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Interested committees:

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## Introduction

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For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

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|                  |                        |
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| 1  | 2                                          | (3)                          | 4               | 5                                                                                                                                  | (6)                                                                      | 7                                                  |
|----|--------------------------------------------|------------------------------|-----------------|------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|----------------------------------------------------|
| MB | Clause No./ Subclause No./Annex (e.g. 3.1) | Paragraph/ Figure/Table/Note | Type of comment | Comment (justification for change) by the MB                                                                                       | Proposed change by the MB                                                | Secretariat observations on each comment submitted |
|    | 3.1                                        | Definition 1                 | ed              | Definition is ambiguous and needs clarifying.                                                                                      | Amend to read '...so that the mains connector to which no connection...' |                                                    |
|    | 6.4                                        | Paragraph 2                  | te              | The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK. | Delete reference to UV photometer.                                       |                                                    |



# DRAFT International Standard

## ISO/DIS 17966

### Assistive products for toileting, bathing and showering — Requirements and test methods

ICS: 11.180.99; 11.180.01

ISO/TC 173

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## Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see [www.iso.org/directives](http://www.iso.org/directives)).

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This document was prepared by Technical Committee ISO/TC 173, *Assistive products*, respectively ISO/TC 173/WG 9, *Assistive products for personal hygiene*.

This document is foreseen to be adopted as an EN-ISO Standard by Technical Committee CEN/TC 293, *Assistive products and accessibility* falling under Standardization Request M/575 given to CEN by the European Commission and the European Free Trade Association and supports essential requirements of Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices. Therefore, the document uses dated references only.

This second edition of ISO 17966 replaces ISO 17966:2016, however, given the technical changes and added requirements in this document compared to ISO 17966:2016, a transition period of 24 months to comply with this document is recommended.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at [www.iso.org/members.html](http://www.iso.org/members.html).

## Introduction

This document specifies requirements and test methods that are relevant to assistive products for toileting, bathing and showering.

[Clause 4](#) to [Clause 22](#) and [Clause 26](#) to [Clause 28](#) contain general requirements for all types of products included in the Scope.

[Clause 23](#) to [Clause 25](#) contain specific requirements for mobile, fixed and portable products. These clauses indicate additional requirements to the general requirement clauses.

In order for a product to claim compliance with this document, all relevant clauses need to be fulfilled, depending on the type of product. For example, some products do not include electrical components; therefore, the clauses related to electrical components may not be relevant.

In addition to the requirements in this document, [Annex B](#) gives general recommendations.

# Assistive products for toileting, bathing and showering — Requirements and test methods

## 1 Scope

This document specifies requirements and associated test methods for assistive products for toileting, bathing and showering (from herein referred as 'assistive product' within the standard) and which are considered to be medical devices, intended by the manufacturer to alleviate or compensate for disability.

NOTE 1 Assistive products are considered to be medical devices in some jurisdictions but not in others.

The standard specifies safety, functional and ergonomic requirements for both persons with disability and assistants that apply during normal use and foreseeable misuse and failure.

This document specifies requirements and test methods for assistive products within the following divisions of EN ISO 9999:2022.

There are no specific requirements and test methods for products marked with \*. Only the relevant general requirements apply when these products are considered to be medical devices.

### 09 12 03 Commode chairs;

Chairs, with or without castors, with a collection receptacle used for toileting away from the bathroom

### 09 12 06 Toilets;\*

Included are, e.g. raised or height adjustable toilets, toilets with built-in douche and air dryers.

### 09 12 09 Toilet seats;\*

Devices attached to the toilet bowl or toilet chair for a person to sit on; they can provide stability and comfort

### 09 12 10 Toilet splash guards;\*

Devices to keep bodily substances from splashing outside the toilet bowl

### 09 12 12 Raised toilet seats, free-standing

Raised toilet seats (separate) standing on floor, where the seat can easily be removed from the toilet bowl

Included are, e.g. over toilet frames.

### 09 12 15 Raised toilet seats, detachable;

Raised toilet seats (loose attachments) placed directly on the toilet bowl/toilet seat where the seat insert can easily be removed from the toilet bowl/toilet seat

### 09 12 18 Raised toilet seats fixed to toilet;

Devices permanently fixed on to a toilet bowl to increase the height of the seat and to facilitate sitting down upon, and standing up from, the toilet

Included are, e.g. plinths.

- 09 12 21 Toilet seats with built-in raising mechanism to help standing up and sitting down;  
Toilet seats that have a built-in lifting mechanism to assist a person to sit down on and get up from the toilet
- 09 12 24 Toilet arm supports and toilet back supports mounted on toilet;  
Devices mounted on the toilet that provide support getting on or off the toilet
- 09 12 25 Toilet arm supports and toilet back supports, free standing;
- 09 12 36 Douches and air dryers for attachment to a toilet;\*
- Devices attached to a toilet to provide a water spray with or without air blowing afterwards to wash, and possibly dry, a person's bottom while sitting on the toilet
- Included are, e.g. toilet seats with that function.
- 09 33 04 Bath boards;  
Seats without back support placed on the rim across the bathtub
- 09 33 05 Bath seats;  
Seats hung from the rim of or placed in the bathtub  
Included are e.g., bath seats with or without backrest
- 09 33 07 Shower chairs with and without wheels;  
Devices for supporting sitting during showering  
Included are, e.g. shower stools.
- 09 33 08 Back supports for bath or shower;  
Excluded are, e.g. back support cushions.
- 09 33 12 Bathing stretchers, shower tables and diaper-changing tables;  
Stationary or portable tables, with or without castors, on which a person lies during bathing, showering or changing  
NOTE 2: Mainstream diaper-changing tables for babies/toddlers are excluded. They are covered by prEN 12221:2023.
- 09 33 15 Wash basins;\*
- Stationary or portable basins for water used when washing parts of the body
- 09 33 18 Bidets;\*
- Stationary or portable basins primarily intended for washing genitals and bottom
- 09 33 36 Assistive products for drying oneself;\*
- Devices and materials for enabling a person to dry his/her own body
- 18 15 06 Height adjustable plinths and brackets;

Height-adjustable surfaces or brackets on which furniture (e.g. wash basins) can be mounted

18 18 03 Handrails and support rails;

Bars, usually cylindrical, attached to a wall, floor or other stable structure that provide the means for a person to support or stabilize himself/herself using hands or arms while walking, e.g. up and down stairs or ramps or moving along corridors

18 18 06 Fixed grab bars and handgrips;

Devices, usually straight or angled bars, that are permanently attached to a wall, a wall and a floor, or a wall, ceiling and floor to provide support to a person while standing or changing position

18 18 10 Removable grab rails and handgrips;

Devices, usually straight or angled bars, that can be temporarily attached to walls, floors, ceilings or furniture using, e.g. clamps or suction pads and removed without tools providing support to a person while changing position

18 18 11 Hinged rails and arm supports;

Devices that provide support to a person when changing her/his position; they can be fixed to a wall or floor and can be folded up or sideways or lowered down to allow access or when they are not needed

This document does not apply for:

- safe mounting in building structures;
- fixed building installations e.g. water, electricity, drainage and sewerage, requirements in relation to excretion-disposal and -wrapping systems;
- bathtub hoists that are covered by EN ISO 10535:2021, namely
  - 12 36 06 Mobile hoists for transferring a person in sitting position with solid seats;
  - 12 36 09 Mobile hoists for transferring a person in lying position;
  - 12 36 12 Stationary hoists fixed to walls, floor or ceiling;
  - 12 36 15 Stationary hoists fixed to, or mounted in or on, another product;
- 09 33 21 Bathtubs;
- stability and friction issues in relation to slippery surfaces due to soap;
- products that have been customised or custom-made for an individual user.

