
Assistive products — General requirements and test methods

Produits d'assistance — Exigences générales et méthodes d'essai

STANDARDSISO.COM : Click to view the full PDF of ISO 21856:2022



STANDARDSISO.COM : Click to view the full PDF of ISO 21856:2022



COPYRIGHT PROTECTED DOCUMENT

© ISO 2022

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

	Page
Foreword.....	vi
Introduction.....	vii
1 Scope.....	1
2 Normative references.....	1
3 Terms and definitions.....	3
4 General requirements.....	7
4.1 Risk analysis and management.....	7
4.2 Intended performance and technical documentation.....	8
4.3 Clinical evaluation and investigation.....	8
4.4 Assistive products that can be dismantled.....	8
4.5 Fasteners.....	8
4.6 Load limits.....	8
4.7 Immobilising means.....	9
4.8 Usability.....	9
4.9 Design requirements in relation to persons with sensory and cognitive impairments.....	9
4.10 Considerations for accessibility.....	9
4.11 Feedback.....	9
5 Materials.....	9
5.1 General.....	9
5.2 Flammability.....	9
5.2.1 General.....	9
5.2.2 Upholstered parts, mattresses, bed bases, bedding and textiles.....	10
5.2.3 Polymeric parts.....	11
5.2.4 Electrical components.....	11
5.2.5 Wiring.....	11
5.3 Biocompatibility and toxicity.....	11
5.4 Contaminants and residues.....	12
5.4.1 General.....	12
5.4.2 Substances that can leak from an assistive product in intended use and in fault conditions.....	12
5.5 Infection and microbiological contamination.....	12
5.5.1 Introduction.....	12
5.5.2 Cleaning and disinfection.....	12
5.5.3 Machine washable assistive products.....	13
5.5.4 Animal tissue.....	14
5.6 Resistance to corrosion.....	14
6 Emitted sound and vibration.....	14
6.1 Noise and vibration.....	14
6.2 Sound levels and frequencies of audible warning devices.....	14
7 Electromagnetic compatibility.....	15
8 Electrical safety.....	15
8.1 General.....	15
8.2 Battery powered assistive products - Charge level indicator.....	15
8.3 Electrically heated blankets, pads and similar flexible heating appliances.....	15
8.4 Ingress of liquids or particulate matter.....	15
8.4.1 Ingress of liquids.....	15
8.4.2 Ingress of particulate matter.....	16
8.5 Pendant controls.....	16
9 Overflow, spillage, leakage and ingress of liquids.....	16
9.1 Overflow.....	16

9.1.1	Requirements	16
9.1.2	Test method	16
9.2	Spillage	17
9.2.1	Requirements	17
9.2.2	Test method	17
9.3	Leakage	17
9.4	Ingress of liquids	17
9.4.1	Requirements	17
9.4.2	Test method	17
10	Surface temperature	17
11	Sterility	18
11.1	Sterility requirements	18
11.2	Sterilization processes	18
11.3	Maintenance of sterility in transit	19
12	Safety of moving parts	19
12.1	Squeezing	19
12.2	Mechanical wear	20
12.3	Emergency stopping functions	20
13	Means to prevent falling out	20
13.1	General	20
13.2	Protection against inadvertent user falls in relation to side rails	20
14	Prevention of traps for parts of the human body	22
14.1	Holes and clearances	22
14.2	V-shaped openings	23
15	Folding and locking mechanisms	23
15.1	General	23
15.2	Locking mechanisms	23
15.3	Prevention of trap and squeeze hazards	24
16	Carrying handles	24
16.1	General	24
16.2	Requirement	24
16.3	Test method	24
17	Assistive products that support or suspend users	25
17.1	General	25
17.2	Static forces	25
17.2.1	Assistive products that support users	25
17.2.2	Assistive products that suspend users	26
17.3	Dynamic forces	26
17.4	Requirements and test method for tips	26
17.4.1	General	26
17.4.2	Friction of tips	26
17.4.3	Durability of tips	26
18	Portable and mobile assistive products	27
18.1	Portable assistive products	27
18.2	Mobile assistive products	27
19	Surfaces, corners, edges and protruding parts	28
20	Hand-held assistive products	28
21	Assistive products for children	29
22	Stability	29
23	Forces in soft tissues of the human body	30
24	Ergonomic principles	30

25	Requirements for information supplied by the manufacturer	30
25.1	General	30
25.2	Instructions for use	31
25.2.1	General	31
25.2.2	Pre-sale information	31
25.2.3	User information	32
25.2.4	Service information	32
25.3	Labelling	33
26	Packaging	34
27	Test report	34
28	Guidelines for accessible information on assistive products	35
Annex A (informative)	General recommendations	36
Annex B (informative)	Environmental and consumer related guidance	44
Annex C (informative)	Guidelines for accessible information on assistive products	49
Bibliography		53

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).

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 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 first edition of ISO 21856 cancels and replaces ISO 16201:2006, which has been technically revised.

The main changes compared to the previous edition are as follows:

- scope changed to requirements and test methods for assistive products in general.

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.

Introduction

This document is developed due to a need to provide safety requirements and recommendations for assistive products that are not covered by another International Standard. Users of this document should check if there is a more relevant standard. Where requirements in this document are not covered in a standard for a particular type of assistive product, this document can be used as a supplement. This document can also serve as reference material when developing standards for a particular type of assistive product.

