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Rail systems for supporting medical equipment

Systèmes de rails de support pour équipement médical

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 19054 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 6, *Medical gas systems*.

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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

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)

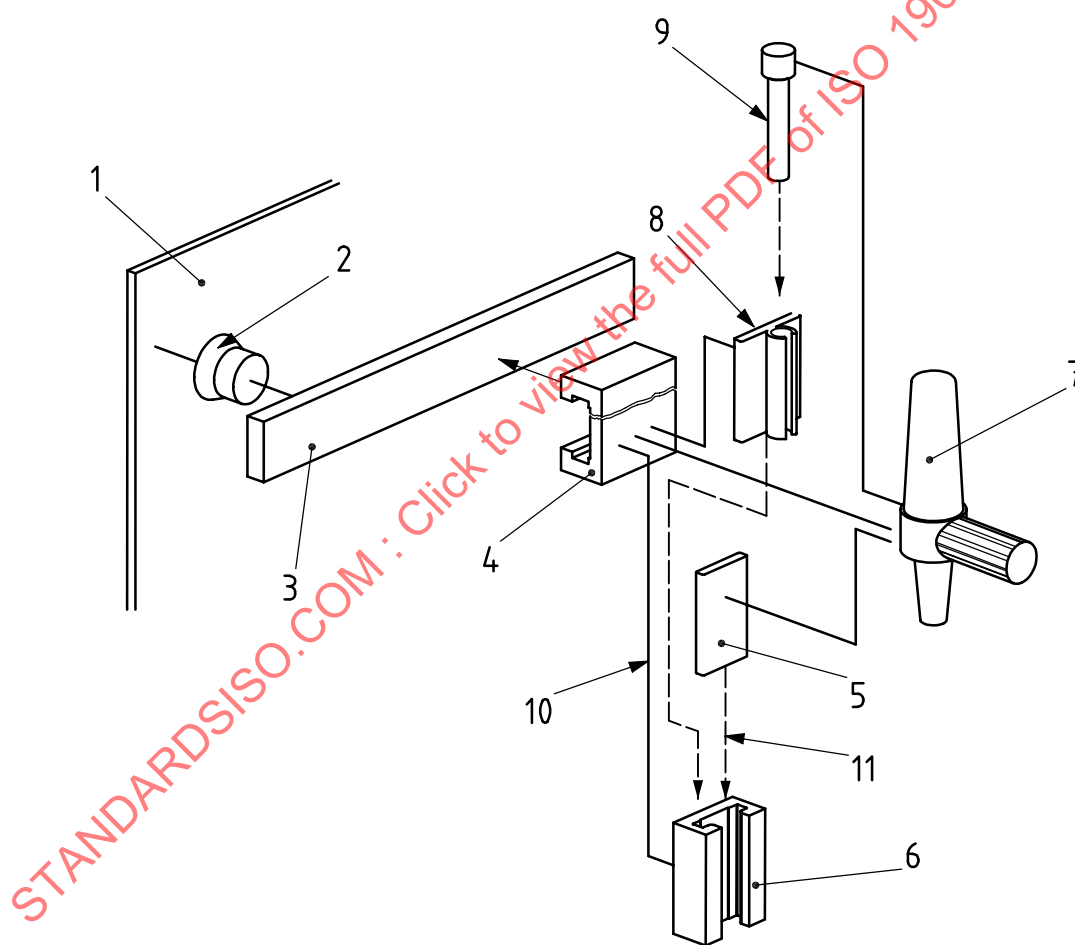
3.15**rail system**

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

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

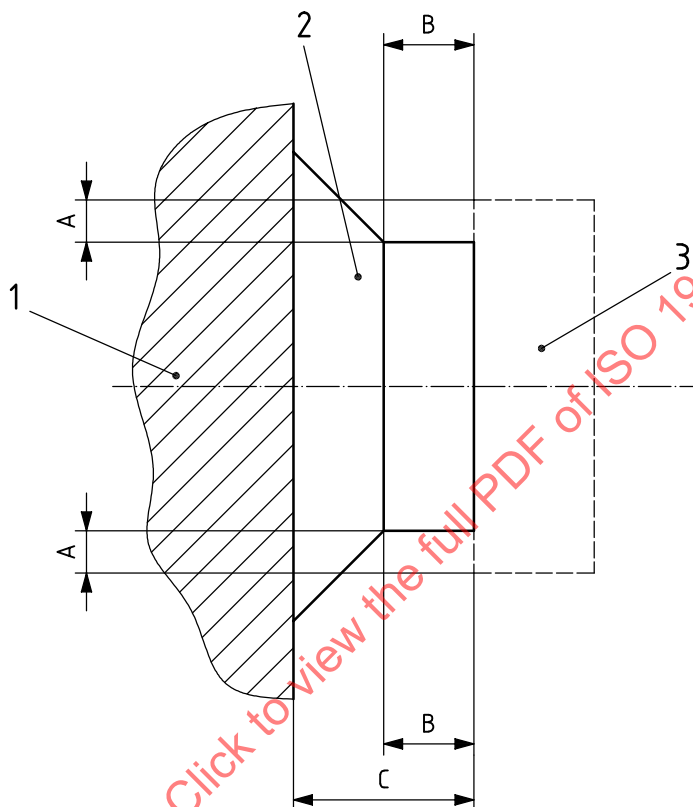
5.2.1 Shape

The rail contact areas shall have a rectangular profile.

Except for the rear surface and end caps, 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 The manufacturer can require special provisions at specified intervals for the purpose of attaching the rail to the rail supports.



Key

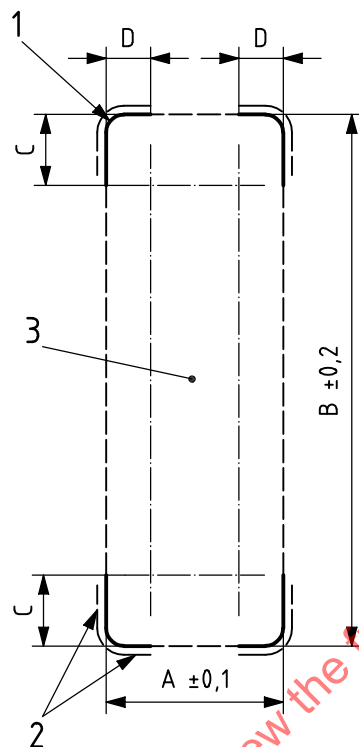
- | | | | |
|---|------------------------|---|---|
| 1 | load-bearing structure | A | clearance behind rear edge of rail (4 mm min) |
| 2 | rail support | B | clearance behind rear edge of rail (8 mm min) |
| 3 | rail | C | clearance between rail contact areas and load-bearing structure (15 mm min) |

Figure 2 — Clearance of the rail supports when a rail is attached

5.2.2 Dimensions

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

Dimensions in millimetres



Key

- | | | | |
|---|--|---|----------------|
| 1 | radius or 45° chamfer min 0,3 max 0,5 mm | A | 10 mm |
| 2 | contact area | B | 25 mm to 35 mm |
| 3 | rail | C | 4 mm min |
| | | D | 2,5 mm min |

Figure 3 — Profile dimensions of the rail and of the rail contact areas

5.2.3 Covering

If a hollow rail is used, means shall be provided of covering the apertures.

5.2.4 Compliance

Compliance with the requirements of 5.2.1, 5.2.2 and 5.2.3 shall be checked by measurement and visual inspection.

5.2.5 * Surface roughness

The surface roughness shall be Ra 1,6 as defined in ISO 1302.

Evidence shall be made available by the manufacturer upon request.

5.2.6 * Surface hardness

The Brinell hardness of the rail contact area shall be not less than HBW 2,5/62,5 as determined in accordance with ISO 6506-1.

Evidence shall be made available by the manufacturer upon request.

5.2.7 * Bending

5.2.7.1 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.

5.2.7.2 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.

5.2.7.3 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 specified by the manufacturer (B in Figure 6), 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.