## 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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.

EN 614-1:2006+A1:2009, *Safety of machinery — Ergonomic design principles — Part 1: Terminology and general principles*

EN 1021-2:2014, *Furniture – Assessment of the ignitability of upholstered furniture – Part 2: Ignition source match flame equivalent*

EN 12527:1998, *Castors and wheels — Test methods and apparatus*

EN 60601-1:2006, + Cor.:2010 + A1:2013 + AC:2014 + A1:2013/AC:2014 + A12:2014 + A2:2021, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005 + Cor1:2006 + Cor2:2007 + A1:2012 + A1:2012/Cor1:2014 + A2:2020)*

EN 60601-1-11:2015, + A1:2021, *Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment (IEC 60601-1-11:2015 + A1:2020)*

EN ISO 845:2009, *Cellular plastics and rubbers — Determination of apparent density (ISO 845:2006)*

EN ISO 2439:2009, *Flexible cellular polymeric materials — Determination of hardness (indentation technique) (ISO 2439:2008)*

EN ISO 3746:2010, *Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Survey method using an enveloping measurement surface over a reflecting plane (ISO 3746:2010)*

EN ISO 9227:2022, *Corrosion tests in artificial atmospheres — Salt spray tests (ISO 9227:2022)*

EN ISO 9999:2022, *Assistive products — Classification and terminology*

EN ISO 10993-1:2020, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018, including corrected version 2018-10)*

EN ISO 12100:2010, *Safety of machinery — General principles for design — Risk assessment and risk reduction (ISO 12100:2010)*

EN ISO 13849 (all parts), *Safety of machinery — Safety-related parts of control systems*

EN ISO 14155:2020, *Clinical investigation of medical devices for human subjects — Good clinical practice (ISO 14155:2020)*

EN ISO 14971:2019, + A11:2021, *Medical devices — Application of risk management to medical devices (ISO 14971:2019)*

EN ISO 15223-1:2021, *Medical devices — Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)*

EN ISO 20417:2021, *Medical devices — Information to be supplied by the manufacturer (ISO 20417:2021, Corrected version 2021-12)*

EN ISO 22442-1:2020, *Medical devices utilizing animal tissues and their derivatives — Part 1: Application of risk management (ISO 22442-1:2020)*

IEC 60068-2-31:2008, *Environmental testing — Part 2-31: Tests — Test Ec: Rough handling shocks, primarily for equipment-type specimens*

IEC 60332-1-2:2015, *Tests on electric and optical fibre cables under fire conditions — Part 1-2: Test for vertical flame propagation for a single insulated wire or cable - Procedure for 1 kW pre-mixed flame*

IEC 60529:2019, *Degrees of protection provided by enclosures (IP code); Amendment 2; Corrigendum 1*

IEC 60695-11-10:2013, *Fire hazard testing — Part 11-10: Test flames — 50 W horizontal and vertical flame test methods; Corrigendum 1*

IEC 61508 (all parts), *Requirements and Guidance in the use of mathematical and logical techniques for establishing exact properties of software and its documentation*

ISO 7176-8:2014, *Wheelchairs — Part 8: Requirements and test methods for static, impact and fatigue strengths*

ISO 7176-11:2012, *Wheelchairs — Part 11: Test dummies*

ISO 8191-2:1988, *Furniture — Assessment of ignitability of upholstered furniture — Part 2: Ignition source: match-flame equivalent*

ISO 8373:2021, *Robotics — Vocabulary*

ANSI/UL 1581:2023, *Standard for Safety for Reference Standard for Electrical Wires, Cables, and Flexible Cords*

### 3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN 60601-1:2022 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

#### 3.1

##### **applied part**

part of device that in *normal use* (3.15) necessarily comes into physical contact with the user to perform its function

#### 3.2

##### **assistant**

person who is helping/supporting a person with disability in using the *assistive product* (3.3)

Note 1 to entry: Examples of the ways assistants help persons with disability are pushing commode chairs, operating height adjustable devices, and assisting with entering and leaving seats, stretchers and commode chairs.

Note 2 to entry: An assistant can be a health care professional or a non-professional, for example, a relative.

#### 3.3

##### **assistive product**

product that optimizes a person's functioning and reduces disability

Note 1 to entry: See Annex B.3.3 of this document.

Note 2 to entry: Assistive products include devices, instruments, equipment, and software.

Note 3 to entry: Assistive products can be specially produced or generally available items.

[SOURCE: EN ISO 9999:2022, 3.3]

##### 3.3.1

##### **fixed assistive product**

product designed to be fastened to a support or otherwise secured in a specific location either by shape or fasteners, herein after referred to as fixed product

Note 1 to entry: Friction bath boards and friction toilet seats are excluded from this definition.

##### 3.3.2

##### **movable mobile assistive product**

equipment that, once installed and placed into service, is intended to be moved from one location to another while supported by its own wheels or equivalent means, herein after referred to as mobile product

##### 3.3.3

##### **movable portable assistive product**

equipment that, once installed and placed into service, is intended to be used with a user in place only when stationary and can be moved from one location to another without the user in place, herein after referred to as portable product

Note 1 to entry: Bath boards and toilet seats secured by friction are included.

### 3.4

#### **autonomy**

ability to perform intended tasks based on current state and sensing, without human intervention

Note 1 to entry: For a particular application, degree of autonomy can be evaluated according to the quality of decision making and independence from human. For example, metrics for degree of autonomy exist for medical electrical equipment in IEC/TR 60601-4-1.

[SOURCE: ISO 8373:2021, 3.2]

### 3.5

#### **backward**

180° to the forward direction of travel

### 3.6

#### **cleaning**

removal of foreign materials from a surface

### 3.7

#### **detachable part**

part designed to be unfastened or disconnected without damage to the part or the product

[SOURCE: EN ISO 20342-1:2022, 3.10]

### 3.8

#### **disinfection**

process to inactivate viable microorganisms to a level previously specified as being appropriate for a defined purpose

[SOURCE: EN ISO 11139:2018, 3.84]

### 3.9

#### **environment**

surrounding in which an assistive product can be used

#### 3.9.1

##### **home care environment**

a domestic area where the assistive product is used to alleviate or compensate for an injury, disability or disease

#### 3.9.2

##### **public area**

surroundings that are available for everyone. Examples are areas used for swimming, public restrooms etc.

### 3.10

#### **forward**

intended direction of travel, as indicated by the manufacturer in the instructions for use

### 3.11

#### **foreseeable misuse**

wrongful use which may be reasonably anticipated

### 3.12

#### **intended use**

#### **intended purpose**

use of a product, process or service intended for medical purposes in accordance with the specifications, instructions and information provided by the manufacturer

[SOURCE: EN ISO 14971:2019 + A11:2021, 3.6, modified — ‘intended for medical purposes’ added and Note 1 to entry deleted. ]

### 3.13

#### **load**

permissible weight

### 3.13.1

#### **maximum user mass**

greatest permissible weight of the *user* (3.26), specified by the manufacturer, intended to be supported by the *assistive product* (3.3)

### 3.13.2

#### **minimum user mass**

lowest possible weight of the *user* (3.26), specified by the manufacturer, needed for activating or using an *assistive product* (3.3)

### 3.13.3

#### **maximum load**

#### **safe working load**

greatest permissible weight on equipment or an equipment part during *normal use* (3.15)

Note 1 to entry: Depending on the type of assistive product, the maximum load can be either higher or lower than the user mass. In case of a product intended to carry both a user and an assistant and possibly accessories and other external load, such as water, the maximum load will be higher than the maximum user mass. In case of a product intended for the user to (just) lean on for support, the maximum user mass will be higher than the maximum load.

[SOURCE: EN 60601-1:2022, 3.109, modified — Note 1 to entry added.]

### 3.14

#### **mechanism**

system of parts working together

### 3.15

#### **normal use**

use of a product, process or service in accordance with the specifications, instructions and information provided by the manufacturer, not only intended for medical use but also maintenance, service, transport, etc.

Note 1 to entry: Normal use is not to be confused with intended use. While both include the concept of use as intended by the manufacturer, intended use focuses on the medical purpose while normal use incorporates not only the medical purposes, but also maintenance, service, transport, etc. "medical use" and "medical purpose" include the purpose of assistive products as described in 3.12.

### 3.16

#### **operator**

person handling the assistive product

Note 1 to entry: The operator can be any person handling the assistive product; the person with disability, an assistant or any other person who comes in contact with the product, e.g. a janitor.

### 3.17

#### **pendant control**

hand-held device, which has a functional connection to the *assistive product* (3.3), controlling, e.g. articulations and/or movements

Note 1 to entry: Pendant controls can be wired or wireless, and can integrate other functions, (e.g. communications, radio/TV, etc.).

[SOURCE: IEC 60601-2-52:2009, 201.3.214, modified — "medical bed" replaced with "assistive product", "at least" replaced with "e.g."]