The general requirements and related test methods in this document are relevant to assistive products in different application environments such as hospitals, home care, and institutions. Some of the devices can apply in more than one application environment. This means that different requirements and test methods can apply to the same assistive product depending on the application environment.

[Annex A](#) gives general recommendations, [Annex B](#) gives environmental and consumer related guidance and [Annex C](#) provides guidelines for accessible information on assistive products.

This document is based on EN 12182:2012.

[STANDARDSISO.COM](https://standardsiso.com) : Click to view the full PDF of ISO 21856:2022

Assistive products — General requirements and test methods

1 Scope

This document specifies general requirements and test methods for assistive products, considered to be medical devices, intended for use to alleviate or compensate for a disability.

This document does not apply to assistive products which achieve their intended purpose by administering pharmaceutical substances to the user.

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

NOTE 2 Requirements and test methods for particular types of assistive products are given in other International Standards, e.g. see Reference [33].

NOTE 3 Not all the items listed in ISO 9999 are medical devices. Contracting parties might wish to consider if this document or specific clauses or subclauses can be used for assistive products that are not medical devices.

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 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 7000, *Graphical symbols for use on equipment — Registered symbols*

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

ISO 11135, *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11137-2, *Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

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

ISO 12952-1, *Textiles — Assessment of the ignitability of bedding items — Part 1: Ignition source: smouldering cigarette*

ISO 12952-2, *Textiles — Assessment of the ignitability of bedding items — Part 2: Ignition source: match-flame equivalent*

ISO 14155:2020, *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 information to be supplied by the manufacturer — Part 1: General requirements*

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

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

ISO 24415-1, *Tips for assistive products for walking — Requirements and test methods — Part 1: Friction of tips*

ISO 24415-2, *Tips for assistive products for walking — Requirements and test methods — Part 2: Durability of tips for crutches*

ISO 25424, *Sterilization of health care products — Low temperature steam and formaldehyde — Requirements for development, validation and routine control of a sterilization process for medical devices*

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

IEC 60204-1, *Safety of machinery — Electrical equipment of machines — Part 1: General requirements*

IEC 60332-1-2, *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, *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 60601-1-2, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances - Requirements and tests*

IEC 60601-1-6, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability*

IEC 60601-1-11, *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 60695-11-10, *Fire hazard testing — Part 11-10: Test flames - 50 W horizontal and vertical flame test methods*

IEC 62366-1:2015, *Medical devices — Part 1: Application of usability engineering to medical devices*

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

EN 556-1, *Sterilization of medical devices — Requirements for medical devices to be designated “STERILE” — Part 1: Requirements for terminally sterilized medical devices*

EN 597-1, *Furniture — Assessment of the ignitability of mattresses and upholstered bed bases — Part 1: Ignition source smouldering cigarette*

EN 597-2, *Furniture — Assessment of the ignitability of mattresses and upholstered bed bases — Part 2: Ignition source: match flame equivalent*

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

EN 716-2:2017, *Furniture — Children’s cots and folding cots for domestic use — Part 2: Test methods*

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

UL 1581(Ed. 4), *Reference Standard for Electrical Wires, Cables, and Flexible Cords*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005+AMD1:2012+AMD2:2020 and the following apply.

ISO and IEC maintain terminological 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 an *assistive product* (3.3) that in *normal use* (3.20) necessarily comes into physical contact with the *user* (3.32) to perform its function

3.2

assistant

person who is helping/supporting a *person with disability* (3.23) in using the *assistive product* (3.3)

Note 1 to entry: Examples of the ways assistants help persons with disability are pushing wheelchairs operating hoists, and assisting with entering and leaving seats, beds and wheelchairs.

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

3.3

assistive product

instrument, equipment, or technical system intended by the *manufacturer* (3.15) to be used for the prevention, treatment, or alleviation of or compensation for *impairment* (3.13)

Note 1 to entry: The definition is not identical to the definition in ISO 9999 because this document is restricted to medical devices.

3.4

assistive product which supports or suspends users

assistive product (3.3) intended to *support* (3.4.1) or *suspend* (3.4.2) persons with *disability* (3.11) and/or an *assistant* (3.2) or *load* (3.16)

3.4.1

support

bear or hold up

3.4.2

suspend

hang by attachment to something above

3.5

autonomy

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

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

[SOURCE: ISO 8373:2021, 3.2]

3.6

bedding

items normally placed on a mattress

Note 1 to entry: Bedding includes mattress covers, underlays, incontinence sheets and pads, sheets, blankets, electric blankets, quilts (duvets) and their covers, pillows and bolsters, and pillow cases.

3.7

body mass index

BMI

simple index of weight-for-height that is commonly used to classify underweight, overweight and obesity in adults and defined as the weight in kilograms divided by the square of the height in meters (kg/m^2)

3.8

clinical evaluation

means for confirming that an *assistive product* (3.3) conforms to the *intended use* (3.14) specified by the *manufacturer* (3.15)

Note 1 to entry: A clinical evaluation can include a compilation of clinical data, any scientific literature and the results of any clinical investigations, taking into account any relevant standards.

