
Assistive products for personal hygiene that support users — Requirements and test methods

*Produits d'assistance pour l'hygiène personnelle soutenant les
utilisateurs — Exigences et méthodes d'essai*





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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.

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).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: [Foreword - Supplementary information](#)

The committee responsible for this document is ISO/TC 173, *Assistive products for persons with disability*.

Introduction

This International Standard specifies requirements and test methods that are relevant to assistive products for personal hygiene that support users in home care, institutions and public places. Some of the devices can be used in more than one environment. This means that different requirements and test methods can be applied to the same product depending on the environment. [Clauses 1 to 21](#) and [Clause 25](#) contain general requirements for all types of products included in the Scope. [Clauses 22 to 24](#) contain specific requirements for mobile, fixed and static products. These clauses indicate additional requirements to the general clauses. In order for a product to claim compliance with this International Standard, 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 International Standard, [Annex B](#) gives general recommendations.

Assistive products for personal hygiene that support users — Requirements and test methods

1 Scope

This International Standard specifies requirements and associated test methods for assistive products for personal hygiene (APPHs) that support users and which are intended by the manufacturer to alleviate or compensate for disability. The work environment and safety aspects for assistants are also included. It specifies safety and performance requirements that apply during normal use and foreseeable misuse and failure. It also specifies methods of measurement of the forces necessary to operate controls and specifies limits on the forces needed for some operations.

This International Standard specifies requirements and test methods for assistive products within the following divisions of ISO 9999:2011:

09 12 03 Commode chairs;

NOTE This covers mobile and static products.

09 12 06 Toilets with built in raising and height adjustable mechanism;

NOTE This excludes toilets with built-in douche and air dryers.

09 12 09 Toilet seats;

09 12 12 Raised toilet seats mounted on frame;

09 12 15 Toilet seats inserts;

09 12 18 Raised toilet seats fixed to toilet;

09 12 21 Toilet seats with built-in raising mechanism to help standing up and sitting down;

09 12 24 Toilet arm supports and toilet back supports mounted on 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;

09 33 03 Bath/shower chairs (with and without wheels), bath boards, stools, back supports and seats;

09 33 12 Bathing stretchers, shower tables and diaper-changing tables;

18 15 06 Height adjustable plinths and brackets;

NOTE Refers to height adjustable plinths and brackets when used as an assistive product for personal hygiene (APPH). Height adjustable mechanisms for other items such as basins may be included.

18 18 03 Handrails and support rails;

18 18 06 Fixed grab bars and handgrips;

18 18 10 Removable grab rails and handgrips;

NOTE This excludes removable grab rails and handgrips which are static as defined in [3.27](#).

18 18 11 Hinged rails and arm supports;

This International Standard does not encompass requirements regarding:

- safe mounting in building structures;
- requirements regarding fixed building installations e.g. water and electricity;
- bathtub hoists that are covered by ISO 10535;
- 09 33 21 Bathtubs of ISO 9999:2011;
- 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 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.

CISPR 11, *Industrial, scientific and medical (ISM) radio-frequency equipment — Electromagnetic disturbance characteristics — Limits and methods of measurement*

ISO 3746, *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 8191-1, *Furniture — Assessment of the ignitability of upholstered furniture — Part 1: Ignition source: smouldering cigarette*

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

ISO 9227, *Corrosion tests in artificial atmospheres – Salt spray tests*

ISO 9999:2011, *Assistive products for persons with disability — Classification and terminology*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 12100, *Safety of machinery — General principles for design — Risk assessment and risk reduction*

ISO 13850, *Safety of machinery – Emergency stop – Principles for design*

ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

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

ISO 15223-1, *Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements*

ISO 22442-1, *Medical devices utilizing animal tissues and their derivatives – Part 1: Application of risk management*

IEC 60335-1, *Household and similar electrical appliances – Safety – Part 1: General requirements*

IEC 60529, *Degrees of protection provided by enclosures (IP Code)*

IEC 60601-1:2005+A1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-2:2014, *Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests*

IEC 60601-2-35, *Medical electrical equipment – Part 2: Particular requirements for the safety of blankets, pads and mattresses, intended for heating in medical use*

IEC 61000-3-2, *Electromagnetic compatibility (EMC) — Part 3-2: Limits — Limits for harmonic current emissions (equipment input current ≤ 16 A per phase)*

IEC 61000-3-3, *Electromagnetic compatibility (EMC) — Part 3-3: Limits – Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16 A per phase and not subject to conditional connection*

IEC 61000-4-3, *Electromagnetic compatibility (EMC) — Part 4-3: Testing and measurement techniques — Radiated, radio-frequency, electromagnetic field immunity test*

IEC 61000-4-8, *Electromagnetic compatibility (EMC) — Part 4-8: Testing and measurement techniques — Power frequency magnetic field immunity test*

IEC 60695-11-10, *Fire hazard testing – Part 11-10: Test flames – 50 W horizontal and vertical flame test methods*

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

EN 1041, *Information supplied by the manufacturer of medical devices*

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

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

applied part

part of device that in normal use necessarily comes into physical contact with the occupant to perform its function

3.2

APPH

assistive product for personal hygiene

assistive product ([3.3](#)) intended to support personal hygiene

3.3

assistive product

any product (including devices, equipment, instruments and software), especially produced or generally available, used by or for persons with disability

- for participation;
- to protect, support, train, measure or substitute for body functions/structures and activities; or
- to prevent impairments, activity limitations or participation restrictions

[SOURCE: ISO 9999:2011, definition 2.3]

3.4

assistant

person who operates the assistive product if not the person with disability

3.5

backward

180° to the forward direction of travel

3.6

cleaning

removal of foreign materials from a surface

3.7

disinfection

the act of disinfecting, using specialized cleansing techniques that destroy or prevent growth of organisms capable of infection

3.8

essential performance

performance necessary to achieve freedom from unacceptable risk

Note 1 to entry: Essential performance is most easily understood by considering whether its absence or degradation would result in an unacceptable risk.

3.9

fixed product

product designed to be fastened to a support or otherwise secured in a specific location

EXAMPLE 1 Fixed by the shape of the fixation and not by friction.

EXAMPLE 2 Products permanently affixed by welding.

EXAMPLE 3 Products affixed by means of fasteners such as screws, nuts, vacuum, etc.

Note 1 to entry: A fixed product can have moving parts.

Note 2 to entry: Friction bath boards and friction toilet seats are excluded from this definition.

3.10

forward

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

3.11

foreseeable misuse

misuse which may be reasonably anticipated

3.12

hand-held product

assistive product intended to be supported by the hand during normal use

3.13

home care

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

Note 1 to entry: See IEC 60601-2-52:2010, subclause 201.3.204.

