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ISO 17966

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

Produits d'assistance pour les toilettes, le bain et la douche — Exigences et méthodes d'essai

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Contents

Page

Foreword ..... **vii**
Introduction ..... **ix**
1 Scope **1**
2 Normative references **3**
3 Terms and definitions **4**
4 General requirements **8**
4.1 General 8
4.2 Risk analysis 9
4.3 Intended performance 9
4.4 Clinical evaluation and investigation 9
4.5 Assistive products that can be dismantled 9
4.6 Fasteners 9
4.7 User mass/load limits 10
4.8 Apparatus 10
4.8.1 Means to apply a force 10
4.8.2 Means to measure force 10
4.8.3 Means to measure distance 10
4.8.4 Means to measure angles 10
4.8.5 Means to measure torque 10
4.8.6 Means to measure sound pressure levels 10
4.8.7 Test plane 10
4.8.8 Stoppers 10
4.8.9 Box 11
4.8.10 Equipment for applying loads 11
4.8.11 Equipment for measuring pressure of water, oil and air 11
4.8.12 Loading pads 11
4.8.13 Equipment for impact test 16
4.8.14 Supporting stands 19
4.8.15 Small parts cylinder 20
4.8.16 Obstruction 21
4.8.17 Hardwood vertical obstacle 21
4.9 Test conditions 21
5 Materials **21**
5.1 General 21
5.2 Flammability 21
5.2.1 General 21
5.2.2 Upholstered parts and other soft parts 22
5.2.3 Polymeric parts 22
5.2.4 Wiring 22
5.3 Biocompatibility and toxicity 22
5.4 Infection and microbiological contamination 23
5.4.1 Cleaning and disinfection 23
5.4.2 Animal tissue 24
5.5 Resistance to corrosion 24
6 Emitted sound and vibration **24**
6.1 Noise and vibration 24
6.2 Sound pressure levels and frequencies of audible warning devices 24
7 Electromagnetic compatibility **24**
8 Electrical safety **25**
8.1 General 25
8.2 Battery powered assistive products – charge level indicator 25
8.3 Electrically heated blankets, pads and similar flexible heating appliances 25

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8.4 Ingress of liquids or particulate matter 25
8.4.1 Ingress of liquids 25
8.4.2 Ingress of particulate matter 26
8.5 Pendant controls 26
9 Overflow, leakage, and ingress of liquids 26
9.1 Ingress of liquids 26
9.1.1 Requirements 26
9.1.2 Test method 26
9.2 Overflow and leakage 27
9.2.1 General 27
9.2.2 Prevention of leaks from an assistive product 27
10 Temperatures of parts that come in contact with human skin 27
11 Safety of moving and folding parts 28
11.1 Moving parts 28
11.2 Folding parts 29
11.3 Locking mechanisms 29
11.4 Velocity of powered lifting and lowering movements 29
11.4.1 Requirements 29
11.4.2 Test method 29
11.5 Mechanical wear 30
11.6 Trapping zones for feet and toes in relation to moving parts 30
12 Means to prevent falling out 31
12.1 General 31
12.2 Side rails to protect against inadvertent user falls 31
13 Prevention of traps for parts of the human body 32
13.1 Holes and clearances 32
13.2 V-shaped openings 32
14 Lifting and carrying means 33
14.1 General 33
14.2 Requirement 33
14.3 Test method 33
15 Portable and hand-held assistive products or hand-held parts 34
16 Static strength, impact and durability 34
16.1 General 34
16.2 Formulae for calculating forces 35
16.3 Number of test cycles for durability 37
16.4 Static strength 38
16.4.1 Requirements 38
16.4.2 Test methods 39
16.5 Durability 45
16.5.1 Requirements 45
16.5.2 Test methods 46
16.6 Impact 53
16.6.1 Requirements 53
16.6.2 Test methods 53
17 Stability 56
17.1 Requirements 56
17.2 Test methods 56
18 Surfaces, corners, edges and protruding parts 57
19 Assistive products for children 57
20 Forces in soft tissues of the human body 57
21 Ergonomic principles 57