3.9

clinical investigation

clinical trial

clinical study

systematic investigation in one or more human subjects, undertaken to assess the clinical performance, effectiveness or safety of a *medical device* (3.18)

[SOURCE: ISO 14155:2020, 3.8, modified — Content of Note 1 to entry incorporated to the terms.]

3.10

detachable part

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

[SOURCE: ISO 20342-1:2019, 3.10]

3.11

disability

umbrella term for *impairments* (3.13), activity limitations and participation restrictions denoting the negative aspects of the interaction between an individual (with a health condition) and that individual's contextual factors (environmental and personal factors)

[SOURCE: ICF 2001, WHO]

3.12

hand-held device

hand-held assistive product

equipment or part of equipment intended to be supported by the hand during *normal use* (3.20)

3.13

impairment

problem in body function or structure

EXAMPLE A significant deviation or loss.

[SOURCE: ICF 2001, WHO]

3.14**intended use**

use of a product, process or service in accordance with the specifications, instructions and information provided by the *manufacturer* (3.15)

Note 1 to entry: This information includes pre-sale information.

3.15**manufacturer**

natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party

3.16**load**

permissible weight

3.16.1**maximum user mass**

greatest permissible mass of the person using the product, measured in kilograms (kg)

3.16.2**minimum user mass**

lowest possible *user* (3.32) mass needed for activating or using an *assistive product* (3.3), measured in kilograms (kg)

3.16.3**maximum load**

safe working load

maximum external mechanical *load* (3.16) (mass) on equipment or an equipment part that is permitted in *normal use* (3.20)

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, the maximum load will be higher than the maximum user mass. In case of a product intended for the user to (just) lean on for support, the maximum user mass will be higher than the maximum load.

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.109, modified —Note 1 to entry added.]

3.17**mechanism**

system of parts working together

3.17.1**locking mechanism**

mechanism (3.17) that ensure that the *assistive product* (3.3) will stay in an intended position

3.18**medical device**

instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the *manufacturer* (3.15) to be used, alone or in combination, for human beings for one or more of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or *disability* (3.11);
- investigation, replacement, modification or support of the anatomy or of a physiological or pathological process or state,
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended

action by pharmacological, immunological or metabolic means, in or on the human body, but which might be assisted in its function by such means.

Note 1 to entry: Devices are different from drugs and their biological evaluation requires a different approach.

Note 2 to entry: Use of the term medical device includes dental devices.

[SOURCE: ISO 13485:2016, 3.11, modified — Parts of the definition removed, Note 1 to entry modified, Note 2 to entry added.]

3.19

mobile assistive product

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

3.20

normal use

use of a product, process, or service in accordance with the specifications, instructions, and information provided by the *manufacturer* (3.15), not only intended for medical use, but also maintenance, service, transport, etc.

Note 1 to entry: Normal use is not to be confused with intended use. While both include the concept of use as intended by the manufacturer, intended use focuses on the medical purpose while normal use incorporates not only the medical purposes, but also maintenance, service, transport, etc. "Medical use" and "medical purpose" include the purpose of assistive products as described in 3.2.

[SOURCE: ISO 17966:2016, 3.19, modified — Note 1 to entry added.]

3.21

operator

person handling the *assistive product* (3.3)

Note 1 to entry: The operator can either be the user or the assistant.

3.22

pendant control

hand-held device (3.12), which has a functional connection to the *assistive product* (3.3), controlling, e.g. articulations and/or movements

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

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

3.23

person with disability

person with one or more *impairments* (3.13), one or more activity limitations, one or more participation restrictions, or a combination thereof

[SOURCE: ICF 2001, WHO]

3.24

portable assistive product

equipment intended to be moved from one location to another while being carried by one or more persons

3.25**protection side rail**

physical barrier that can be a detachable accessory or integral to the overall construction of an *assistive product* (3.3) and is positioned to the side(s) of the assistive product that will prevent the *user* (3.32) from getting out of the assistive product by itself

Note 1 to entry: It can be movable, e.g. sliding sides, drop sides, folding sides.

[SOURCE: EN 50637:2017, 201.3.223]

3.26**risk management file**

set of records and other documents that are produced by risk management

3.27**robot**

programmed actuated *mechanism* (3.17) with a degree of *autonomy* (3.5) to perform locomotion, manipulation or positioning

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

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

3.28**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 user accidentally slipping or rolling off the lying support surface.

[SOURCE: EN 50637:2017, 201.3.224, modified]

3.29**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 also includes an error of the software.

[SOURCE: ISO 17966:2016, 3.26, modified — Note 1 to entry added.]

3.30**technical documentation**

manufacturer's (3.15) data that shows that an *assistive product* (3.3) conforms to specific requirements

3.31**usability**

characteristic of the *operator* (3.21) interface that establishes effectiveness, efficiency, ease of operator learning and operator learnability and satisfaction

3.32**user**

person with a *disability* (3.11) for whom the *assistive product* (3.3) is intended

4 General requirements**4.1 Risk analysis and management**

The safety of an assistive product 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

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

An assistive product may only be used as specified by the manufacturer in the intended use.

Risk management shall include all involved persons.