3.14

institution

established or organized society, usually with its own premises

EXAMPLE Hospital, rehabilitation, residential care or educational facility.

3.15

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: ISO 14971:2007, definition 2.5, modified]

3.16**maximum load**

greatest permissible load specified by the manufacturer

3.17**maximum user mass**

greatest permissible mass of the user, specified by the manufacturer, intended to be supported by the assistive product

3.18**mobile product**

transportable equipment intended to be moved from one location to another while being supported by its own wheels or equivalent means

3.19**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.

3.20**occupant**

person in or on an assistive product with a support surface

3.21**operator**

person who operates the assistive product

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

3.22**permanent deformation**

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

3.23**portable product**

transportable equipment intended to be moved from one location to another while being carried

3.24**public use**

use of a product in a surrounding that is available for everyone

Note 1 to entry: Public use includes areas for swimming, public restrooms etc.

3.25**risk**

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

3.26**single fault condition**

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

3.27**static product**

product intended to be stationary with the occupant in place during its intended use and not intended to be fastened to a support or otherwise secured in a specific location

Note 1 to entry: A static product may be portable in normal use. It may have moving parts during intended use.

Note 2 to entry: Bath boards and toilet seats secured by friction are included.

3.28

system

set or series of interconnected or interdependent parts or entities that act together in a common purpose or produce results that are impossible by the action of one alone

3.29

test cycle

full cycle for the intended action

3.30

user

person who uses/occupies the device

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 APPH shall be assessed by identifying hazards and estimating the risks associated with them using the procedures specified in ISO 14971 and, if relevant, ISO 12100.

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

NOTE 1 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 APPH 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 International Standard, 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 APPH 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

If the risk management demonstrates a need for a clinical evaluation, a clinical evaluation shall be done for all APPHs. If, as part of the product conformity assessment, the clinical evaluation requires a clinical investigation, the clinical investigation shall conform to the requirements of ISO 14155. 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 APPH can be dismantled for storage or transportation, it shall not be possible to reassemble it in a manner that presents a hazard.

4.5 Fasteners

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. Bolts are examples of fasteners that can be used more than once.

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

4.6 Means to prevent falling out

If there is a risk of the user falling out of the product during normal use, means to prevent the user falling out shall be available, e.g. side rails, a seat belt or a harness.

4.7 User mass/load limits

The maximum user mass shall be declared. If the maximum load is different both shall be declared by the manufacturer.

All products with the intended purpose of supporting an occupant/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 International Standard.

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

4.8 Apparatus

4.8.1 Means to apply a force between 25 N and 2000 N with an accuracy of $\pm 5\%$ and with a rate of application less than 5 N/s.

4.8.2 Means to measure force with an accuracy of $\pm 5\%$ in increments of 1 N in the range of 0 N to 2000 N (occasionally larger forces than 2000 N might be needed).

4.8.3 Means to measure distance in the range of 0 m to 3 m with an accuracy of ± 5 mm or $\pm 2\%$ whichever is the greater.

4.8.4 Means to measure angles to an accuracy of $\pm 0,25^\circ$.

4.8.5 Means to measure torque with an accuracy of $\pm 5\%$ in increments of 1 Nm in the range of 0,5 Nm to 10 Nm.

4.8.6 Means to measure sound levels and frequencies calibrated in accordance with the manufacturer's instructions, using an acoustic calibrator class 1 as described in ISO 3746 with an accuracy of ± 3 dB(A).

4.8.7 A hard horizontal and inclinable test plane, of sufficient size to support the APPH 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. $> 600 \text{ kg/m}^3$) is an example of material used.

4.8.8 Stoppers, for mobile APPHs not smaller than half of the wheel diameter and not greater than the wheel diameter. See [Figure 1](#).

For static APPH the stopper shall be designed to prevent the APPH 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 APPH, it shall be the minimum height required to prevent the APPH from sliding.