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22 Mobile assistive products **58**
22.1 General 58
22.2 Immobilizing means 58
22.2.1 General 58
22.2.2 Requirements for locking devices 58
22.2.3 Test methods for locking devices 58
22.2.4 Test methods for durability of brakes 59
22.2.5 Brake-operated by a lever 59
22.3 Power-driven mobile assistive products 59
22.4 Rough handling and movement 59
22.4.1 General 59
22.4.2 Requirements 59
22.4.3 Test method for movement over a threshold 59
22.4.4 Test method for door frame shock 60
22.5 Functional requirements for mobile assistive products 60
22.5.1 Foot supports 60
22.5.2 Position of push handles or points 60
22.5.3 Turning diameter of mobile assistive products 60
22.6 Moving forces 61
22.6.1 Requirements for moving forces 61
22.6.2 Test methods for moving forces 61

23 Fixed assistive products **61**
23.1 General 61
23.2 Requirements 62
23.3 Shower seats 62
23.3.1 Description 62
23.3.2 Test methods 62
23.4 Bathing stretchers, shower tables and diaper changing tables 64
23.4.1 Description 64
23.4.2 Test methods 64
23.5 Bath boards, back supports and seats 65
23.5.1 Description 65
23.5.2 Test method for durability 65
23.6 Raised toilet seats 66
23.6.1 Description 66
23.6.2 Requirements 66
23.6.3 Test methods 66
23.7 Handrails, grab bars and handgrips 67
23.7.1 Description 67
23.7.2 Ergonomic principles 68
23.7.3 Requirements 68
23.7.4 Test methods 68
23.8 Removable grab rails and handgrips 69
23.8.1 Description 69
23.8.2 Ergonomic principles 69
23.8.3 Safety 70
23.8.4 Test methods 70
23.9 Hinged rails and arm supports 71
23.9.1 Description 71
23.9.2 General 71
23.9.3 Test methods 71

24 Portable assistive products **72**
24.1 General 72
24.2 Stability and strength tests 72
24.3 Raised toilet seats, detachable 72
24.3.1 Description 72
24.3.2 Requirements 72

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24.4 Toilet seats with built-in raising mechanism to help standing up and sitting down (non-fixed) 72
24.4.1 Description 72
24.4.2 Durability 73
24.5 Bath boards, stools, back supports and seats 73
24.5.1 Description 73
24.5.2 Materials 73
24.5.3 Stability 73
24.5.4 Stability tests for assistive products designed to be supported by the sides of a bathtub 73
24.5.5 Strength test of brackets 78
24.5.6 Friction test of bath board or seat 81
24.5.7 Static horizontal force test on handle 82
24.5.8 Static vertical force test of handle 82
24.6 Arm support, free-standing 83
24.6.1 Requirements 83
24.6.2 Test methods 83

25 Requirements for information supplied by the manufacturer 83
25.1 General 83
25.2 Instructions for use 84
25.2.1 General 84
25.2.2 Pre-sale information 84
25.2.3 User information 85
25.2.4 Service information 86
25.3 Labelling 86

26 Packaging 87

27 Test report 87

Annex A (informative) **Cognitive impairment 89**

Annex B (informative) **General recommendations 90**

Annex C (informative) **Environmental and consumer-related recommendations 98**

Annex D (informative) **Periodic inspection 103**

Annex E (informative) **Lithium batteries 104**

Bibliography 106

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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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 173, *Assistive products*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 293, *Assistive products and accessibility,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 17966:2016), which has been technically revised.

The main changes are as follows:

— new terms and definitions were added, and a few definitions updated (Clause 3);

— new apparatus was added and a few updated (4.8);

— requirements for flammability were updated, and requirements for other soft parts, polymeric parts and wiring were added (5.2);

— requirements for infection and microbiological contamination were updated, and requirements, test methods, performance criteria and marking requirements for machine washable assistive products were added (5.4);

— requirements for electromagnetic compatibility were removed from this document, reference to requirements in IEC 60601-1:2005 was added instead (Clause 7);

— reference to electrical standards was adjusted, and requirements for electrical systems, safe positioning, single fault safety, hold to run activation, emergency stopping functions and continuity of power supply were therefore removed from this document (8.1);

— charge level indication for battery powered assistive products was modified for better understanding (8.2);

— requirement for ingress of particulate matter was specified (8.4.2);