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

4.2 Intended performance and technical documentation

- a) An assistive product shall have sufficient strength and durability to sustain all loads expected during its intended use. This can be confirmed by using, as appropriate, references to relevant clinical and scientific literature in addition to requirements in this document, strength and/or durability calculations, and appropriate test standards, and their test results.
- b) The intended performance including, if appropriate, strength, durability and tipping stability of an assistive product shall be described in technical documentation which sets out its functional characteristics, its application(s) and conditions of use.

The technical documentation shall include, if appropriate, references to relevant clinical and scientific literature, any strength and/or life calculations, and conformity with appropriate test standards, and their test results.

4.3 Clinical evaluation and investigation

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

4.4 Assistive products that can be dismantled

If it is intended that an assistive product can be dismantled for storage, transportation and/or cleaning, the reassembly shall not create an unacceptable risk.

Manufacturer's design and instruction shall not allow reassembly in a way that presents a hazard.

4.5 Fasteners

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

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

4.6 Load limits

The maximum user mass, the minimum user mass and the maximum load shall all be declared by the manufacturer both in the instructions for use and labelling, if applicable.

NOTE Minimum user mass can be relevant, if a minimum mass is required to activate, e.g. cushions or systems added to seats to assist a person to stand or sit.

4.7 Immobilising means

If the movement of an assistive product or of any of its parts constitutes a risk for the user or a nearby person, there shall be immobilising means that provide control of the speed and/or prevent any undesired movement.

4.8 Usability

The manufacturer shall address usability when applicable, using IEC 60601-1-6 or IEC 62366-1:2015. These International Standards provide a methodology for manufacturers to assess the usability of a medical device.

The result of such considerations shall be described in the manufacturer's technical documentation.

4.9 Design requirements in relation to persons with sensory and cognitive impairments

Persons with sensory impairment, e.g. visual or hearing impairments and persons with cognitive impairments shall always be considered potential users of all assistive products.

The result of such considerations shall be described in the manufacturer's technical documentation.

NOTE 1 For guidance on cognitive impairments, see [A.4.9](#), ISO 21801-1 and ISO 21802.

NOTE 2 For guidance on hearing impairments, see [A.4.9](#).

4.10 Considerations for accessibility

Assistive products can be used by persons with disabilities other than the target users intended by manufacturers. To meet such diverse needs, accessibility considerations should be addressed concerning other disabilities than the target one(s). For guidance, see ISO/IEC Guide 71 and [Annex C](#).

4.11 Feedback

All user commands shall have some kind of feedback, e.g. audible, visible or haptic that clearly indicates that a command has been given and/or effectuated. The feedback shall be accessible for all relevant operators.

The sound level for a feedback or speech system shall be within 50-80 dB(A). Measurements shall be done in accordance with ISO 3746.

5 Materials

5.1 General

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

NOTE For guidance, see IEC 60601-1-9.

5.2 Flammability

5.2.1 General

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

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

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

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

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

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

When an assistive product is tested for flammability requirements, the test shall be performed within the flammability standard's guidelines.

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

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

5.2.2 Upholstered parts, mattresses, bed bases, bedding and textiles

5.2.2.1 General

Upholstered parts, mattresses and bed bases and bedding shall conform to the requirements of [5.2.2.1 a\)](#) or [5.2.2.1 b\)](#).

- a) If the manufacturer claims that an assistive product is resistant to ignition by cigarette or a small flame, it shall conform to the appropriate requirements in [5.2.2.2](#), [5.2.2.3](#), [5.2.2.4](#) or [5.2.2.5](#);
- b) if the clinical requirements prevent the use of materials that confirm to [5.2.2.1 a\)](#), the manufacturer shall adopt appropriate means to eliminate or reduce as far as reasonably practicable, the risk of hazardous situations developing from the ignition of the assistive product using the risk management process specified in ISO 14971. The assistive product shall be supplied with
 - 1) a warning that the assistive product is not flame retardant, placed on the product if possible, and included in the instructions for use, and
 - 2) a description of the precautions required to mitigate the increased risk.

5.2.2.2 Upholstered parts

If the manufacturer claims that the upholstered parts are resistant to ignition, progressive smouldering ignition and flaming ignition shall not occur when the materials used for the upholstered parts of an assistive product are tested in accordance with EN 1021-2 or other standards with an equivalent or higher safety level.

5.2.2.3 Other parts

If the manufacturer claims that the other parts are resistant to ignition, progressive smouldering ignition and flaming ignition shall not occur when the materials used for the upholstered parts of an assistive product are tested in accordance with EN 1021-2 or other standards with an equivalent or higher safety level. For instance, sling seats, sling backs, belts, restraint harnesses, foot supports and clothing guards - the material of each item shall be tested with the source applied centrally to surface intended to contact or support the occupant by the methods specified in EN 1021-2 or other standards with an equivalent or higher safety level.

5.2.2.4 Mattresses and bed bases

If the manufacturer claims that mattresses and/or bed bases are resistant to ignition, progressive smouldering ignition and flaming ignition shall not occur when tested in accordance with EN 597-1 and EN 597-2 or other standards with an equivalent or higher safety level.

NOTE Further information on flammability on mattresses to prevent pressure injuries can be found in ISO 20342-1:2019.