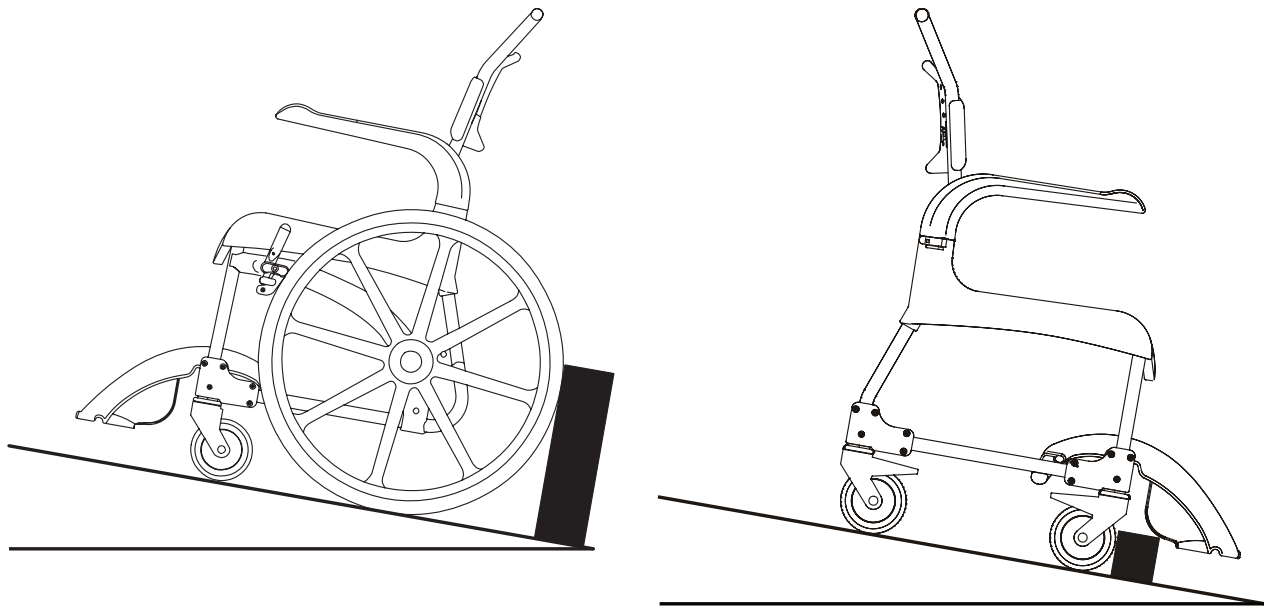


Figure 1 — Wheel-stopper

4.8.9 Equipment capable of simulating human body parts as used in practice (e.g. test fingers).

4.8.10 Equipment for applying loads, with negligible dynamic factor.

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

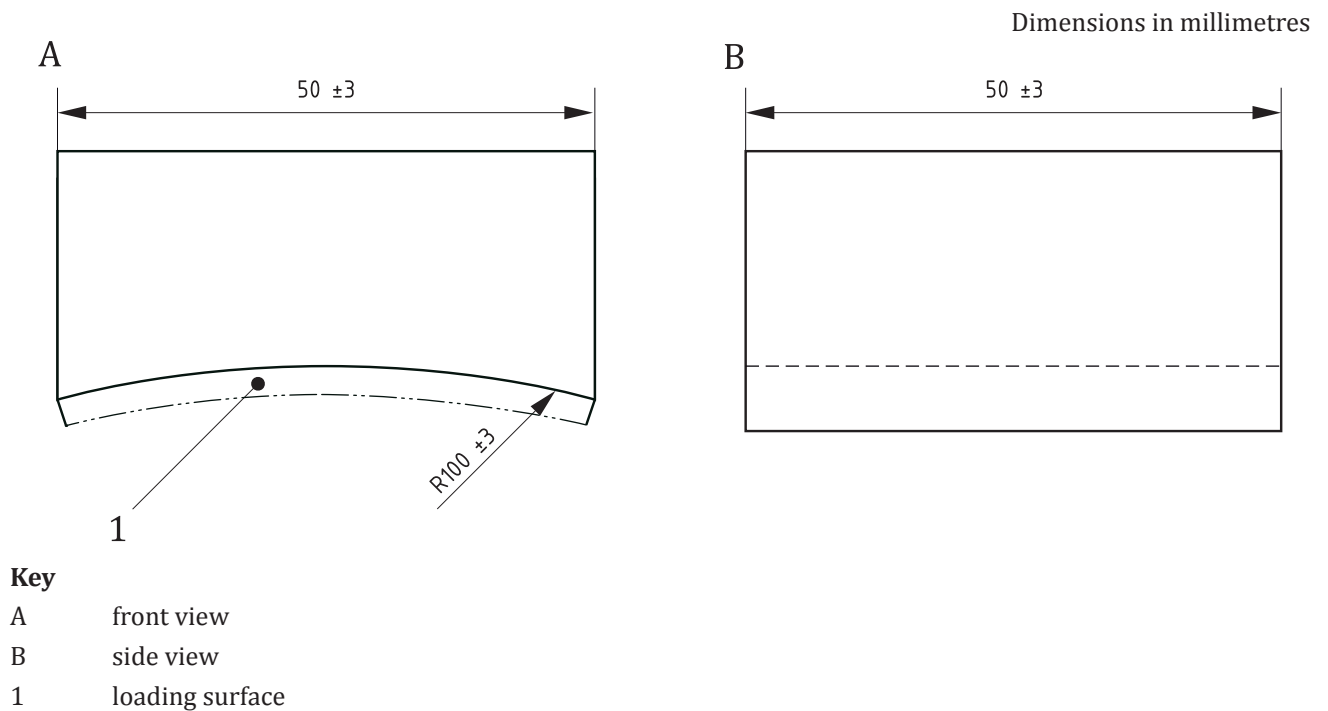
4.8.11 Equipment for measuring pressure of water, oil and air with an accuracy of $\pm 5 \%$.

4.8.12 Loading pads, as follows.

4.8.12.1 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 $\pm 3 \%$.

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



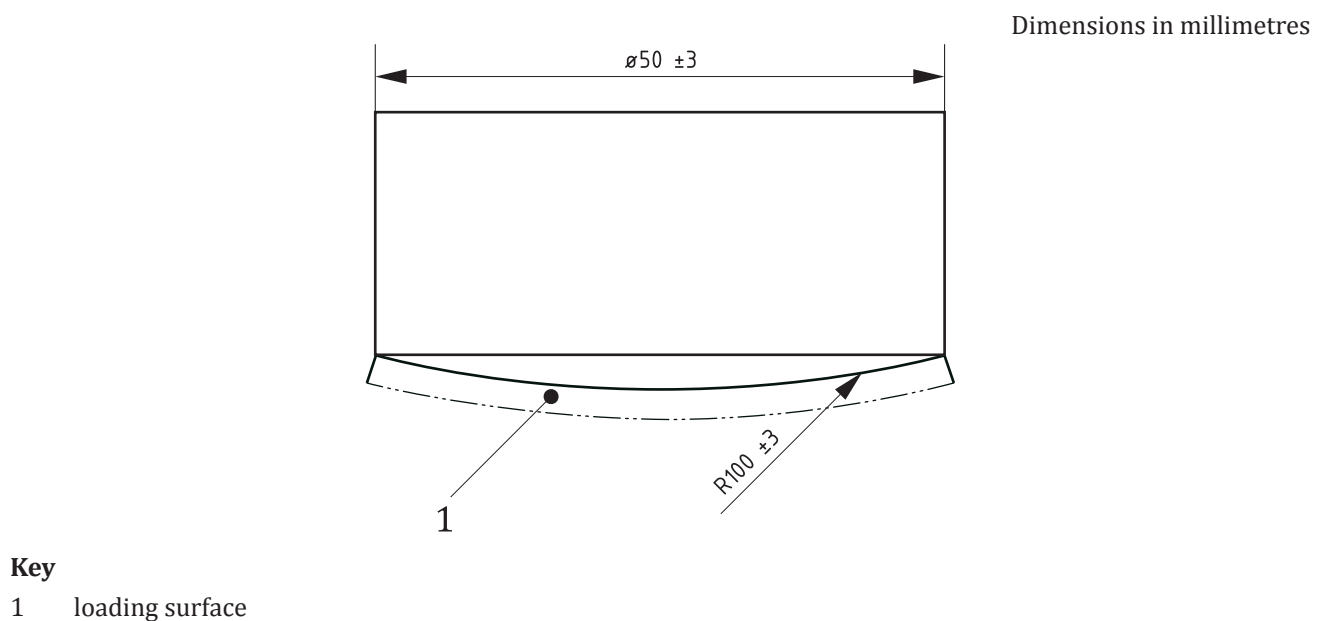
NOTE The loading surface may be covered with non-slip material up to 3 mm thick e.g. plastic foam.

Figure 2 — Concave loading pad for static loads

4.8.12.2 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 $\pm 3\%$.

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



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

4.8.12.3 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 $\pm 3\%$.