### 3.18

#### **permanent deformation**

alteration in shape or structure of a previously normally formed part that will stay altered as the test is completed

### 3.19

#### **risk**

combination of the probability of occurrence of harm and the severity of that harm

### 3.20

#### **robot**

programmed actuated mechanism with a degree of *autonomy* (3.4) to perform locomotion, manipulation or positioning

Note 1 to entry: A robot includes the control system and interface of the control system.

[SOURCE: ISO 8373:2021, 3.3, modified — Example removed.]

### 3.21

#### **side rail**

physical barrier, which may be detachable or integral to the overall construction of an assistive product and is mounted to the side(s) of an assistive product.

Note 1 to entry: When a side rail is closed/fully raised, it provides a physical barrier, which is intended to reduce the risk of the person with disability accidentally slipping or rolling off the lying support surface.

[SOURCE: ISO 21856:2022, 2.8]

### 3.22

#### **single fault condition**

condition in which a single means for reducing a risk is defective or a single abnormal condition is present

Note 1 to entry: In this document, a single fault includes an error of the software.

[SOURCE: EN 60601-1:2006 + Cor.:2010 + A1:2013 + AC:2014 + A1:2013/AC:2014 + A12:2014 + A2:2021, 3.116, modified — Note 1 to entry added.]

### 3.23

#### **single patient multiple use**

intended by the manufacturer to be reused on an individual user

Note 1 to entry: A single patient multiple use medical device or accessory may require processing between uses

[SOURCE: EN ISO 20417:2021, 3.25]

### 3.24

#### **single use**

#### **do not re-use**

#### **use only once**

intended by the manufacturer to be used on an individual patient or specimen during a single procedure and then disposed of

Note 1 to entry: A single use medical device or accessory is not intended by the manufacturer to be further processed and used again.

[SOURCE: EN ISO 20417:2021 3.26]

### 3.25

#### **test cycle**

full cycle for the intended action

### 3.26

#### **user**

person who is lying, sitting or leaning on the product

Note 1 to entry: The user can be either the person with disability or an assistant.

## 4 General requirements and test methods

### 4.1 Risk analysis

The safety of an assistive product shall be assessed by identifying hazards and estimating the risks associated with them using the procedures specified in EN ISO 14971:2019 + A11:2021 and, if relevant, EN ISO 12100:2010.

When an assistive product is intended by the manufacturer to be used in combination with a device that is not a medical device, the resulting combination of the assistive product and device shall behave in a safe way as a system.

Risk management shall include all involved persons in normal use, and third persons (e.g. a child) in the surrounding coming into contact with the assistive product.

**NOTE** In the case of certain disabilities there may be a need for higher levels of safety for equipment used to offset the effects of that disability.

### 4.2 Intended performance

An assistive product shall have sufficient strength and durability to sustain all loads expected during intended use. This shall be confirmed by using, as appropriate, references to relevant clinical and scientific literature in addition to the requirements in this document, strength and/or durability calculations, appropriate test standards and their test results.

The intended performance including, if appropriate, strength, durability and tipping stability of an assistive product shall be described in the information supplied by the manufacturer which sets out its functional characteristics, its application(s) and conditions of use.

The information supplied by the manufacturer shall include, if appropriate, references to relevant clinical and scientific literature, any strength and/or life calculations, conformity with appropriate test standards and their test results.

### 4.3 Clinical evaluation and investigation

A clinical evaluation shall be done for all assistive products. If, as part of the product conformity assessment, the clinical evaluation requires a clinical investigation, the clinical investigation shall conform to the requirements of EN ISO 14155:2020. A clinical evaluation shall always be done before performing a clinical investigation.

### 4.4 Assistive products for personal hygiene that can be dismantled

If it is intended that an assistive product can be dismantled for storage, transportation and/or cleaning, the reassembly shall not create an unacceptable risk. Manufacturer's design and instruction shall not allow reassembly in a way that presents a hazard.

### 4.5 Fasteners

If it is intended that an assistive product can be dismantled for storage, transportation and/or cleaning, the fasteners which are loosened or removed to allow this dismantling shall not be single use fasteners.

**EXAMPLE** Single use fasteners include wood screws and self-tapping screws.

All load-bearing fasteners shall be either self-locking or fitted with a locking device to prevent inadvertent detachment.

## 4.6 User mass/load limits

The maximum user mass shall be declared. If the maximum load is different from the maximum user mass, both shall be declared by the manufacturer. The minimum user mass shall be declared if needed for the functioning of the assistive product.

All products with the intended purpose of supporting a user in a seated or lying position shall be capable of supporting a person with at least 100 kg body mass.

If a product is intended by the manufacturer to be used by a person of less than 100 kg body mass, there shall be a limitation in the design of the product to prevent the potential misuse by a person with higher body mass than the one stated by the manufacturer.

The maximum user mass and the maximum load as specified by the manufacturer shall be used in the relevant test methods of this document.

When the loading pad is used for testing, the mass thereof shall be taken into account for the test value of loading.

## 4.7 Apparatus

### 4.7.1 Means to apply a force

Between 25 N and 2 000 N with an accuracy of 5 % and with a rate of application less than 5 N/s.

### 4.7.2 Means to measure force

With an accuracy of 5 % in increments of 1 N in the range of 0 N to 2 000 N (occasionally larger forces than 2 000 N might be needed).

### 4.7.3 Means to measure distance

In the range of 0 m to 3 m with an accuracy of 5 mm or 2 % whichever is the greater.

### 4.7.4 Means to measure angles

To an accuracy of 0,25°.

### 4.7.5 Means to measure torque

With an accuracy of 5 % in increments of 1 Nm in the range of 0,5 Nm to 10 Nm.

### 4.7.6 Means to measure sound pressure levels

Calibrated in accordance with the apparatus manufacturer's instructions, using an acoustic calibrator class 1 as described in EN ISO 3746:2010 with an accuracy of 3 dB(A).

### 4.7.7 Test plane

A hard and horizontal and inclinable test plane of sufficient size to support the assistive product during testing, such that the whole surface is contained between two imaginary parallel planes 5 mm apart. A non-adjustable test plane can be used, if it is set to the correct angle.

NOTE A hardwood board (e.g. > 600 kg/m<sup>3</sup>) is an example of material used.

### 4.7.8 Stoppers

For mobile assistive products not smaller than half of the wheel diameter and not greater than the wheel diameter, see [Figure 1](#).

For portable assistive product the stopper shall be designed to prevent the assistive product from sliding, and not to prevent it from overturning. The height of the stopper shall be 12 mm or less. In the case where a stopper larger than 12 mm is required because of the construction of the assistive product, it shall be the minimum height required to prevent the assistive product from sliding.

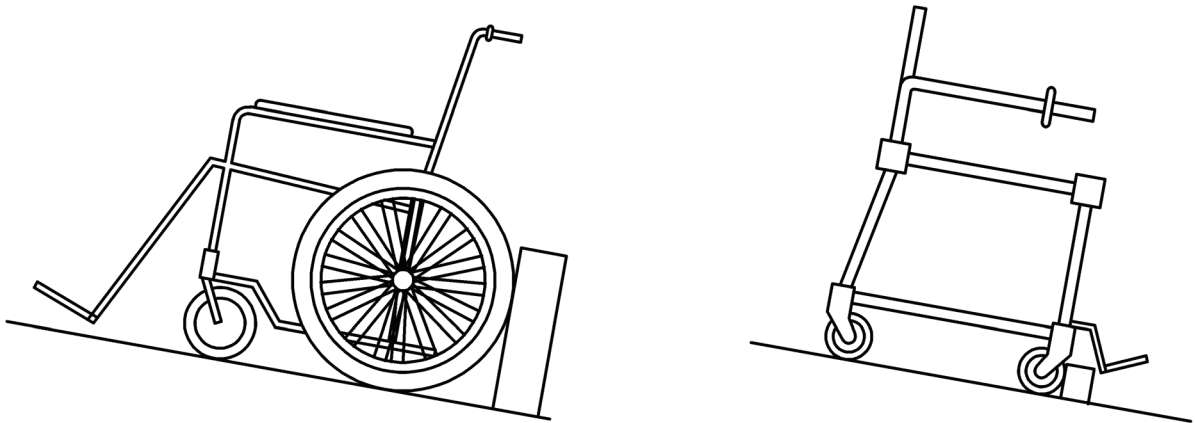


Figure 1 — Wheel-stopper

#### 4.7.9 Box

350 mm wide, 350 mm deep and 300 mm high.

#### 4.7.10 Equipment for applying loads

With negligible dynamic factor.