— requirement and test of pendant controls was added (8.5);

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— update of test method for velocity of powered lifting and lowering movement (11.4.2);

— means to prevent falling out (e.g. side rails) were added (Clause 12);

— Table 6 for calculating forces was updated, formula to find F1 was modified for several products and drawing examples were given for explanation (16.2);

— designed lifetime t_{DL} was changed to expected lifetime t_{EL} in the formula for calculating number of test cycles, expected lifetime was changed from a minimum of 3 years to 5 years, Table 7 and Table 8 were updated (16.3);

— modification of test methods and new test methods added for static strength (16.4) and durability (16.5);

— modification of test methods for stability (Clause 17);

— Clause 19 for assistive products for children has been modified;

— ergonomic requirement for surface of buttons from previous version were removed (Clause 21);

— ergonomic requirement for hand-operated controls were adjusted to a height of 870 mm to 1 100 mm above the surface of the floor (Clause 21);

— test method for movement over a threshold and door frame were modified so it is no longer possible to use a test dummy, and a reference to suitable loading pads was added (22.4.3, 22.4.4);

— requirement for handles for pushing and pulling or both was changed to be positioned between 800 mm to be operated at a height of 1 200 mm above the surface of the floor (22.5.2);

— starting force in the requirements for moving forces was changed to maximum 170 N (22.6.1);

— modification of test methods for fixed assistive products (Clause 23);

— modification of test methods for portable assistive products (Clause 24);

— Annex E on lithium batteries was added.

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.

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Introduction

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

Clauses 4 to 21 and Clauses 25 to 27 contain general requirements for all types of products included in the scope.

Clauses 22 to 24 contain specific requirements for mobile, fixed and portable assistive products. These clauses contain additional requirements to the requirement in Clauses 25 to 27.

An assistive product is deemed to conform with this document when it fulfils the general requirements as well as the additional requirements in the clauses relevant to the type of product (mobile, fixed or portable).

In addition to the requirements in this document, Annex B gives general recommendations.

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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 to as 'assistive product' within this document).

NOTE 1 Some of the assistive products can be classified as medical devices.

This document 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 ISO 9999:2022.

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;[1)]

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

09 12 09 Toilet seats;[1)]

devices attached to the toilet bowl or toilet chair for a person to sit on, which can provide stability and comfort.

09 12 10 Toilet splash guards;[1)]

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.

1) There are no specific requirements and test methods for these products. Only the relevant general requirements apply when these products are considered to be assistive products.

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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;[2)]

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 EN 12221-1.

09 33 15 Wash basins;[2)]

stationary or portable basins for water used when washing parts of the body.

09 33 18 Bidets;[2)]

stationary or portable basins primarily intended for washing genitals and bottom.

09 33 36 Assistive products for drying oneself;[2)]

devices and materials for enabling a person to dry their own body.

18 15 06 Height adjustable plinths and brackets;

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2) There are no specific requirements and test methods for these products. Only the relevant general requirements apply when these products are considered to be assistive products.

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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 themselves 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 their 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 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.

ISO 845:2006, *Cellular plastics and rubbers — Determination of apparent density*

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

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*

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ISO 10993-1:2025, *Biological evaluation of medical devices — Part 1: Requirements and general principles for the evaluation of biological safety within a risk management process*

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

ISO 14155:2025, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 14971:2019, *Medical devices — Application of risk management to medical devices*

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

ISO 20417:2021, *Medical devices — Information to be supplied by the manufacturer*

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

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

IEC 60332-1-2:2025, *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 60529:1989+AMD2:2013+COR1:2019, *Degrees of protection provided by enclosures (IP code)*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-11:2015+AMD1:2020, *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 60601-2-35:2020, *Medical electrical equipment — Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads, and mattresses and intended for heating in medical use*

IEC 60695-11-10:2013+COR1:2014, *Fire hazard testing — Part 11-10: Test flames — 50 W horizontal and vertical flame test methods*

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

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005+AMD1:2012+AMD2:2020 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* (3.17) necessarily comes into physical contact with the *user* (3.27) to perform its function

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3.2
assistant
person who is helping or 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 Clause B.2.