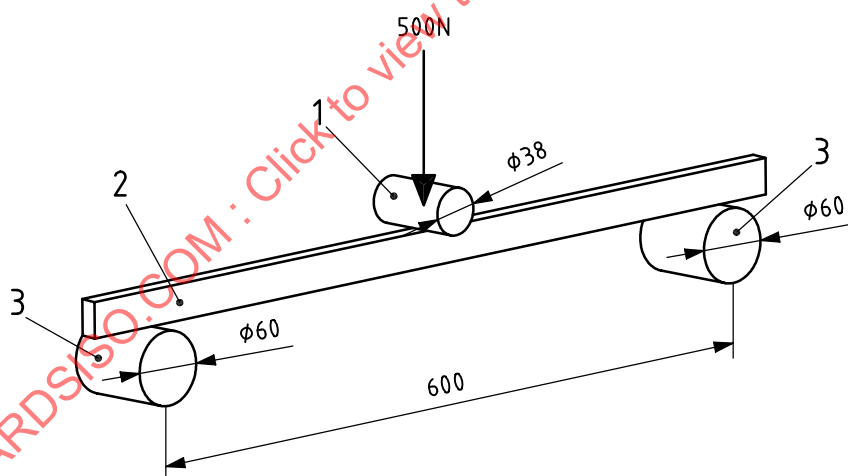
Evidence shall be made available by the manufacturer upon request.

5.2.8 * Torsion

When the maximum torque specified by the manufacturer is applied to a rail centrally between rigid supports at the maximum distance apart specified by the manufacturer (B in Figure 7), the angle of deflection (α°) at the central point shall not exceed 5° . When the test torque is removed, the rail shall return to its original configuration without permanent deformation.

Evidence shall be made available by the manufacturer upon request.

Dimensions in millimetres

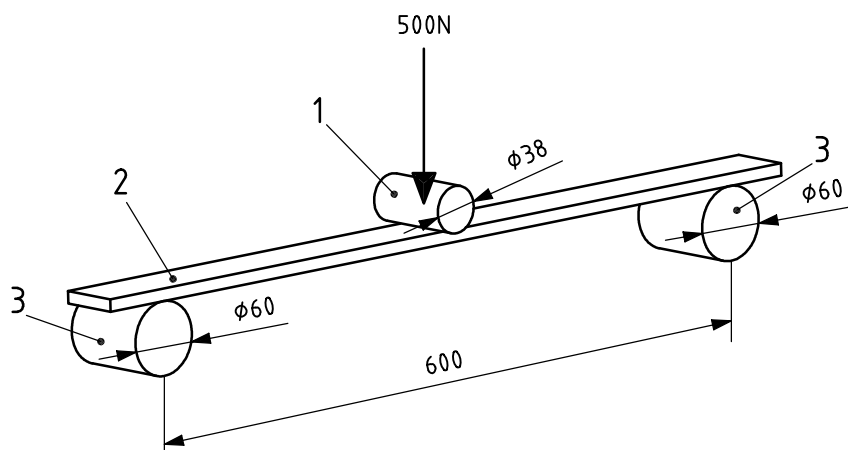


Key

- 1 device for the application of the test force
- 2 rail
- 3 rigid support

Figure 4 — Typical configuration for bending test of the rail
(force applied to the narrow side)

Dimensions in millimetres

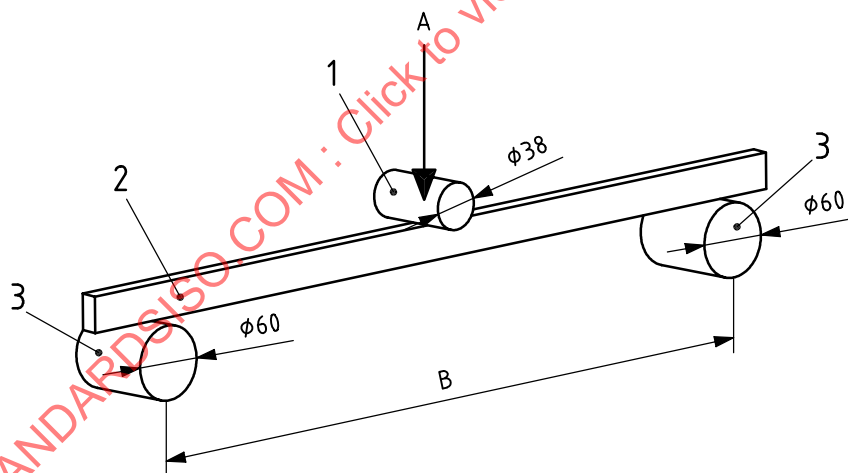


Key

- 1 device for the application of the test force
- 2 rail
- 3 rigid support

Figure 5 — Typical configuration for bending test of the rail
(force applied to the wide side)