NOTE Negligible dynamic force is a small force that does not have a big impact.

#### 4.7.11 Equipment for measuring pressure of water, oil and air

With an accuracy of 5 %.

#### 4.7.12 Loading pads

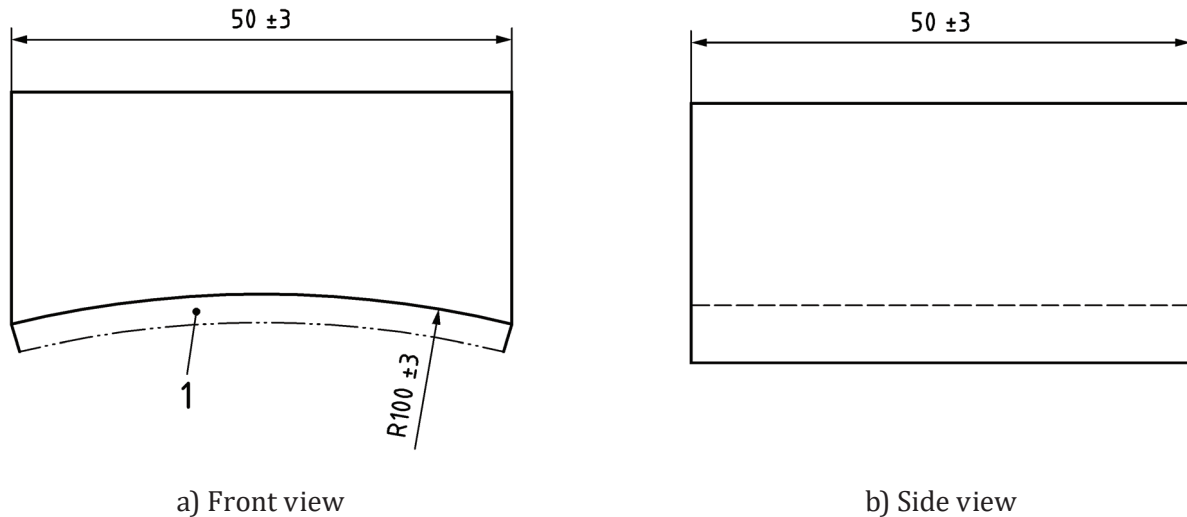
The loading surface of the loading pad should be covered with a layer of flexible foam with a bulk density of  $(120 \pm 25) \text{ kg/m}^3$ , 25 mm or 10 mm thick. The foam may be attached to the loading pads or alternatively positioned between the loading pad and the test structure.

##### 4.7.12.1 Concave loading pad

The loading device shall be capable of applying forces (compressive or tensile) in the range 15 N to 1 000 N with an accuracy of 3 %.

The concave loading pad for static loads shall be made of metal or hard wood as shown in [Figure 2](#).

Dimensions in millimetres

**Key**

1 loading surface

NOTE The loading surface may be covered with non-slip material up to 3 mm thick, e.g. plastic foam.

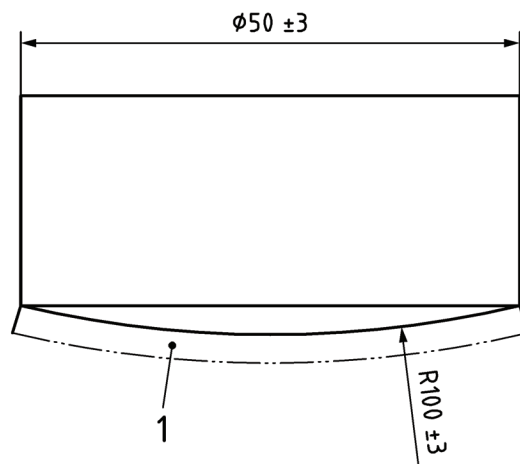
**Figure 2 — Concave loading pad for static loads (Source: ISO 7176-8:2014, 5.2)**

#### 4.7.12.2 Convex loading pad

The loading device shall be capable of applying forces (compressive or tensile) in the range 15 N to 1 000 N with an accuracy of 3 %.

The convex loading pad shall be circular and made of metal or hard wood, as shown in [Figure 3](#).

Dimensions in millimetres

**Key**

1 loading surface

NOTE The loading surface may be covered with non-slip material up to 3 mm thick e.g. plastic foam.

**Figure 3 — Convex loading pad for static loads (Source: ISO 7176-8:2014, 5.3)**

#### 4.7.12.3 Back support loading pad

The loading device shall be capable of applying forces (compressive or tensile) in the range 15 N to 2 000 N to an accuracy of 3 %.

The loading pad shall be made of metal or hard wood and have the shape and dimensions as shown in [Figure 4](#).

Dimensions in millimetres

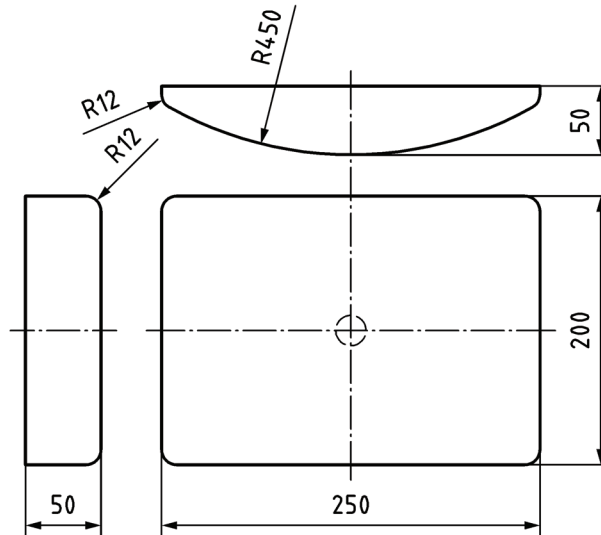
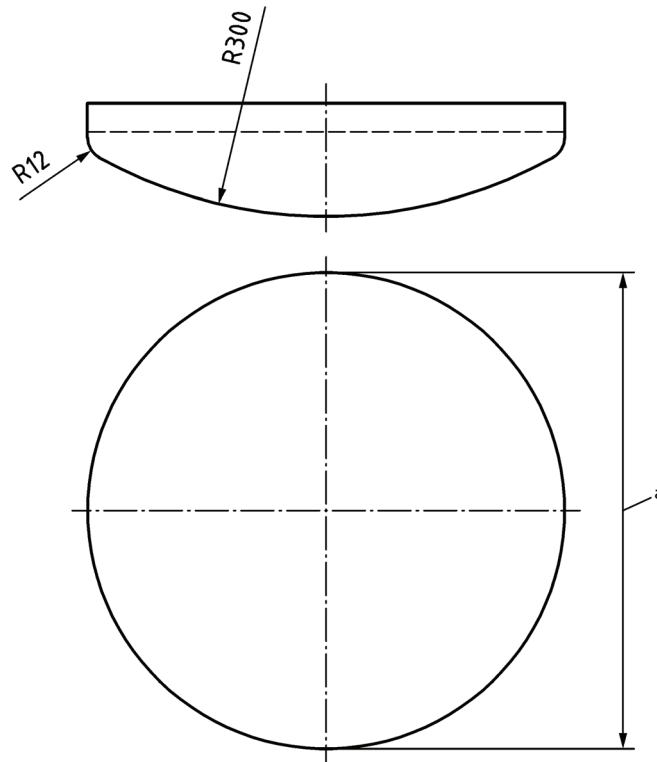


Figure 4 — Loading pad for back support (Source: EN 1728:2014, 5.6)

#### 4.7.12.4 Seat loading pad

The loading pad shall be made of metal or hard wood and have the shape and dimensions as shown in [Figure 5](#) with rounded edges, with various diameters depending on the test item.

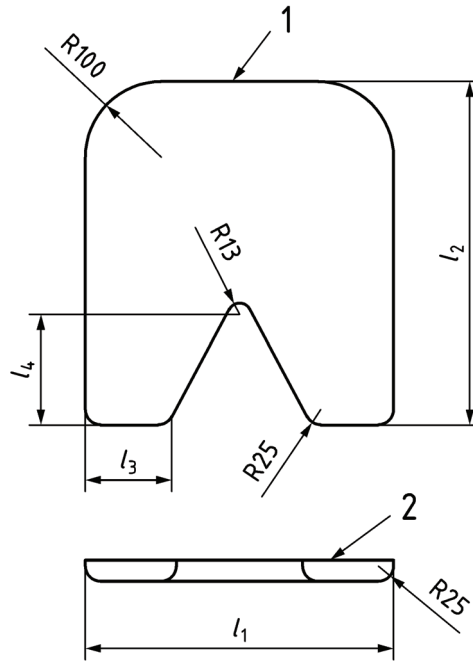


<sup>a</sup> Diameter 350 mm, 250 mm or 200 mm.

