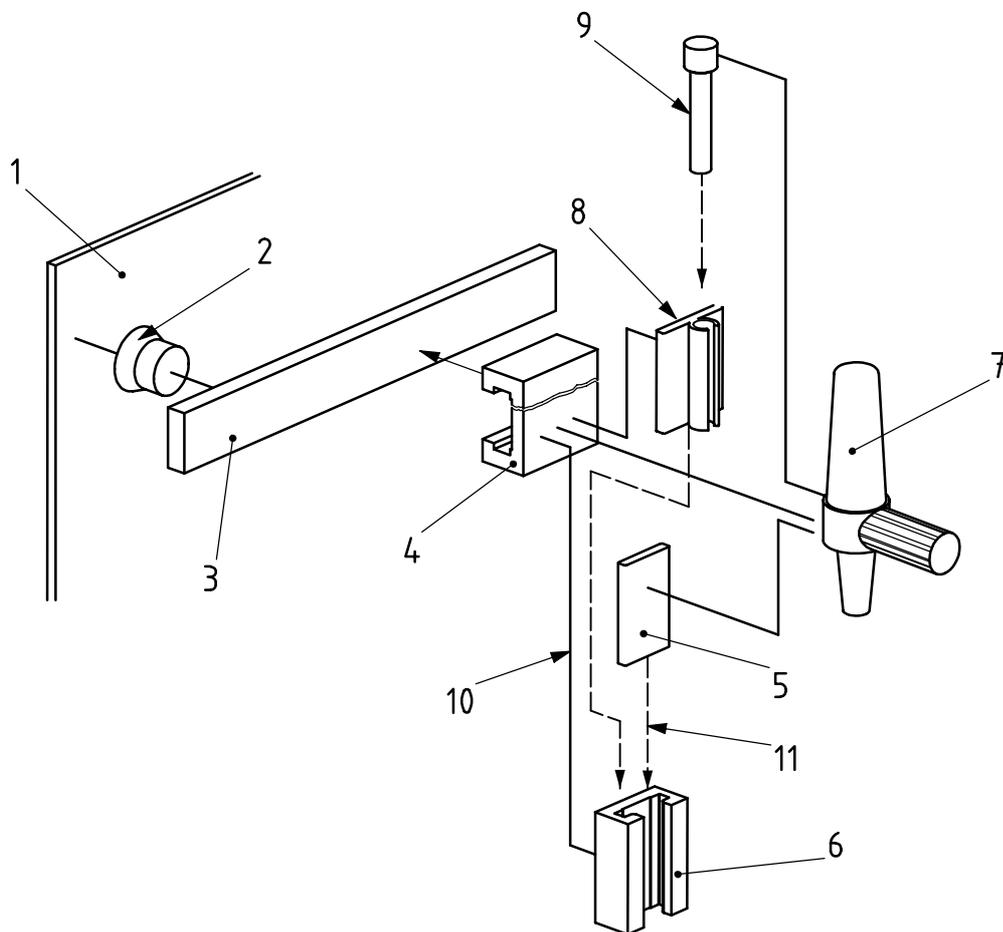
assembly of components comprising at least a rail, rail supports and rail clamps

(See Figure 1)

3.16

single fault condition

condition in which a single means of protection against a hazard in equipment is defective or a single external abnormal condition is present



Key

- | | |
|--------------------------|------------------------------|
| 1 load-bearing structure | 7 medical equipment |
| 2 rail support | 8 equipment mount pin holder |
| 3 rail | 9 equipment mount pin |
| 4 rail clamp | 10 permanent connection |
| 5 equipment mount | 11 operator connection |
| 6 equipment mount holder | |

Figure 1 — Examples of connections of medical equipment to a rail system

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4 General Requirements

4.1 Safety

Rail systems shall, when installed, operated and maintained according to the instructions of the manufacturer, cause no safety hazard which could be foreseen using risk management procedures in accordance with ISO 14971.

NOTE Components that ensure compatibility between a rail system and medical equipment can be provided by different manufacturers.

4.2 * Alternative construction

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

Evidence shall be made available by the manufacturer upon request.

4.3 Materials

4.3.1 * The materials shall be resistant to corrosion and compatible with the cleaning and disinfecting products and procedures recommended by the manufacturer.

Evidence shall be made available by the manufacturer upon request.

4.3.2 The materials shall allow the rail system to comply with the requirements in Clause 5.

4.4 Electrical requirements

The rail system shall be connected to the equipotential bonding installation if required by national or regional regulations.

The relevant parts of national or regional regulations for electrical installations in buildings shall apply.

NOTE Annex C lists some national and regional regulations for electrical installations.

5 Rail system requirements

5.1 Rail supports

5.1.1 The rail supports shall leave a clearance of at least 15 mm between the rail contact areas and the surface of the load-bearing structure (see Figures 2 and 3).

5.1.2 The rail supports shall leave a clearance area behind the upper and lower rear edges of the rail with minimum dimensions of 8 mm × 4 mm (see Figure 2).

5.1.3 Compliance with the requirements of 5.1.1 and 5.1.2 shall be checked by measurement.

5.2 Rail

5.2.1 Shape

The rail contact areas shall have a rectangular profile.