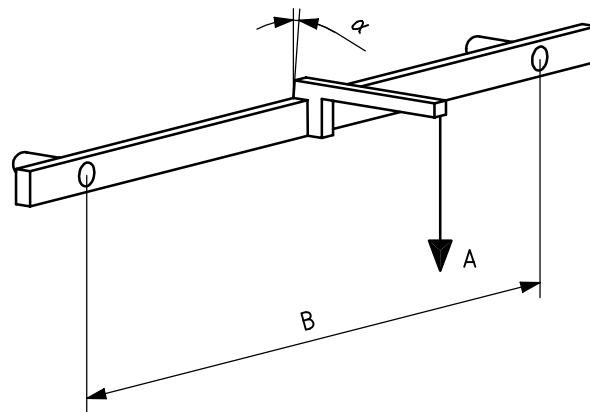
Dimensions in millimetres



Key

- 1 device for the application of the test force
- 2 rail
- 3 rigid support
- A maximum load specified by the manufacturer
- B maximum distance specified by the manufacturer

Figure 6 — Typical configuration for bending test of the rail
(force applied to the narrow side)



Key

- A maximum torque specified by the manufacturer
 B maximum distance specified by the manufacturer
 α° angle of deflection

Figure 7 — Typical configuration for torsion test of the rail (maximum torque)

5.3 Joining of rails

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 4.4, 5.2.7 and 5.2.8 shall be met at each location where the rails meet.

5.4 Rail clamp

5.4.1 The rail clamp shall meet the requirements of this International Standard when fitted to rails with all dimensions complying with 5.2.2 over the range specified for dimension B in Figure 3.

5.4.2 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.

5.4.3 The rail clamp shall fit to and release from any rail complying with Figure 3 without the use of a tool.

5.4.4 The rail clamp shall not touch the rail support when fitted to the rail.

5.4.5 The rail clamp shall comply with the dimensions in Figure 8.

5.4.6 Compliance with the requirements of 5.4.1 to 5.4.5 shall be checked by visual inspection and measurement.

5.4.7 * If the locking mechanism is designed to prevent lateral movement, the rail clamp shall not move when a horizontal force of 50 N is applied in either direction parallel to the rail (see Figure 9).

Evidence shall be made available by the manufacturer upon request.

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

Evidence shall be made available by the manufacturer upon request.

5.4.9 A rail clamp designed for acceptance of an equipment mount shall be fitted with an equipment mount holder.

NOTE The rail clamp can be fitted with means of preventing the equipment mount from being accidentally dislodged.