5.2.2.5 Bedding and textiles

If the manufacturer claims that bedding and textiles is resistant to ignition, progressive smouldering ignition and flaming ignition shall not occur when tested in accordance with ISO 12952-1 and ISO 12952-2 or other standards with an equivalent or higher safety level.

5.2.3 Polymeric parts

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

5.2.4 Electrical components

The enclosure of electrical components shall conform to flammability classification according to IEC 60601-1:2005+AMD1:2012+AMD2:2020.

5.2.5 Wiring

Insulated wiring shall have a flammability classification IEC 60332-1-2 and/or UL 1581 with classification VW-1, or better.

5.3 Biocompatibility and toxicity

Materials that come into contact with the human body shall be assessed for biocompatibility using the guidance in ISO 10993-1 and shall fulfil the following requirements.

The assessment shall take into account the people exposed during intended and normal uses.

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 that are carcinogenic, mutagenic or toxic to reproduction and other substances of very high concern (SVHCs). The assessment should follow the guidance given in [Annex B](#).

The result of the assessment shall be incorporated in the risk analysis and management (see [4.1](#)).

Additional issues should also be considered, e.g. in relation to nanotechnology, anti-microbial functions, environmental impact (e.g. micro plastic) and performance over life.

NOTE This includes contact by those involved in user care or transportation and storage of the product.

5.4 Contaminants and residues

5.4.1 General

The requirements given in 5.4.2 do not apply to the body fluids that can be collected in an assistive product (e.g. stoma care products) but only to those substances which are an integral part of an assistive product or are needed for its function (e.g. oil and grease).

5.4.2 Substances that can leak from an assistive product in intended use and in fault conditions

Substances that can leak from the assistive product shall either

- a) be assessed for biocompatibility in accordance with the guidance given in ISO 10993-1, or

The assessment shall take into account the people exposed during intended and normal uses.

NOTE 1 This includes contact by those involved in user care or transportation and storage of the product.

- b) be provided with protection that minimizes the possibility of such substances becoming a biological hazard.

NOTE 2 Substances that can leak include lubricants and hydraulic fluids.

NOTE 3 An example of a method of protection from a hazardous substance is where batteries are placed in a container made from acid resistant material.

5.5 Infection and microbiological contamination

5.5.1 Introduction

An assistive product should be designed to minimize fluid ingress to help prevent cross infection.

Throughout its working life, the outside of an assistive product might be regularly subject to contamination with blood, urine, faeces, other bodily secretions, viruses and bacteria. It is important that these contaminants can easily be removed from the surface and that they are not able to reach the internal components of the assistive product. Manufacturers shall incorporate liquid and moisture management into the design, manufacture and risk management process to prevent the ingress of fluids that support microbial growth.

5.5.2 Cleaning and disinfection

If an assistive product is intended to be cleaned, deodorized and/or disinfected, the method and suitable cleaning or disinfection materials shall be described in the information supplied by the manufacturer. The effect of these cleaning and disinfection processes should be verified and validated.

In addition, the methods for inspection in relation to the continued safe use shall be described in the information supplied by the manufacturer.

If an assistive product is intended to be cleaned by automatic washing systems or hand-held jet stream/steam washing, the details of the procedure, such as temperature, pressure, flow and pH value of cleaning/rinsing solution shall be described in the instructions for use.

Where practicable, the assistive product shall be labelled with appropriate symbols to represent the method of cleaning. See examples of labelling in [A.5.5.2](#).

NOTE It is only practicable when the assistive product is of sufficient size.

5.5.3 Machine washable assistive products

5.5.3.1 Requirements for machine washable assistive products

Assistive products specified by the manufacturer to be machine washable by an automatic machine washing system shall function normally after the test. Variations to the test procedure regarding test-cycle, temperature, time and cleaning fluids shall be covered in the risk management file of the manufacturer. The present test method represents a basic procedure for disinfection of an assistive product in a washing machine.

5.5.3.2 Test methods for machine washable assistive products

The requirements are verified through the following tests:

- a) parts and access covers that can be detached/opened without the use of a tool should be detached/opened:
 - 1) temperature preconditioning treatment of 10 days at $65\text{ °C} \pm 2\text{ °C}$ or at maximum value of the rated storage temperature, if higher, is carried out;
 - 2) the assistive product should then be kept at room temperature for not less than 16 hours.
- b) 50 test cycles according to the procedure the manufacturer described in the instruction for use or consisting of:
 - 1) 2 minutes wash with 70 °C water at a pH-value 5-8, 0,5 % cleaning and disinfectant solution as specified by the manufacturer;
 - 2) 20 seconds rinse with 85 °C water at a pH-value 5-8, and 0,2 % clear rinsing solution according to the data of the manufacturer;
 - 3) 10 minutes cooling at 20 °C ambient temperature.

Acceptance criteria:

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

ii) 24 h ($\pm$ 30 min) after the test cycles.

- 7) Perform a visual inspection for ingress of water that may result in an unacceptable risk (e.g. shorting of isolation barriers and violation of creepage distances).

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

5.5.3.3 Marking for machine washable assistive products

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

“For cleaning purposes this product can be used with automatic washing systems”.

or provided with a label (see example in [A.5.5.2](#)).

5.5.4 Animal tissue

Where a device has been manufactured utilizing tissues of animal origin or their derivatives, a risk management shall be performed and documented according to ISO 22442-1.