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

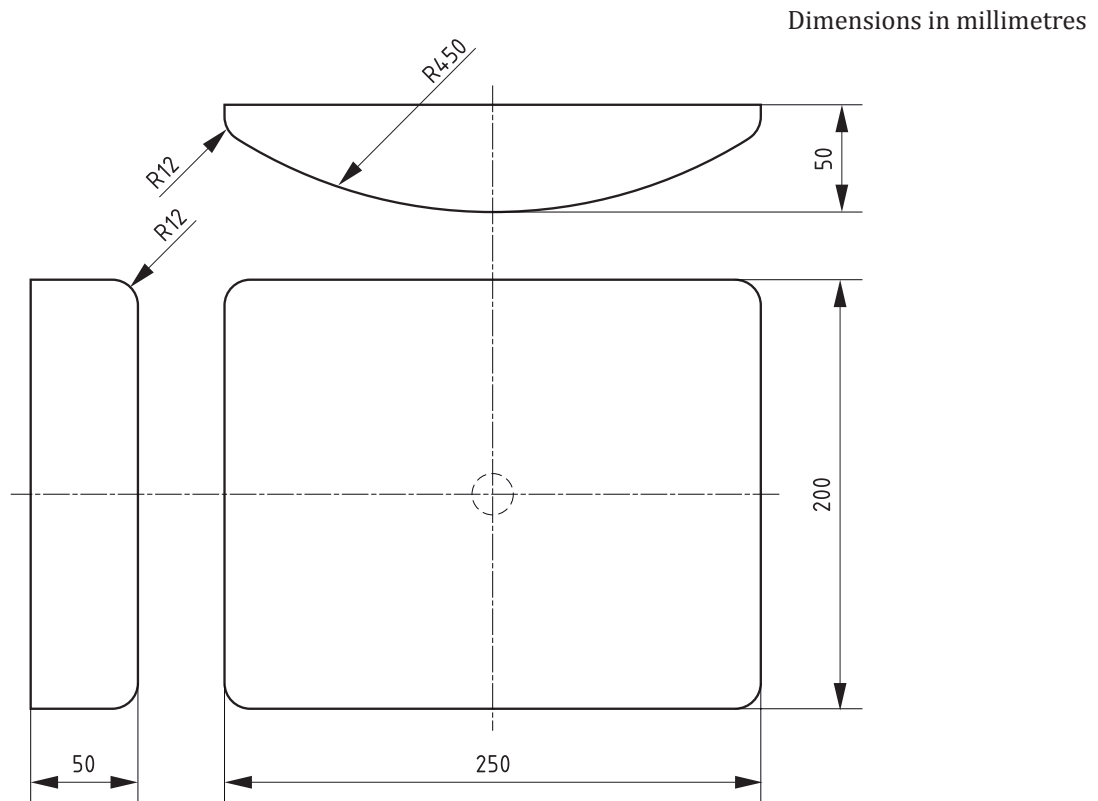
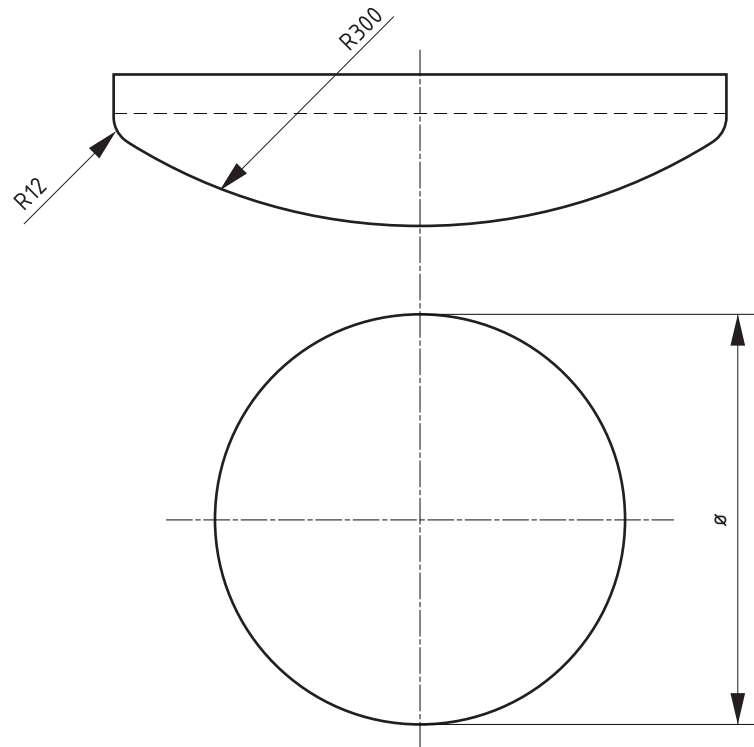


Figure 4 — Loading pad for back support

4.8.12.4 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.