5.4.10 A rail clamp designed to accept an equipment mount pin shall be fitted with an equipment mount pin holder.

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

5.4.11 Compliance with 5.4.9 and 5.4.10 shall be checked by visual inspection.

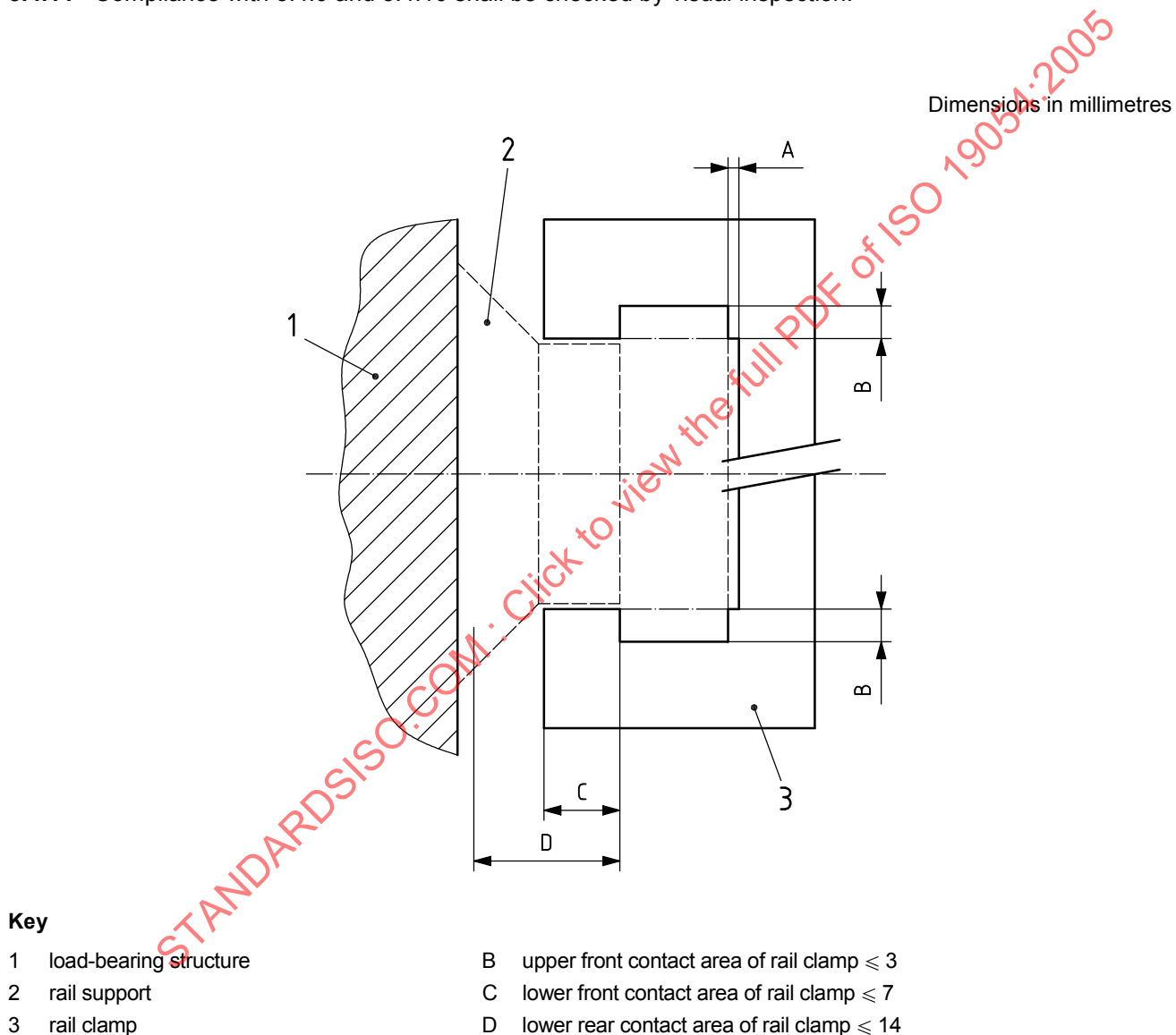
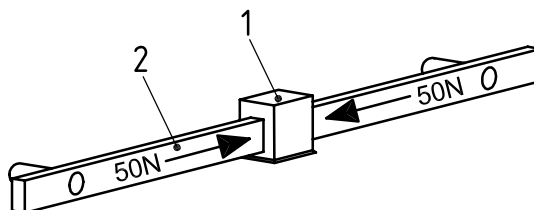


Figure 8 — Dimensions of the rail clamp and of the rail clamp contact areas

**Key**

- 1 rail clamp
- 2 rail

Figure 9 — Typical configuration for testing resistance to sliding of the locked rail clamp

5.5 Equipment mount holder

5.5.1 Dimensions

The dimensions of the equipment mount holder shall comply with Figure 10.

Compliance shall be verified by measurement.

5.5.2 * Mechanical characteristics

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

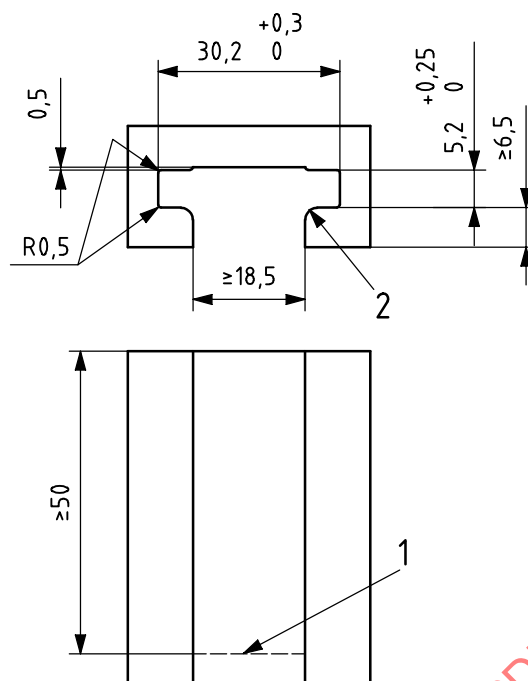
The equipment mount holder shall withstand a vertical force of 500 N applied centrally without permanent deformation.