NOTE For guidance, see [A.5.5.4](#).

5.6 Resistance to corrosion

The risk of corrosion affecting the safety of the user or an assistant shall be assessed in the risk analysis and management (see [4.1](#)). The assessment shall be based on the intended use, the intended environment(s) and expected lifetime

NOTE As a guidance, ISO 9227 might be used for the assessment of corrosion resistance of metallic materials.

6 Emitted sound and vibration

6.1 Noise and vibration

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

Measurements for noise of power operated assistive products shall be done in accordance with ISO 3746 and the result of the measurement shall be recorded in the pre-sale information and in the instructions for use.

NOTE For guidance, see [A.6.1](#).

6.2 Sound levels and frequencies of audible warning devices

The frequency shall be within the range 500 Hz to 16000 Hz and is recommended to be within the range of 500 Hz and 3000 Hz.

The A-weighted sound pressure level of auditory alarms shall be 65 dB or higher. It is recommended that the level is higher than 75 dB.

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

Measurements shall be made in accordance with ISO 3746.

7 Electromagnetic compatibility

Assistive products containing electrical or electronic devices/components shall conform to the requirements of IEC 60601-1-2.

NOTE For guidance, see [A.7](#).

8 Electrical safety

8.1 General

An electrically operated assistive product shall conform to IEC 60601-1:2005+AMD1:2012+AMD2:2020 regarding electrical safety unless the requirements are covered by this document. For electrical safety covered by both IEC 60601-1:2005+AMD1:2012+AMD2:2020 and this document, the requirements of this document prevail over the ones given in IEC 60601-1:2005+AMD1:2012+AMD2:2020.

For assistive products intended to be used in a home care environment, IEC 60601-1-11 shall be applied.

When software is used to control the motion of the assistive product, the requirements specified in IEC 60601-1:2005 +AMD1:2012, Clause 14 shall apply.

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

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

8.2 Battery powered assistive products - Charge level indicator

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

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

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

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

8.3 Electrically heated blankets, pads and similar flexible heating appliances

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

8.4 Ingress of liquids or particulate matter

8.4.1 Ingress of liquids

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

Assistive products that are not in contact with water during normal use or reasonably foreseeable misuse (e.g. during the cleaning process) shall at least be protected to IPX2. Conformity is checked by tests in IEC 60529 with the assistive product placed in the least favourable position for normal use within 5 minutes after the water test and after 1 hour to verify its functions.

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

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

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

8.4.1.1 Requirements

If liquid can come into an enclosure unintentionally, there shall be a way for the liquid to get out of the enclosure, or the liquid shall not cause any harm. The hazards that can be caused by the ingress of liquids to non-electrically powered assistive products shall be assessed in the risk analysis and management (see 4.1).

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

8.4.2 Ingress of particulate matter

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

Conformity with the requirements in IEC 60601-1:2005+AMD1:2012+AMD2:2020, 5.9.2 accessible parts (test finger) automatically ensures a protection rating of min. IP2X according to IEC 60529.

8.5 Pendant controls

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

Conformity is checked by the following tests:

The pendant control has to fall 1000 times as specified in IEC 60068-2-31.

After the test, the pendant control is checked by inspection, functional test and relevant electrical safety tests.

9 Overflow, spillage, leakage and ingress of liquids

9.1 Overflow

9.1.1 Requirements

If an assistive product incorporates a reservoir or liquid storage chamber that can be overfilled or can overflow in the manufacturer's intended use, liquid overflowing from the reservoir or chamber shall not wet electrical insulation and live parts, which are liable to be adversely affected by such a liquid, nor shall a safety hazard be created. Unless restricted by a marking or by the instructions for use, no safety hazards shall develop if assistive products are tilted through an angle that is 15° greater than the maximum inclination that can occur during intended use.

9.1.2 Test method

Fill the reservoir to the maximum level specified by the manufacturer and, if possible, add further liquid equal to 15 % of the capacity of the reservoir or until the reservoir is full.

Tilt the assistive product through an angle of $15^{\circ} \begin{smallmatrix} +1^{\circ} \\ -0^{\circ} \end{smallmatrix}$ in each direction(s) starting from the position of the manufacturer's intended use or the maximum angle of intended use, whichever is the most severe. If necessary, refill the reservoir between tests.

If the working position is a specified range the $15^{\circ} \begin{smallmatrix} +1^{\circ} \\ -0^{\circ} \end{smallmatrix}$ shall add to the extreme position of this range.

These procedures shall not wet parts of the assistive product that will cause a hazard. In particular, an assistive product shall show no signs of wetting of un-insulated live parts or electrical insulation of parts which can cause a safety hazard. For electrical insulation, in case of doubt, the assistive product shall be subjected to the dielectric strength test as described in IEC 60601-1:2005+AMD1:2012+AMD2:2020.

9.2 Spillage

9.2.1 Requirements

Assistive products requiring the use of liquids for the manufacturer's intended use shall be so constructed that spillage does not wet parts that can cause a safety hazard in the product.

9.2.2 Test method

Pour $200 \text{ ml} \begin{smallmatrix} +5 \text{ ml} \\ -0 \text{ ml} \end{smallmatrix}$ of water steadily on the top surface of the assistive product.