**Figure 5 — Loading pad for seat support surface (Source: EN 1728:2014, 5.5)**

#### 4.7.12.5 Thigh loading plate

Alternative to the seat loading pad, a thigh loading plate can be used. It could be relevant if the seat has an aperture. Dimensions as in [Table 1](#).

**Key**

1 rear edge

2 upper face

 $l_x$  see [Table 1](#) for dimensions 1-4Tolerances on radii shall be  $\pm 5$  mm**Figure 6 — Thigh loading plate (Source: ISO 7176-11:2012, 7.3)****Table 1 — Dimensions of thigh loading plates**

| Dummy mass range<br>kg            | $l_1$<br>mm | $l_2$<br>mm | $l_3$<br>mm | $l_4$<br>mm |
|-----------------------------------|-------------|-------------|-------------|-------------|
| $25 \leq m_{\text{dummy}} < 50$   | 200         | 300         | 80          | 150         |
| $50 \leq m_{\text{dummy}} < 75$   | 260         | 350         | 100         | 175         |
| $75 \leq m_{\text{dummy}} < 100$  | 320         | 380         | 105         | 160         |
| $100 \leq m_{\text{dummy}} < 125$ | 380         | 420         | 110         | 135         |
| $125 \leq m_{\text{dummy}} < 150$ | 430         | 440         | 115         | 110         |
| $150 \leq m_{\text{dummy}} < 175$ | 480         | 440         | 120         | 100         |
| $175 \leq m_{\text{dummy}} < 200$ | 530         | 440         | 120         | 100         |
| $200 \leq m_{\text{dummy}} < 250$ | 570         | 440         | 120         | 100         |
| $250 \leq m_{\text{dummy}} < 300$ | 630         | 440         | 120         | 100         |
| $300 \leq m_{\text{dummy}}$       | 680         | 440         | 120         | 100         |

The tolerance for all linear dimensions shall be  $\pm 15$  mm.

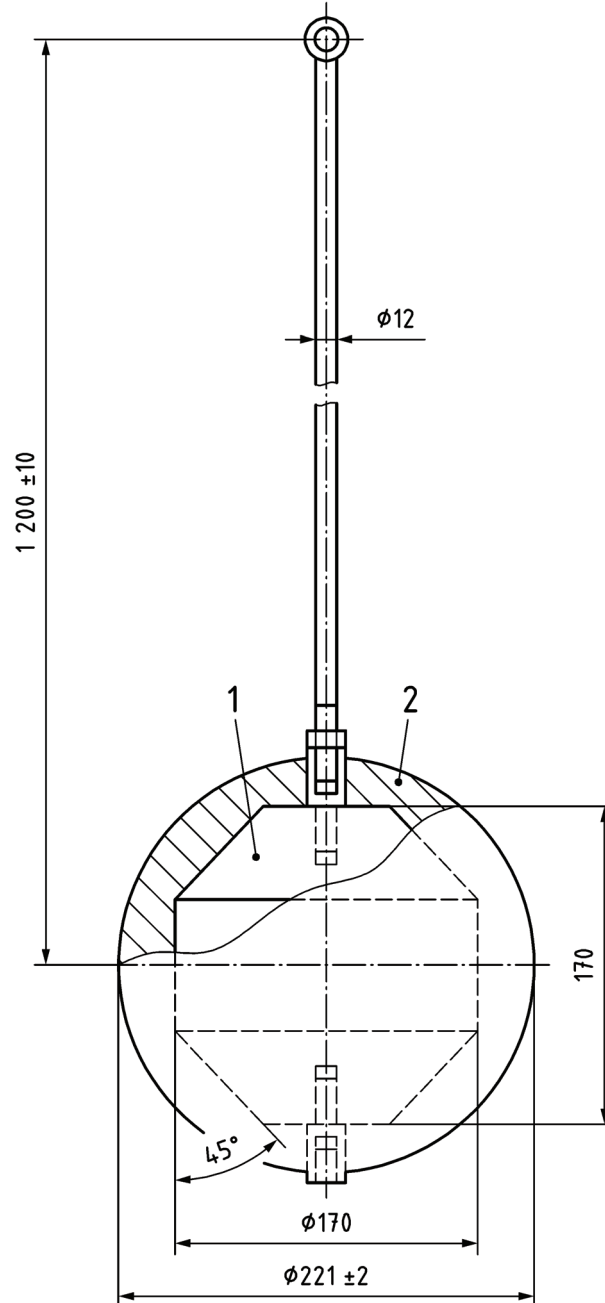
NOTE The dimensions are derived from seating dimensions typically provided for wheelchairs in each specified occupant mass range.

### 4.7.13 Equipment for impact test

#### 4.7.13.1 Back support impact test pendulum

The back support impact test pendulum shall meet the requirements in [Figure 7](#) or [Figure 8](#).

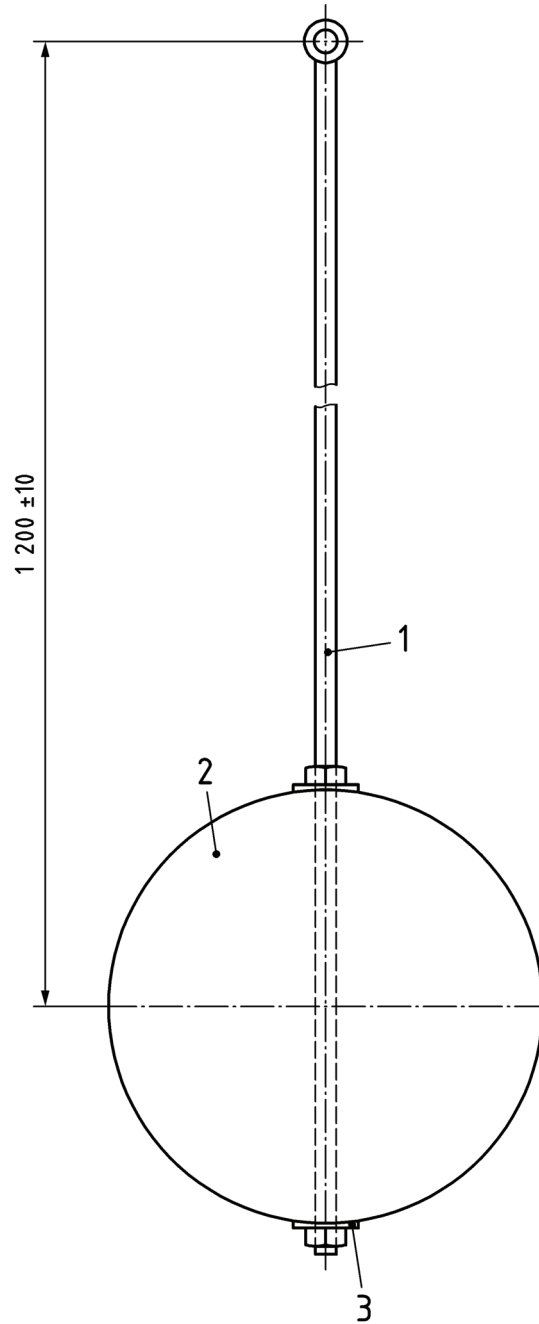
Dimensions in millimetres



#### Key

- 1 steel block
- 2 polyurethane with the following specifications:  
Density: 1 150 kg/m<sup>3</sup>; Hardness: 80+ shore A; Resilience: 20 %. The total mass of the ball shall be 25 kg ± 0,5 kg.

**Figure 7 — Back support impact test pendulum (Source: ISO 7176-8:2014, 5.5)**

**Key**

- 1 threaded bar
- 2 regulation association football (soccer ball size 5), with a diameter of 220 mm filled with lead shot ( $3,5 \pm 1$ ) mm diameter and closed cell high density foam of Density: ( $75 \pm 15$ ) kg/m<sup>3</sup> (according to EN ISO 845:2009); Hardness: ( $325 \pm 60$ ) N (according to EN ISO 2439:2008)
- 3 washer

**Figure 8 — Alternative back support pendulum (Source: ISO 7176-8:2014, 5.5)**

#### 4.7.13.2 Toilet seat impact test pendulum

With the following properties:

- a) total mass  $10 \text{ kg} \pm 0,25 \text{ kg}$ ;

b) distance ( $d$ ) from pivot to centre of percussion  $1,000 \text{ m} \pm 0,005 \text{ m}$ .