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 5.6.1.

Evidence shall be made available by the manufacturer upon request.

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

**Key**

- 1 stop limit for equipment mount
- 2 R2 or 2 × 45° chamfer

Figure 10 — Dimensions of equipment mount holder**5.6 Equipment mount****5.6.1 Dimensions**

The dimensions of the equipment mount shall comply with Figure 11.

Compliance shall be verified by measurement.

5.6.2 * Mechanical characteristics

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

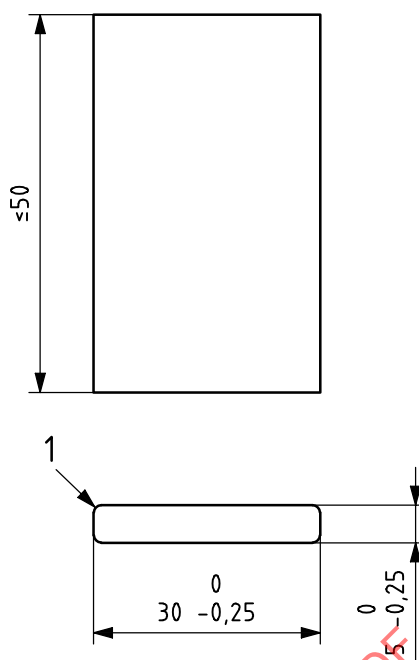
The equipment mount shall withstand a torque of 100 N·m without permanent deformation.

Both the force and the torque shall be applied using a test equipment mount holder made of metal (e.g. steel) and complying with 5.5.1.

Evidence shall be made available by the manufacturer upon request.

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

Dimensions in millimetres

**Key**

- 1 R1 or $1 \times 45^\circ$ chamfer on all external corners

Figure 11 — Dimensions of equipment mount

5.7 Equipment mount pin holder

5.7.1 Dimensions

The dimensions of the equipment mount pin holder shall comply with Figure 12.

Compliance shall be verified by measurement.

5.7.2 * Mechanical characteristics

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

The equipment mount pin holder shall withstand a vertical force of 100 N applied centrally without permanent deformation.

The equipment mount pin holder shall withstand a torque of 20 N·m without permanent deformation.

Both the force and the torque shall be applied using a test equipment pin made of metal (e.g. steel) and complying with 5.8.1.

Evidence shall be made available by the manufacturer upon request.

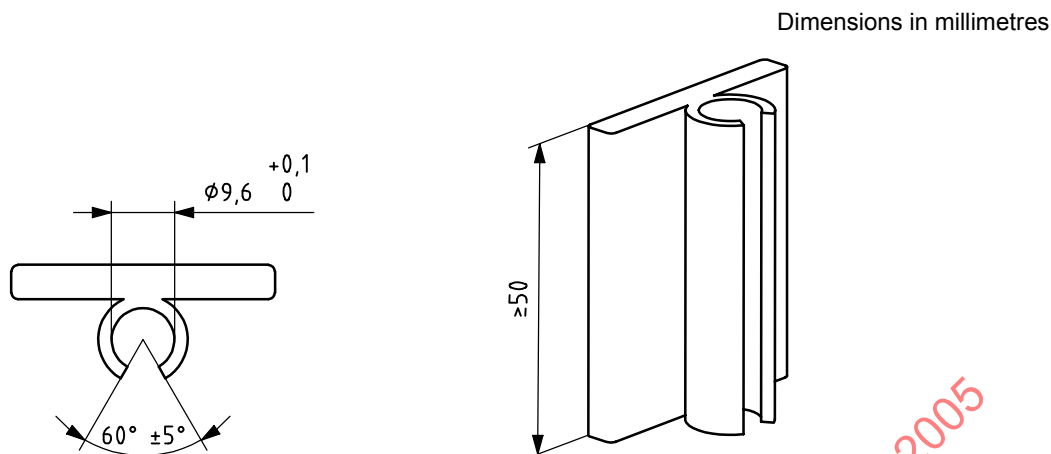


Figure 12 — Dimensions of equipment mount pin holder

5.8 Equipment mount pin

5.8.1 Dimensions

The dimensions of the equipment mount pin shall comply with Figure 13.

Compliance shall be verified by measurement.