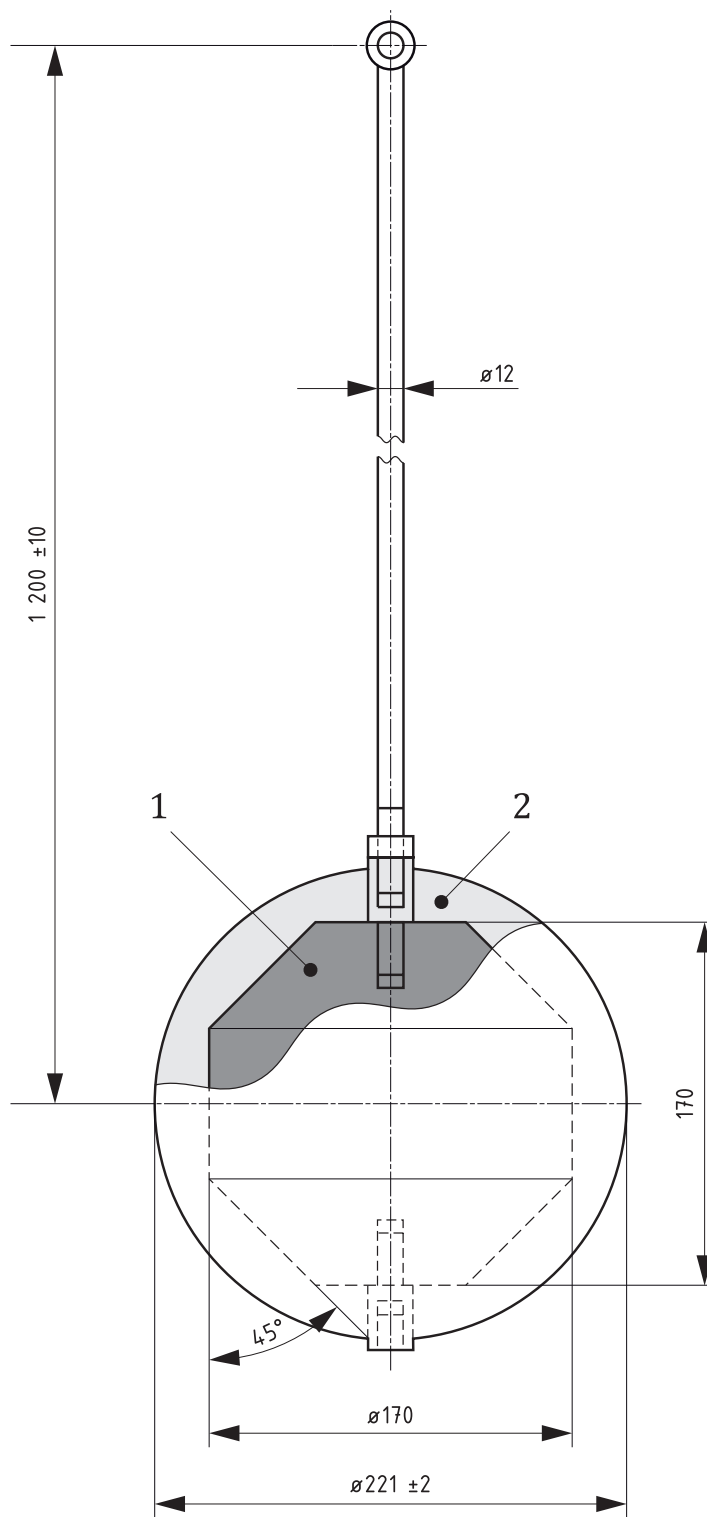
Ø 350 mm, 250 mm or 200 mm

Figure 5 — Loading pad for seat support

4.8.13 Back support impact test pendulum, which shall meet the requirements shown in [Figures 6](#) or [7](#).

The total mass of the ball shall be $25 \text{ kg} \pm 0,5 \text{ kg}$.

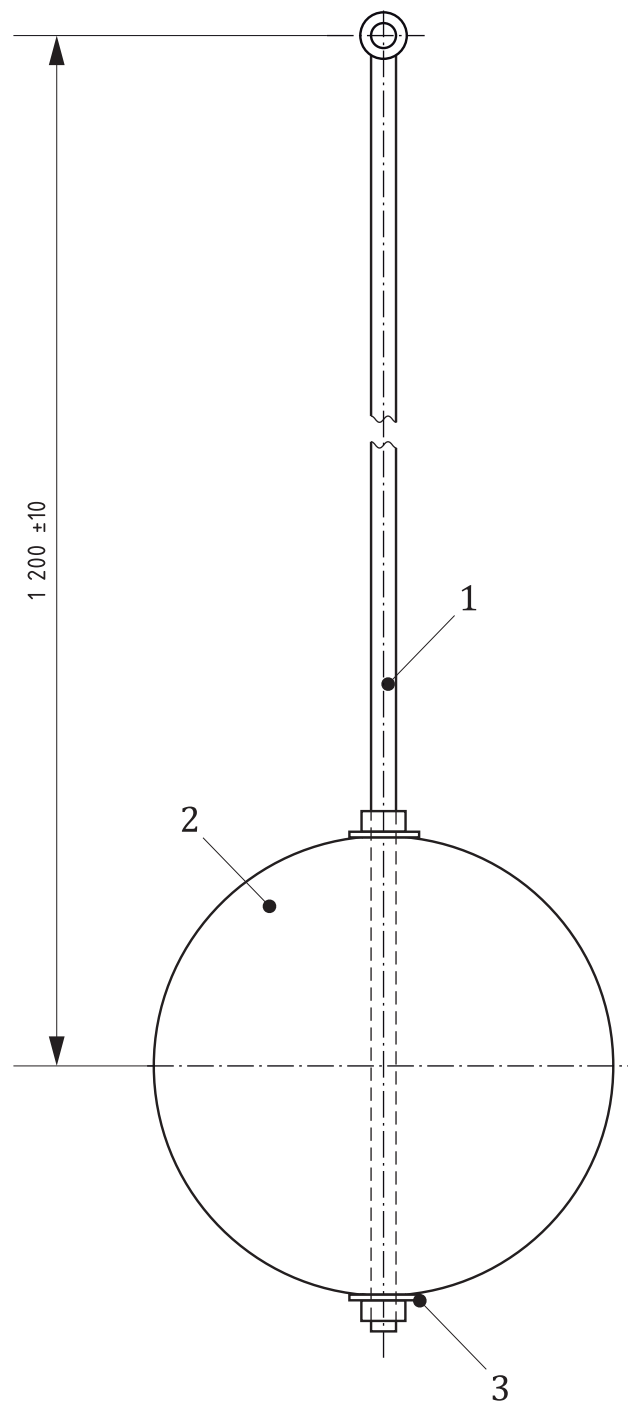
Dimensions in millimetres

**Key**

- 1 steel block
- 2 polyurethane with the following specifications: Density: 1150kg/m³; Hardness: 80+ shore A; Resilience: 20%