The impact test pendulum shown in [Figure 9](#) may be used although other shapes may be required to accommodate different layouts and sizes.

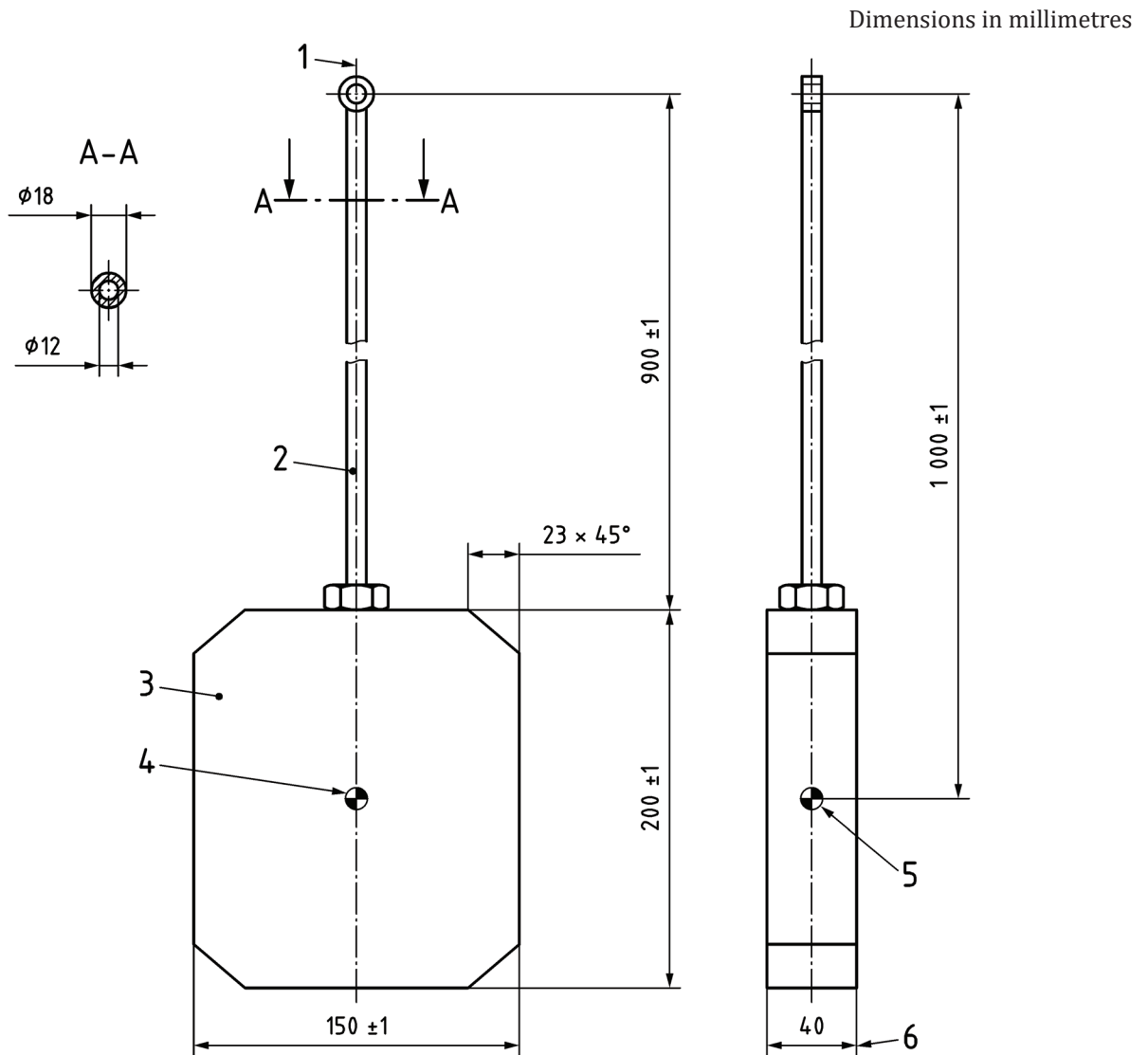
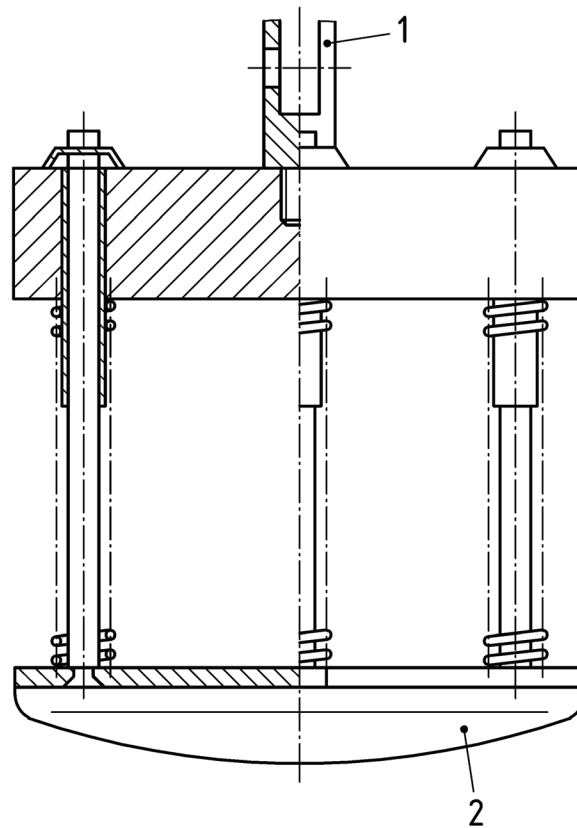


**Figure 9 — Example of toilet seat impact test pendulum (Source: ISO 7176-8:2014, 5.6)**

#### 4.7.13.3 Lying support impactor

Which has the following properties.

- The impactor body is approximately 200 mm in diameter and is separated from the striking surface by helical compression springs. The body is free to move on a line perpendicular to the plane of the central area of the striking surface.
- The total mass of the assembly shall be  $25 \text{ kg} \pm 0,1 \text{ kg}$  and the body and its associated parts (minus the springs) shall have a mass of  $17 \text{ kg} \pm 0,1 \text{ kg}$ .
- The combined spring rate (for the system) shall be  $6,9 \text{ N/mm} \pm 1 \text{ N/mm}$  and the total friction resistance of the moving parts is between 0,25 N and 0,45 N. When the spring system is compressed to a load of  $1\,040 \text{ N} \pm 5 \text{ N}$ , the remaining compression distance shall be 60 mm minimum. The striking surface shall be a rigid circular object,  $(200 \pm 5) \text{ mm}$  in diameter, the face of which has a convex spherical curvature of 300 mm radius with a 12 mm front edge radius. See [Figure 10](#).



#### Key

- joint of lifting device not inhibiting free fall
- striking surface

Figure 10 — Lying support impactor

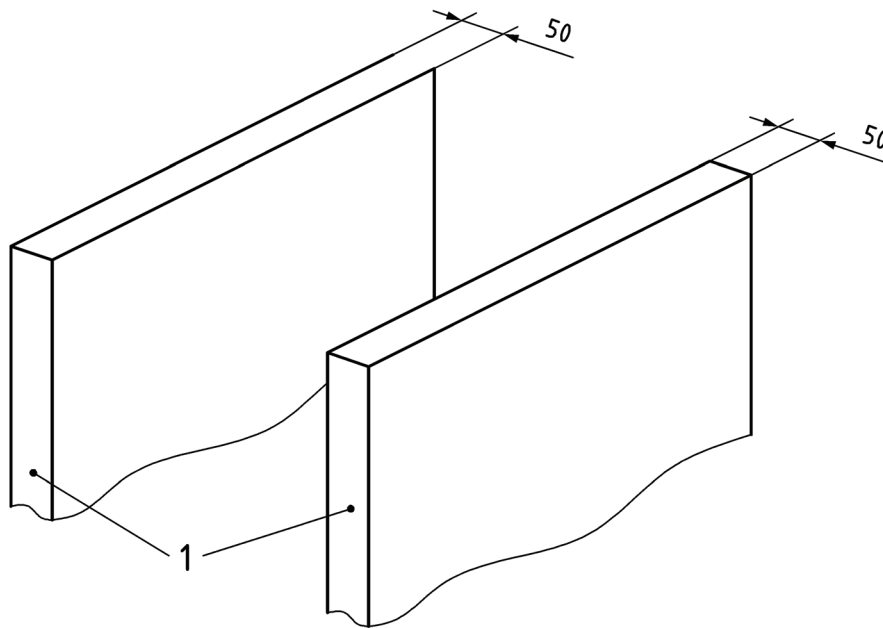
#### 4.7.14 Supporting stands

Flat, of appropriate materials. The height shall be  $1 \text{ m} \pm 0,1 \text{ m}$ , the width of upper surface shall be  $50 \text{ mm} \pm 5 \text{ mm}$  and the side wall shall be perpendicular to the upper surface (see [Figure 11](#)). The stands shall have an adjustable width and angle seen from distance at the bottom and top in order to accommodate for positioning of different designs.