5.8.2 * Mechanical characteristics

The equipment mount pin shall withstand a vertical force of 100 N without permanent deformation.

The equipment mount pin shall withstand a torque of 20 N·m without permanent deformation.

Both the force and the torque shall be applied using a test equipment mount pin holder made of metal (e.g. steel) and complying with 5.7.1.

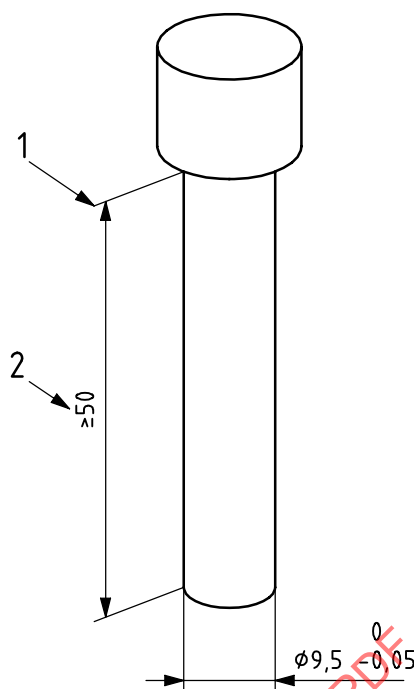
Evidence shall be made available upon request by the manufacturer.

5.9 * Mechanical characteristics of the rail after installation

After installation, the rail supports shall be capable of supporting a vertical force of 150 N and a pullout force of 150 N simultaneously applied to a support position without rupture or permanent deformation of the rail supports or load-bearing structure. All support positions shall be tested.

Evidence that this requirement is met shall be made available by the installer upon request.

Dimensions in millimetres

**Key**

- 1 stop limit for equipment mount pin
- 2 diameter applicable over this length

Figure 13 — Dimensions of equipment mount pin**6 Marking, labelling and packaging**

6.1 Rail system components, labels or packaging shall include the following information:

- a) instructions for use;
- b) the name or tradename and address of the manufacturer;
- c) component identification and contents of the packaging;
- d) the batch code, preceded by the symbol LOT in accordance with EN 980 or by the serial number;
- e) the recommended method(s) of cleaning, disinfection and sterilization.

Compliance shall be checked by visual inspection.

6.2 The rail shall be durably marked with the following:

- a) the name or trade name of the manufacturer;
- b) the maximum permitted load as specified in 8.1 a).

The test for the durability of marking is given in 7.1.5.

Evidence shall be made available by the manufacturer upon request.

7 Testing, commissioning and certification

NOTE The aim of testing and commissioning of the rail system is to verify that all safety aspects and performance requirements of this International Standard are met. A typical form for the certification of the rail system is given in Annex A.

7.1 Tests after installation

7.1.1 General

Tests after completion of installation shall be carried out by the installer and witnessed by an authorized person who should certify the results of the tests to the owner or client. The results of the tests, showing details of the areas where rail systems have been installed, shall be part of the permanent record of the health care institution.

7.1.2 Mechanical tests

It shall be verified that the requirements of 5.9 are met.

7.1.3 Distance between supports

Measurements shall be taken to ensure that the maximum distance between supports specified by the manufacturer has not been exceeded.

7.1.4 Marking

It shall be verified that the requirements in Clause 6 are met.

7.1.5 Durability of markings

Rub markings by hand, without undue pressure, first for 15 s with a cloth rag soaked in distilled water, then for 15 s with a cloth rag soaked in ethanol and then for 15 s with a cloth rag soaked in isopropanol. Carry out the test at ambient temperature.

7.2 Certification of the installed rail system

Before a rail system is used, it shall be documented in writing that the device was installed according to the manufacturer's instructions, that the tests after installation required in 7.1 and any additional test(s) recommended by the manufacturer have been carried out and that the rail system meets the requirements of this International Standard.

8 Information to be supplied by the manufacturer

8.1 Upon delivery of rail and supports

The manufacturer shall supply information including:

- a) the maximum recommended distance between two supports and the maximum load and torque which may be applied to the rail with supports at that distance on various load-bearing surfaces or structures;
- b) instructions for mounting the rail supports on various load-bearing surfaces or structures;
- c) instructions for connection of the rail system to the equipotential bonding bus bar if required;
- d) the procedures to be used for cleaning and disinfection, including the recommended cleaning and disinfecting agents;