At the worst case, as determined in the manufacturer's risk assessment, in relation to safety hazard, the assistive products shall function as specified by the manufacturer.

9.3 Leakage

Assistive products can be so constructed that liquid that might escape in single fault condition does not cause a safety hazard.

9.4 Ingress of liquids

9.4.1 Requirements

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

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

NOTE 1 See [A.9.4](#).

NOTE 2 For requirements for electrically powered assistive products, see [Clause 8](#).

9.4.2 Test method

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

10 Surface temperature

The risk analysis (see [4.1](#)) shall identify hazards and evaluate the risks associated with the surface temperature of parts that can come into contact with human skin during the intended conditions of use.

If the assistive product is intended to increase the user temperature, the assistive product shall be provided with a specific safety mechanism that will warn the operator when 41 °C is exceeded as required in IEC 60601-2-35.

The risk analysis and management shall take into account of:

- a) the range of ambient temperatures to be expected during the intended use and foreseeable misuse;
NOTE These temperatures could include direct exposure to sunshine, hot water, hot air, extreme cold, saunas, etc.
- b) temperatures that can result from single fault conditions;
- c) the ergonomic data on acceptable temperatures of touchable surfaces in IEC 60601-1:2005+AMD1:2012+AMD2:2020, Table 24 adapted to the use of assistive products by people with insensitive skin (e.g. cannot feel heat) and/or damaged skin for a duration of 10 min or more. In this case, the maximum temperature shall not exceed 41 °C (see [Table 1](#)) when measured by the methods of test in IEC 60601-1:2005+AMD1:2012+AMD2:2020.

If a manufacturer cannot meet the requirement of c) without impairing the intended performance of the assistive product, each assistive product should be supplied with a warning identifying which surfaces may reach a higher temperature than that specified in [Table 1](#) and a description of the precautions necessary to offset the increased risk.

Table 1 — Allowable maximum temperature for skin contact with assistive products (applied parts)

Applied parts of assistive product		Maximum temperature ^a		
		°C		
		Metals and liquids	Glass, porcelain, vitreous material	Moulded material, plastic, rubber, wood
Applied part having contact with a person for a time t	$t < 1$ min	51	56	60
	$1 \text{ min} \leq t < 10 \text{ min}$	48	48	48
	$10 \text{ min} \leq t$	41	41	41

^a According to ISO 17966:2016, these temperature limit values are applicable for the healthy skin of adults, but in the temperature limitation for durations of more than 10 min, persons with disability with sensitive skin or no sensation have also been considered. They are not applicable when large areas of the skin (10 % of total body surface or more) can be in contact with a hot surface. They are not applicable in the case of skin contact with over 10 % of the head surface. Where this is the case, appropriate limits shall be determined and documented in the risk management file.

11 Sterility

11.1 Sterility requirements

If the assistive product is intended to be sterilized, the method shall be described in the information supplied by the manufacturer.

An assistive product which is labelled "STERILE" shall conform to the requirements of EN 556-1.

11.2 Sterilization processes

Sterilization processes shall be validated and routinely controlled.

If an assistive product is sterilized by ethylene oxide, the process shall conform to the requirements of ISO 11135.

If an assistive product is sterilized by steam, the process shall conform to the requirements of ISO 25424.

If an assistive product is sterilized by radiation, the process shall conform to the requirements of ISO 11137-1 and ISO 11137-2.

11.3 Maintenance of sterility in transit

The packaging shall conform to the requirements of ISO 11607-1.

12 Safety of moving parts

12.1 Squeezing

Unless the intended purpose of an assistive product, or part of an assistive product, is to grip, cut, squeeze etc., or if the intended use cannot be achieved without a hazard such as risk of squeezing (e.g. the elbow or knee flexion of a limb prosthesis):

- a) any moving parts that constitute a safety hazard shall be provided with guards that can only be removed by the use of a tool; or
- b) the gap between exposed parts of an assistive product that move relative to each other shall be maintained throughout the range of movement at less than the minimum value or more than the maximum value set out in [Table 2](#):

Table 2 — Safe distances between moving parts

To avoid	Safe distances for adults	Safe distances for children ^a
Finger traps	Less than 8 mm or more than 25 mm	Less than 4 mm or more than 25 mm
Foot traps	Less than 35 mm or more than 120 mm	Less than 25 mm or more than 120 mm
Head traps	Less than 120 mm or more than 300 mm	Less than 60 mm or more than 300 mm
Genitalia traps	Less than 8 mm or more than 75 mm	Less than 8 mm or more than 75 mm

^a According to ISO 17966:2016, it also includes adults with a height of less than 146 cm, or a mass of less than 40 kg, or BMI of less than 17.

or,

- c) if cords (ropes), chains and drive belts are used, they shall either be confined so that they cannot run off or jump out of their guiding devices, or a safety hazard shall be prevented by other means. Mechanical means applied for this purpose shall be removable only by the use of a tool; or
- d) the movement is in the operator's field of view and the assistive product shall incorporate a continuous activation system which initiates the movement when it is operated and stops the movement when it is released (e.g. a spring-loaded control device that returns to the stop position when released).