Figure 6 — Back support impact test pendulum

Dimensions in millimetres

**Key**

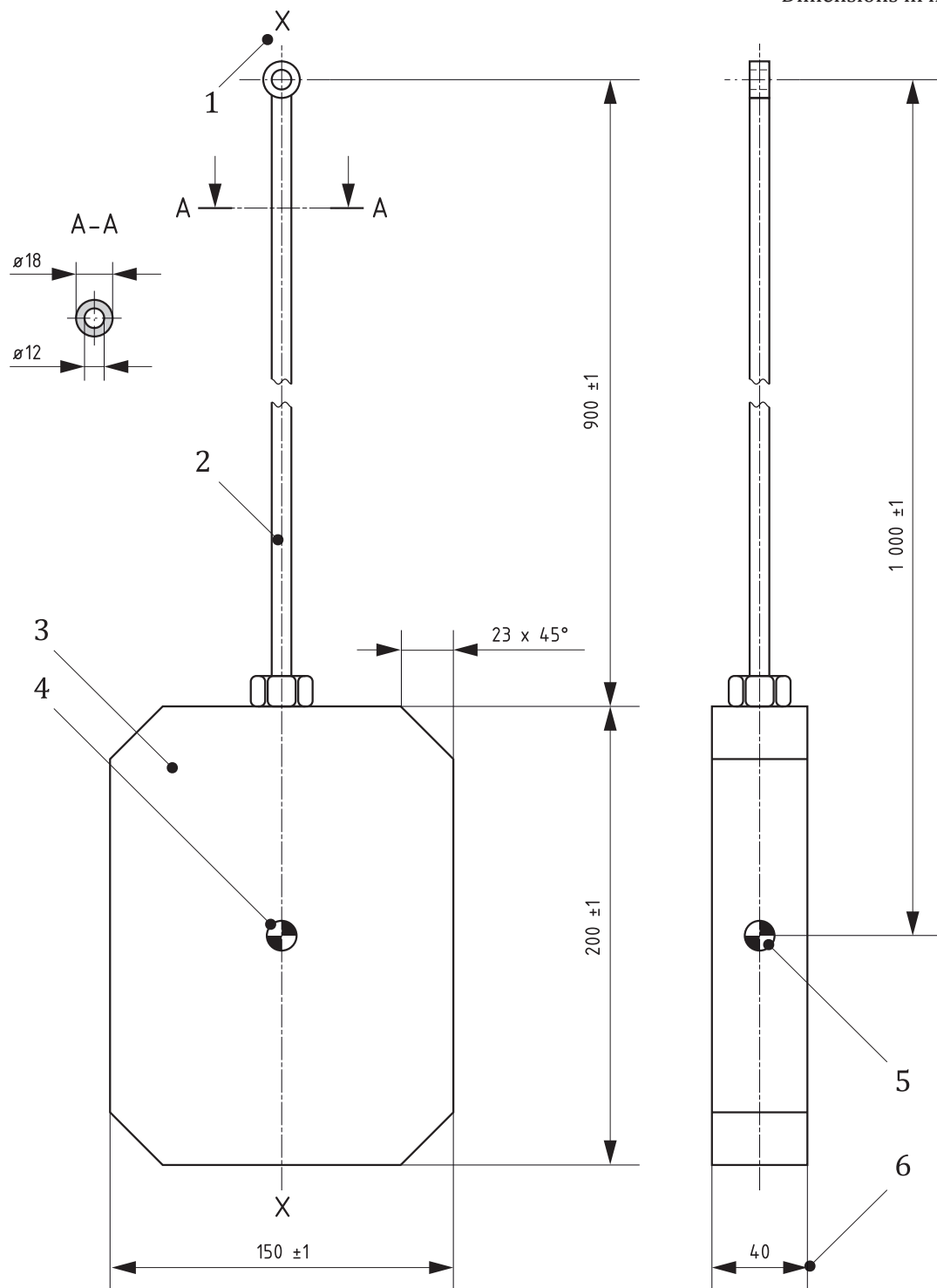
- 1 threaded bar
- 2 regulation association football (soccer ball) size 5, with diameter of 220 mm filled with lead shot 3.5 ± 1 mm diameter and closed cell high density foam of Density: 75 ± 15 kg/m³ (ISO 845); Hardness: 325 ± 60 N (ISO 2439)
- 3 washer

Figure 7 — Alternative back support pendulum**4.8.14 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 8](#) may be used although other shapes may be required to accommodate different layouts and sizes.

Dimensions in millimetres



Key

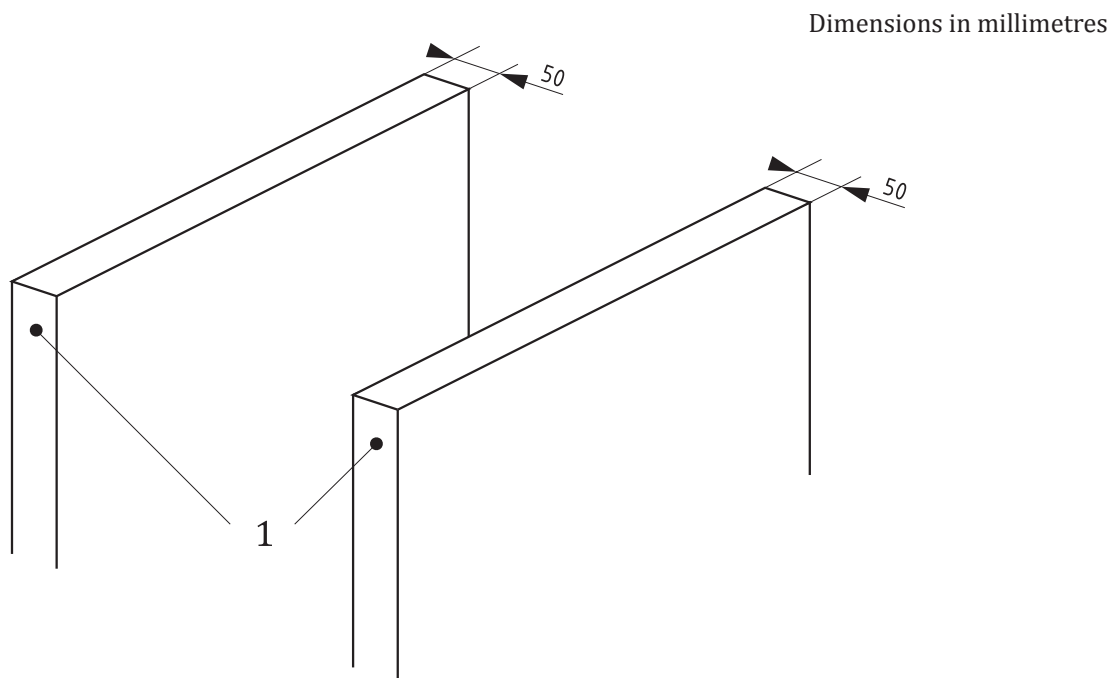
- 1 centre adjustment
- 2 steel tube
- 3 steel block
- 4 centre of percussion flat face
- 5 centre of percussion side face
- 6 reference dimension

Figure 8 — Example of toilet seat impact test pendulum

4.8.15 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 9](#)). 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.