It shall be possible to adjust the upper surface so that it always stays horizontal when used at different angles.

EXAMPLE A bathtub can have sloped sides which the supporting stands can simulate.

Dimensions in millimetres



**Key**

1 supporting stand

**Figure 11 — Supporting stand**

**4.7.15 Small parts cylinder**

The small parts cylinder shall have the dimensions specified in [Figure 12](#).

Dimensions in millimeters

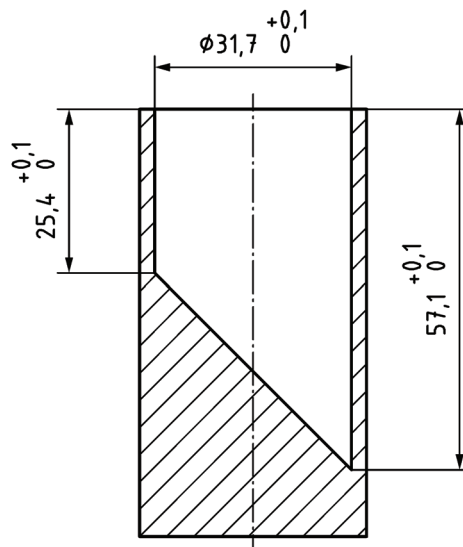


**Figure 12 — Small parts cylinder (SOURCE: ISO 31110:2020, Figure 22, modified)**

#### 4.7.16 Obstruction

An obstruction to be fixed on the floor, with a rectangular cross-section, 10 mm high and at least 80 mm wide with a radius of 2 mm at the top edges.

#### 4.7.17 Hardwood vertical obstacle

An obstacle to be affixed to a vertical rigid support (e.g. concrete) with a width and thickness of 40 mm. The height of the obstacle shall be at the same level as the height of the contact points of the assistive product.

### 4.8 Test conditions

The product shall be tested in the as-delivered state (to the customer). However, if the product is of a multi-purpose design that can be assembled in different formats, it shall be assembled according to instructions given by the manufacturer. If the product is intended to be used in different combinations, then the most adverse combination shall be tested. If the product is delivered disassembled it shall be assembled according to manufacturer's instructions before testing.

Unless otherwise specified, the tests shall be performed under normal indoor conditions:

- with temperatures between 15 °C and 30 °C;
- with humidity between 20 % RH and 85 % RH.

All tests shall be performed on a single product. A new product can be chosen if the original test object breaks down and cannot be repaired. Some tests relevant to the safe functioning of the product might have to be repeated on the new product. This is up to the manufacturer of the product to consider in each separate case.

If the product is tested by a test house, the decision shall be taken in cooperation between the third party and the manufacturer.

Unless otherwise stated in a specific clause of this document the order of tests is not important.

## 5 Materials

### 5.1 General

Manufacturers should, wherever possible, use materials that can be recycled for further use.

See also [clause 26.2.3](#).

### 5.2 Flammability

#### 5.2.1 General

Manufacturers shall consider the environments and methods of use to which an assistive product or any materials that are usually used in combination with this assistive product, will be exposed to and take appropriate steps to minimize any fire hazard.

The manufacturer shall include a warning in the instruction for use about safe combination of flame-retardant and non-flame-retardant materials.

NOTE 1 If flammable materials are used, it can be displayed on an easily recognizable label on the assistive product and indicated in the documentation.

If the manufacturer's risk management process determines that there is significant risk of product combustion, an easily recognizable warning label shall be applied to the assistive product and indicated in the documentation.

Every effort should be made to use materials that meet the flammability requirements as it is of particular importance to persons with disability who might not be able to escape from a fire. The use of non-flame-retardant materials should be reviewed regularly, as there is continuous development in this field.

Where possible, the efficacy of any flame-retarding agents should last for the lifetime of the product, and the manufacturer should advise the user of cleaning or care requirements to ensure the continued efficacy of a flame-retardant. Should the flame-retardant effect not last the lifetime of the product, the manufacturer shall warn and advise the user (for example, the number of washes that will remove the flame-retardant effect).

Special attention shall be paid to assistive products where the main purpose is protection from fire.

NOTE 2 For guidance, see [B.5.2](#).

Manufacturers should identify the relevant standards for their intended uses and specify which test methods the product passes in relevant documentation, product tags and labelling as appropriate and required by statute, if relevant.

If the manufacturer claims that an assistive product is resistant to ignition, it shall comply with the appropriate requirements in [5.2.2](#), [5.2.3](#), [5.2.4](#), and/or [5.2.5](#).

If the clinical requirements prevent the use of materials that comply with the above-mentioned appropriate requirements, the manufacturer shall adopt appropriate means to eliminate or reduce, as far as reasonably practicable, the risk of hazardous situations developing from the ignition of the assistive product, using the risk management process specified in EN ISO 14971:2019 + A11:2021. In this case, the assistive product shall be supplied with the following:

- a warning that the assistive product is not flame retardant, placed on the product if possible, and included in the instructions for use; and
- a description of the precautions required to mitigate the increased risk.

### 5.2.2 Upholstered parts

If the manufacturer claims that the upholstered parts are resistant to ignition, then progressive smouldering ignition and flaming ignition shall not occur when the materials used for the upholstered parts of an assistive product are tested in accordance with EN 1021-2:2014 or ISO 8191-2:1988.

### 5.2.3 Other soft parts

If the manufacturer claims that other parts are resistant to ignition, then progressive smouldering ignition and flaming ignition shall not occur when the materials used for the other soft parts of an assistive product are tested in accordance with EN 1021-2:2014 or ISO 8191-2:1988.

For sling seats, sling backs, belts, restraint harnesses, foot supports and clothing guards, the material of each item shall be tested with the source applied centrally to surface intended to contact or support the user by the methods specified in EN 1021-2:2014 or ISO 8191-2:1988.

### 5.2.4 Polymeric parts

If the manufacturer claims that a polymeric part is resistant to ignition, then progressive smouldering ignition and flaming ignition shall not occur when tested in accordance with FV-1 of IEC 60695-11-10:2013 or better. If the product is of a type that the user normally (by himself) cannot escape from or detect as a dangerous situation it shall be FV-0.

### 5.2.5 Wiring

Insulated wiring shall have a flammability classification according to IEC 60332-1-2:2015 and/or ANSI/UL 1581:2023 with classification WW-1, or better.

### 5.3 Biocompatibility and toxicity

Materials which come into contact with the human body shall be assessed for biocompatibility using the guidance in EN ISO 10993-1:2020.

The assessment shall also take into account the intended use and contact by those involved in user care. The result of the assessment shall be incorporated in the risk analysis (see [4.1](#)).

The assistive products shall be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the assistive product. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction and other substances of very high concern (SVHCs).

The assessment should follow the guidance given in [Annex C](#).

### 5.4 Infection and microbiological contamination

#### 5.4.1 Cleaning and disinfection

The method and suitable cleaning or disinfection materials shall be described in the instructions for use.

The degree of cleaning and/or disinfection needs to be appropriate for the use of the assistive product being processed. For guidance for medical devices, see EN ISO 17664-2:2021.

Where an assistive product is intended to be cleaned by automatic washing systems or hand-held jet stream/steam washing the details of the procedure, such as temperature, pressure, flow and pH value of cleaning/rinsing solution shall be described in the instructions for use. Where practicable, the assistive product shall be labelled with appropriate symbols to represent the method of cleaning. See examples of labelling in [B.5.4.1](#).

