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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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ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

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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).

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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 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;

NOTE This covers mobile and static products.

18 15 06 Height adjustable plinth 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, *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 machineryErgonomic design principlesPart 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, specified by the manufacturer, of the user 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.