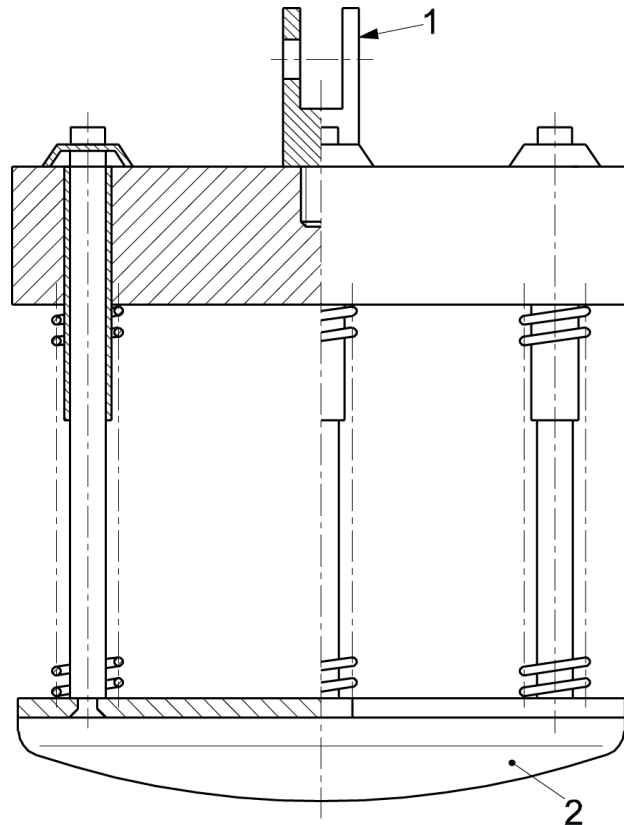
Key

1 supporting stand

Figure 9 — Supporting stand

4.8.16 Lying support impactor, with the following properties.

- a) 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.
- b) 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 $17\text{ kg} \pm 0,1\text{ kg}$.
- c) 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

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

Figure 10 — Lying support impactor

4.9 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.

EXAMPLE A shower seat converted into a toilet seat.

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 testhouse, the decision shall be taken in cooperation between the third party and the manufacturer.

Unless otherwise stated in a specific clause of this International Standard 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. It should be stated in the instructions for use which parts can be recycled.

5.2 Flammability

5.2.1 General

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

The manufacturer shall include a warning in the instructions for use about safe combinations of flame resistant and non-flame resistant materials.

NOTE For guidance see B.5.2.

5.2.2 Moulded parts used as enclosures for electrical equipment

If a risk can potentially be caused by an electrical component the housing of the moulded part shall be tested in accordance with FV-1 of IEC 60695-11-10 or better. If the product is of a type that the person with disability cannot escape from or detect as a dangerous situation it shall be FV-0.

5.2.3 Upholstered parts and moulded parts

If the manufacturer claims that the upholstered parts are resistant to ignition by cigarette, 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 ISO 8191-1 and ISO 8191-2.

If the manufacturer claims that moulded parts are resistant to ignition by small flames, such as those from a match, progressive smouldering ignition and flaming ignition shall not occur when tested in accordance with IEC 60695-11-10.

5.3 Biocompatibility and toxicity

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

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

If an APPH is intended to be cleaned and/or disinfected, the method and suitable cleaning or disinfection materials shall be described in the information supplied by the manufacturer.

NOTE For guidance see B.5.4.1.

If an APPH 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 APPH shall be labelled with appropriate symbols to represent the method of cleaning. See examples of labelling and an example of testing of machine washable APPH in B.5.4.1.

5.4.2 Resistance against temperature alternations

If an APPH is intended to be heated up during the disinfection or washing process, it shall pass the following test.

The test sample is exposed to the maximum temperature $\pm 2^{\circ}\text{C}$ during the washing and disinfection process as described by the manufacturer and afterwards cooled down to a temperature of 30°C . This cycle of alternating temperatures is repeated ten times.

For products intended to be disinfected by heat one of the following three temperatures and duration of exposition can be used:

- a) a temperature of 90°C for 1 minute;
- b) a temperature of 85°C for 3 minutes;
- c) a temperature of 80°C for 10 minutes.

The test shall be performed before any strength and/or durability tests of the product.

After the test, the product shall fulfil the following requirements: coating or any relevant labelling on the product shall not come loose from the basic sheet metal, show blisters or any other quality-reducing changes.

5.4.3 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 ISO 22442-1.

NOTE For guidance see B.5.4.3.

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 confirmed by using the salt spray test according to ISO 9227 with a test duration of 72 hours.

6 Emitted sound and vibration

6.1 Noise and vibration

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

Measurements of noise from a power operated APPH shall be made in accordance with ISO 3746, and the result of the measurement shall be recorded in the pre-sale information of 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

7.1 General

An APPH containing electrical or electronic devices/components shall conform to IEC 60601-1-2 and shall, in addition, conform to [7.2](#), [7.3](#) and [7.4](#).

7.2 Emissions

When tested in CISPR 11, the equipment shall meet the radiated emissions limits specified in CISPR 11 for group 1, class B equipment.

The APPH shall meet the requirements of IEC 61000-3-2 and IEC 61000-3-3, if applicable.

7.3 Immunity

In addition to the requirements in IEC 60601-1-2:2014, APPH shall also be tested with a field strength of 10V/m (RMS value of the unmodulated carrier) in the frequency range of 800 MHz to 2,5 GHz. The test shall be performed in accordance with IEC 61000-4-3.

If, as a result of the application of this test, the APPH presents a hazard, or there is any unintentional operation of the APPH, the APPH fails the test.

NOTE 1 It may be necessary to assess the risk associated with the APPH when used in close proximity to mobile telephone(s) or other forms of transmitter. In this case higher field strength values over a broader range of frequency may apply.

NOTE 2 APPHs are used in a wide range of environments and may be used in the presence of other electronic equipment. The electromagnetic compatibility (EMC) needs to be carefully matched to the intended use of the APPH.

7.4 Power frequency magnetic field immunity

When the equipment is tested in accordance with IEC 61000-4-8, test level 4, at any voltage using either 50 Hz or 60 Hz:

- a) the equipment shall behave safely in the presence of the applied field;
- b) electrically powered devices or electrically moved functions shall not move in the presence of the applied field.

Perform the continuous field immunity test specified in IEC 61000-4-8 on the equipment as table-top equipment. Test the equipment for not less than one minute for each orientation of the applied field.

For guidance see B.7.4.

8 Electrical safety

8.1 General

An APPH shall fulfill the relevant requirements stated in [Table 1](#) regarding electrical safety. An APPH connected to mains shall be either of class I (protective earth) or class II (double isolation). For APPHs which are marketed by the manufacturer as medical electrical equipment and are intended to be used in the home care environment and which are not permanently installed only class II is allowed according to IEC 60601-1-11.

NOTE Local building regulations may have more stringent requirements.

Table 1 — Applicable standards for electrical safety

APPH that fall within the scope of IEC 60601-1:2005 are tested according to:	APPH that fall within the scope of IEC 60335-1 are tested according to:
IEC 60601-1	IEC 60335-1
IEC 60601-1-11	IEC 60335-2-xx
IEC 60601-2-xx	

8.2 Electrical systems

An electrical system can consist of several components, each tested to different standards.

