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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

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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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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

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

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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.

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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.

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09 12 09 Toilet seats;

09 12 12 Raised toilet seats mounted on frame;

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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;

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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*

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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

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

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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

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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.

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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

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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]

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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

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

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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.

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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.

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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.

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4.2 Intended performance

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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.

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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.

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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.

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4.8 Apparatus

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

4.8.2 Means to measure force with an accuracy of ± 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 ± 2 % whichever is the greater.

4.8.4 Means to measure angles to an accuracy of ± 0,25°.

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

4.8.6 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.

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