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: 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

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

3.3.2
mobile assistive product
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

3.3.3
portable assistive product
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

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

3.3.4
robotic assistive product
assistive product (3.3) that has programmed actuated mechanisms with a degree of autonomy to perform locomotion, manipulation or positioning

3.4
backward
180° to the forward direction of travel

3.5
cleaning
removal of foreign materials from a surface

3.6
detachable part
part designed to be unfastened or disconnected without damage to the part or the product

[SOURCE: ISO 20342-1:2022, 3.10, modified — "whole" was changed to "product".]

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3.7
disinfection
process to inactivate viable microorganisms to a level previously specified as being appropriate for a defined purpose

[SOURCE: ISO 11139:2018, 3.84]

3.8
environment
surrounding in which an *assistive product* (3.3) can be used

3.8.1
home care environment
a domestic area where the *assistive product* (3.3) is used to alleviate or compensate for an injury, disability or disease

3.8.2
public area
surroundings that are available for everyone

EXAMPLE Areas used for swimming, public restrooms.

3.9
forward
intended direction of travel, as indicated by the manufacturer in the instructions for use

3.10
foreseeable misuse
wrongful use which can be reasonably anticipated

3.11
intended performance
functional characteristics of a product, process or service, as intended by the manufacturer according to the given specifications, instructions and information

Note 1 to entry: They can include, but are not limited to, strength, durability, stability, noise and vibration, application of use and conditions of use.

3.12
intended purpose
function that a product, process or service has, as intended by the manufacturer according to the given specifications, instructions and information

Note 1 to entry: Adapted from ISO 14971:2019, 3.6.

3.13
intended use
act of using a product, process or service as intended by the manufacturer according to the given specifications, instructions and information

Note 1 to entry: The intended medical indication, patient population, part of the body or type of tissue interacted with, user profile, use environment, and operating principles are typical elements of the intended use.

Note 2 to entry: Adapted from ISO 14971:2019, 3.6.

3.14
lay user
individual who does not have formal education in a relevant field of healthcare or medical discipline

[SOURCE: ISO 18113-1:2022, 3.1.40, modified — The preferred term “lay person” was removed; the example and notes to entry were deleted.]

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3.15
load and mass

3.15.1
maximum user mass
greatest permissible weight of the *user* (3.27), specified by the manufacturer, intended to be supported by the *assistive product* (3.3)

3.15.2
minimum user mass
lowest possible weight of the *user* (3.27), specified by the manufacturer, needed for activating or using an *assistive product* (3.3)

3.15.3
maximum load
safe working load
greatest permissible weight on equipment or an equipment part during *normal use* (3.17)

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.

Note 2 to entry: Adapted from IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.109.

3.16
mechanism
system of parts working together

3.17
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 should not be confused with *intended use* (3.13). While both include the concept of use as intended by the manufacturer, intended use focuses on the *intended purpose* (3.12) while normal use incorporates not only the intended purpose, but maintenance, service, transport, etc. as well.

3.18
operator
person handling the *assistive product* (3.3)

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

3.19
pendant control
hand-held device, which has a functional connection to the *assistive product* (3.3), to control function(s) of the product, e.g. articulations and movements

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

[SOURCE: IEC 60601-2-52:2009, 201.3.214, modified — “medical bed” replaced with “assistive product”, “controlling at least medical bed” replaced with “to control function(s) of the product, e.g.”.]

3.20
permanent deformation
alteration in shape or structure of a previously normally formed part that will stay altered as the test is completed

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3.21
risk
combination of the probability of occurrence of harm and the severity of that harm

3.22
side rail
physical barrier, which can be a detachable accessory or integral to the overall construction of an *assistive product* (3.3)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, 3.28, modified — In Note 1 to entry, “user” was replaced with “person with disability”.]

3.23
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: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.116, modified — Note 1 to entry was added.]

3.24
single patient multiple use
intended by the manufacturer to be reused on an individual patient for multiple uses

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

[SOURCE: ISO 20417:2021, 3.25, modified — Note 2 to entry was deleted.]

3.25
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: ISO 20417:2021 3.26]

3.26
test cycle
full cycle for the intended action

3.27
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

4.1 General

In order for a product to conform with this document, all relevant clauses, depending on the type of product, shall be fulfilled.

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