For the applicability of standards for components of electrical systems see [Table 1](#).

8.3 Safe positioning

The APPH shall always be capable of being set into a position that enables safe transfer of the occupant in case of a single fault failure or by loss of power.

8.4 Single fault safety

The APPH shall be so designed and manufactured that it remains single fault safe, or the risk remains acceptable as determined through the risk analysis process according to IEC 60601-1:2005, 4.7.

8.5 Hold to run activation

Electrically operable movements shall only be possible by the activation of control device(s) which initiate and maintain operation of the device only as long as the manual control is actuated and where the manual control automatically returns to the 'Stop' or 'Off' position when released.

NOTE Non-electrically operable movements (e.g. by hand or foot) are considered to comply with this clause, as long as mass and velocity allow adequate control of e.g. positioning without causing an unacceptable risk.

8.6 Emergency stopping functions

If the risk analysis demonstrates that there is a risk for the user or any other person around the APPH to be squeezed or a single fault appearing that might create a safety hazard there shall be an emergency stop as specified in ISO 13850 together with the following requirements:

- the APPH shall be designed to prevent accidental damage. If this is not feasible the APPH shall stop moving;

- the emergency stopping device shall be readily accessible to the operator, and stop the dangerous situation within one action;
- the stopping device shall maintain the equipment in a safe position, but not interfere with any essential performance functions, as defined by the manufacturer;
- the emergency stopping device shall maintain the APPH in a stopped position until it is released by a designated procedure;
- a safe stopping distance shall be considered in the risk analysis;
- the designated procedure for the release of the emergency stop shall be different from the movement needed to activate the emergency stop.

8.7 Continuity of power supply

If the safety of a person using an APPH powered from electrical supply mains depends upon the continuity of the power supply, the APPH shall be provided with a level of protection as follows.

- In case of a power cut, it shall be possible to return the APPH to a position enabling safe transfer using an auxiliary source of power or to provide sufficient power to allow further actions.
- If the power is cut, an auxiliary source of power is automatically connected to the APPH and a means to signal to the assistant that a discontinuity of the power supply has occurred. The auxiliary source of power shall provide sufficient power to allow for further actions.
- If the intended operator is able to react in a reasonable and timely manner by himself as power is cut, an auxiliary source of power and a means to signal to the operator that a discontinuity of the power supply has occurred, the auxiliary power source shall provide sufficient power to allow for further actions.
- If it is feasible, a method of non-electrical operation shall be provided that reduces the risk to users to an acceptable level until they can be moved from the APPH, or until power is restored together with a means to signal power failure to the operator/assistant who is intended for such emergency operations.

If there is a battery backup when there is a failure in the mains, this shall start to function as fast as possible and have a performance time long enough to bring the user into a position to enable safe transfer.

NOTE 1 A timely reaction may be providing access to the supply mains without interruption of the continuity of the power supply.

If the safety of a person using an internally powered APPH depends upon the continuity of the power supply, a means of informing the operator of a critical charge of the power supply shall be provided. At the time of reaching the critical charge, either an auxiliary source of sufficient power or a sufficient reserve charge of the internal power supply shall be available to allow timely reaction.

EXAMPLE Means of informing the operator of critical charge can be visual or auditory (e.g. symbols/lights and/or beeps).

NOTE 2 A timely reaction might be either recharging/replacing an internal power supply without interruption of the continuity of the power supply or by allowing the return to a safe place that provides the possibility to recharge/replace the internal power supply.

8.8 Battery powered assistive products for personal hygiene

8.8.1 Battery housings

Battery housings shall provide protection so that it shall not be possible for the following safety risks to occur.

- a) The need for, and the design of, battery housings shall be based on the risk analysis (see 4.1) and shall identify the hazards and evaluate the risks associated with:
 - 1) leakage of acid and/or other substances from the battery(ies);
 - 2) ventilation of gases generated during charging and/or use;
 - 3) short circuits of the battery(ies);

when operated in accordance with the conditions of use.

- b) Housings containing batteries from which gases can escape during charging or discharging, shall be ventilated.

NOTE Ventilation minimizes the risk of accumulation and ignition of flammable gases.

- c) If a short circuit of a battery could result in a safety hazard, the battery shall be contained in a housing/compartment that prevents the risk of accidentally short circuiting the battery(ies).
- d) Any battery housing/compartment shall collect and store any fluids and/or substances (other than gases) which may leak from the battery(ies) specified by the manufacturer.
- e) The materials used in the manufacture of battery housings shall be resistant to the substances that might leak from the battery(ies) specified by the manufacturer.

8.8.2 Connection

If a safety hazard can develop from the incorrect connection or replacement of a battery, an APPH shall be fitted with a means of preventing incorrect polarity.

8.8.3 Charge level indicator

If the safety of a person using an internally powered APPH 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 for a timely reaction.

NOTE A timely reaction may be either recharging or replacing the power supply without interruption of the availability of the power or by allowing the return to a safe place that provides the possibility to re-charge/replace the internal power supply.

There shall be some kind of indication of the status of the battery that is adapted to all the needs of operators with different functional limitations, e.g. persons with a vision or hearing impairment.

EXAMPLE Audible, visible or tactile indication that clearly indicates the status of the battery.

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

8.9 Circuit protection

The APPH shall meet the requirements and test methods for circuit protection as in IEC 60601-1+A1:2012:2005.

For guidance, see B.8.9.

8.10 Electrically heated blankets, pads and similar flexible heating appliances

An electrically heated blanket, pad or similar flexible heating appliances shall fulfil the requirements in IEC 60601-2-35 with a maximum temperature according to [Table 2](#).

8.11 Ingress of liquids

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

Compliance is checked by tests in IEC 60529 with the APPH placed in the least favourable position for normal use.

APPHs 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.

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

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

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

If water unintentionally can come 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.

Test the APPH within 5 minutes after the water test and after 1 hour to verify its functions.

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 APPHs shall be assessed in the risk analysis (see [4.1](#)).

NOTE 1 See B.9.1.

NOTE 2 For requirements for electrically powered APPH, see [8.11](#).

NOTE 3 Hazards might be risk of corrosion or bacterial growth.

9.1.2 Test method

Test if there is a way for the liquid to get out of the enclosure, by using procedures as in normal use and handling of the product. If possible tilt the product in different directions to verify this.

9.2 Overflow and leakage

9.2.1 General

The requirements given in [9.2.2](#) do not apply to the body fluids which may be collected in an APPH (e.g. a commode chair) but only to those substances which are an integrated part of an APPH or are needed for its function (e.g. oil and grease).