##### 5.4.1.1 Machine washable assistive products

###### 5.4.1.1.1 Requirements for machine washable assistive products

Assistive products specified by the manufacturer to be machine washable by an automatic machine-washing system shall function normally after the test. variations to the test procedure regarding test cycle, temperature, time and cleaning fluids shall be covered in the risk management file of the manufacturer.

NOTE Requirements for automated washer-disinfectors for medical devices are covered by ISO 15883 series.

###### 5.4.1.1.2 Test method for machine washable assistive products

Perform 50 test cycles according to the procedure the manufacturer described in the instruction for use.

###### 5.4.1.1.3 Performance criteria

- 1) Immediately after the test cycles, the assistive product is connected to the energy source, if applicable; no unintentional movements should arise;
- 2) The assistive product should function as specified by the intended use at the following intervals:
  - i) immediately after the test cycles;
  - ii) 60 min ( $\pm 5$  min) after the test cycles;
  - iii) 24 h ( $\pm 30$  min) after the test cycles.
- 3) Perform dielectric strength and leakage current tests according to IEC 60601-1:2005+AMD1: 2012+AMD2: 2020 at the following intervals:
  - i) immediately after the test cycles;

- ii) 24 h ( $\pm 30$  min) after the test cycles.
- 4) Perform a visual inspection for ingress of water that may result in an unacceptable risk (e.g. shorting of isolation barriers and violation of creepage distances).

NOTE For some assistive products, not all performance criteria apply.

#### 5.4.1.2 Marking for machine washable assistive products

Assistive product(s) intended for use with an automatic washing system shall be marked with the following text to distinguish them from assistive product(s) that cannot tolerate such cleaning methods:

“For cleaning purposes this product can be used with automatic washing systems” or they shall be provided with a label depicting the symbol in [B.5.4.1](#).

#### 5.4.2 Animal tissue

Where a device has been manufactured utilising tissues of animal origin or their derivatives, a risk assessment shall be performed and documented according to EN ISO 22442-1:2020.

NOTE For guidance see [B.5.4.2](#).

### 5.5 Resistance to corrosion

The risk of corrosion affecting the safety of the user, or an assistant shall be assessed in the risk analysis. Assistive products that are identified to be at risk of corrosion shall be sufficiently protected against corrosion, which can be assessed by using the salt spray test according to EN ISO 9227:2022 with a test duration of 72 hours.

The environment in which the product is to be used and cleaning solutions shall be taken into consideration.

## 6 Emitted sound and vibration

### 6.1 Noise and vibration

If noise and vibration are not part of the intended performance of an assistive product, hazards and nuisance from noise and vibration shall be assessed in the risk analysis (see [4.1](#)).

Measurements of noise from a power operated assistive product shall be made in accordance with EN ISO 3746:2010, and the result of the measurement shall be disclosed in the pre-sale information and in the instructions for use.

NOTE For guidance see [B.6.1](#).

### 6.2 Sound pressure levels and frequencies of audible warning devices

The frequency shall be within 500 Hz and 3 000 Hz.

NOTE Normal hearing is usually within the frequency range 500 Hz to 16 000 Hz. For people with hearing disabilities the range will be less and in severe cases down to 500 Hz to 3 000 Hz.

A-weighted sound pressure levels shall be at least 65 dB for audible alarms.

The alarm or feedback signal shall be distinguished from the noise of the product itself either by frequency or sound level.

## 7 Electromagnetic compatibility

An assistive product containing electrical or electronic devices/components shall comply with requirements of EN IEC 60601-1-2:2021.

For guidance see [B.7](#).

## 8 Electrical safety

### 8.1 General

An electrically operated assistive product shall conform to EN 60601-1:2006 + Cor.:2010 + A1:2013 + AC:2014 + A1:2013/AC:2014 + A12:2014 + A2:2021 regarding clauses on electrical safety unless requirements are covered by this document. For electrical safety covered by both standards, the requirements of this document prevail over the ones given in EN 60601-1:2006 + Cor.:2010 + A1:2013 + AC:2014 + A1:2013/AC:2014 + A12:2014 + A2:2021.

For guidance on circuit protection, see [B.8.1](#).

For assistive products intended to be used in home care environment EN 60601-1-11:2015 + A1:2021 shall be applied.

When software is used to control the motion of the assistive product, requirements in EN 60601-1:2006 + Cor.:2010 + A1:2013 + AC:2014 + A1:2013/AC:2014 + A12:2014 + A2:2021, Clause 14 shall apply.

In addition, [8.2](#), [8.3](#), [8.4](#), [8.5](#) shall apply.

For robotic assistive products, functional safety design as stipulated in IEC 61508 (all parts) and ISO 13849 (all parts) may be used.

### 8.2 Battery powered assistive products – charge level indicator

If the safety of a person using an internally powered assistive product depends upon the power supply, a means of informing the operator of the state of the charge of the power supply shall be provided.

At the time of indicating the critical charge, sufficient reserve charge of the internal power supply shall be available to allow a timely reaction.

**NOTE** A timely reaction can be either recharging or replacing the power supply without interruption of the availability of the power or by allowing the return to a place that provides the possibility to recharge/replace the internal power supply.

There shall be some kind of indication of the status of the battery that is adapted to all kind of users, e.g. persons with a visual or a hearing disability.

For guidance see ISO/IEC guide 71:2001, Tables 5 and 6.

See [Annex E](#) for special considerations regarding Lithium batteries.

### 8.3 Electrically heated blankets, pads and similar flexible heating appliances

An electrically heated blanket, pad or similar flexible heating appliances shall fulfil the requirements in EN IEC 60601-2-35:2021.

### 8.4 Ingress of liquids or particulate matter

#### 8.4.1 Ingress of liquids

Enclosures shall be classified according to the degree of protection against harmful ingress of water as detailed in IEC 60529:2019.

Conformity is checked by tests in IEC 60529:2019 with the assistive product placed in the least favorable position for normal use within 5 minutes after the water test and after 1 hour to verify its functions.

Assistive products that are not in contact with water during normal use or reasonably foreseeable misuse (e.g. during the cleaning process) shall at least be protected to IPX2.

Assistive products that are normally in contact with water or body fluids shall at least be protected to IPX4 and assistive products that are available in public areas at least IPX5.

Assistive products that are temporarily submerged into water during normal use shall at least be protected to IPX7.

Assistive products that are normally submerged into water during normal use shall at least be protected to IPX8.

#### 8.4.1.1 Requirements

If liquid can come into an enclosure unintentionally, there shall be a way for the liquid to get out of the enclosure, or the liquid shall not cause any harm. The hazards that can be caused by the ingress of liquids to non-electrically powered assistive products shall be assessed in the risk analysis and management.

Test if the liquid can get out of the enclosure by tilting it 10° in each direction. If there is still liquid in the enclosure, test if the equipment fails to work, or if the liquid is likely to cause any harm.

#### 8.4.2 Ingress of particulate matter

If applicable, enclosures shall be classified according to the degree of protection against harmful ingress of particulate matter as detailed in IEC 60529:2019.

Conformity with the requirements in EN 60601-1:2006 + Cor.:2010 + A1:2013 + AC:2014 + A1:2013/AC:2014 + A12:2014 + A2:2021, 5.9.2 accessible parts (test finger) automatically ensures a protection rating of minimum IP2X according to IEC 60529:2019.

### 8.5 Pendant controls

If there is a risk of a pendant control falling to the floor, it shall not result in an unacceptable risk as a result of a free fall.

Conformity is checked by the following tests:

- The pendant control shall fall 1 000 times from a height of 1 meter as specified in IEC 60068-2-31:2008.
- After the test, the pendant control is checked by inspection, functional test and relevant electrical safety tests.

## 9 Overflow, leakage, and ingress of liquids

### 9.1 Ingress of liquids

#### 9.1.1 Requirements

If liquid can come unintentionally into an enclosure there shall be a way for the liquid to get out of the enclosure, or the liquid shall not cause any kind of hazard.

The hazards that can be caused by the ingress of liquids to non-electrically powered assistive products shall be assessed in the risk analysis (see [4.1](#)).

NOTE 1 See [B.9.1](#).

NOTE 2 For requirements for electrically powered assistive product, see [8.4.1](#).