If the continuous activation system is defeated in a single fault condition, then a second risk control measure shall be provided, such as one or more emergency stopping device(s) (see [12.3](#)), or the assistive product shall otherwise be single fault safe; or

- e) the assistive product shall incorporate a means for detecting that a person is in danger of being trapped and automatically activating a means of preventing injury (e.g. by stopping the movement). In case the programmable control system is used as the risk control measure, the system should conform to the requirements given in IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 14; or

- f) the assistive product shall be provided with an electronic control system consisting of one or more sensors, logic units, and actuators that interrupts the operation in an orderly manner in accordance with IEC 60204-1.

For moving parts that can cause squeezing, manufacturers shall take into consideration what part/parts of the body that are at risk. The user/user group has to be specified, so that correct safety distances can be applied.

NOTE A product intended to be used by a child can also be operated by an adult.

12.2 Mechanical wear

Parts subject to mechanical wear likely to result in a safety hazard shall be accessible for inspection as specified in the instructions by the manufacturer.

12.3 Emergency stopping functions

If the device has electrical functions, IEC 60601-1:2005+AMD1:2012+AMD2:2020, 9.2.4 shall apply.

13 Means to prevent falling out

13.1 General

The manufacturer shall evaluate the risk of falling out, taking into account the characteristics of the users, user's posture in intended use and the environmental factors.

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

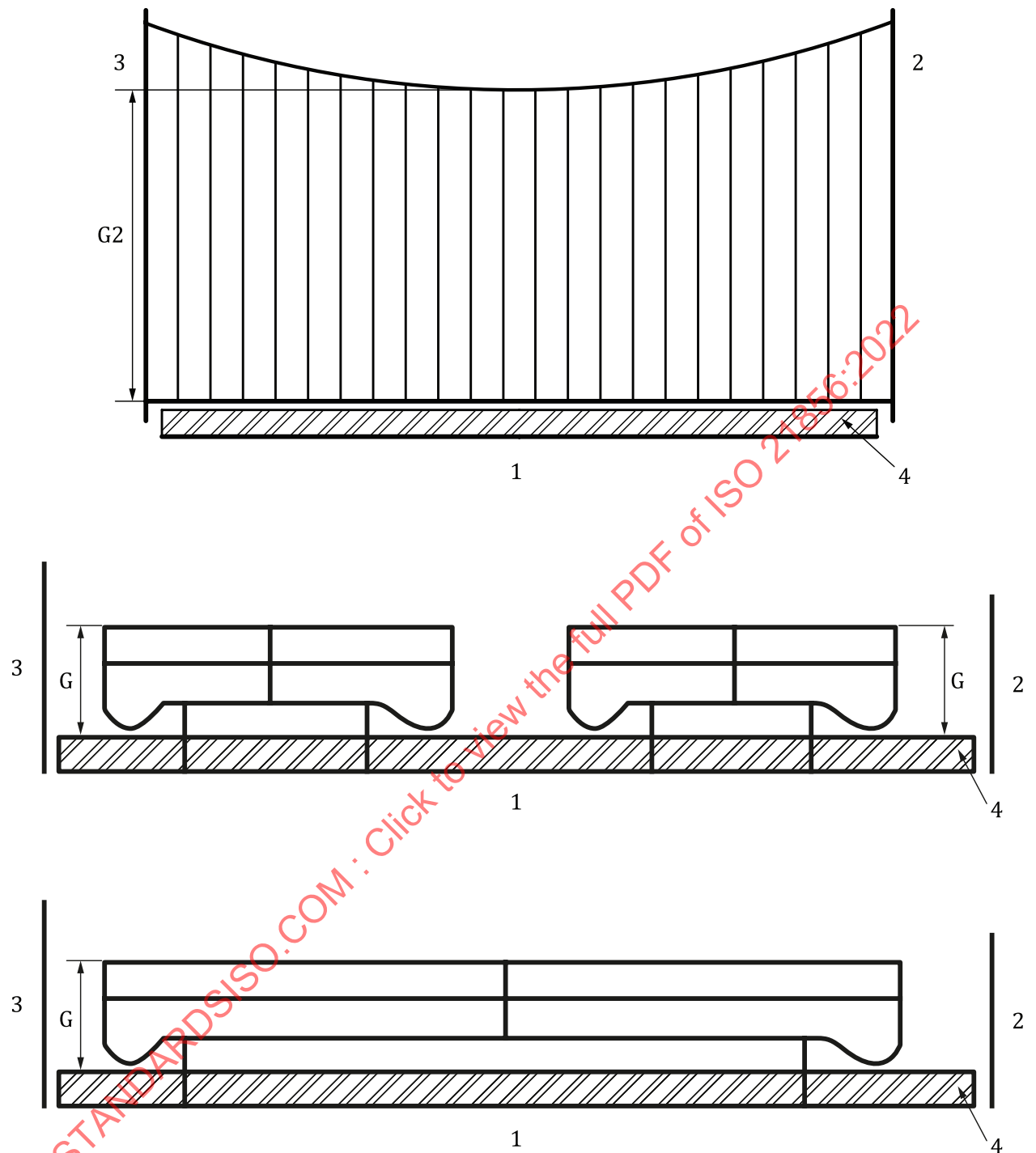
Conformity is checked by inspection of the risk management file. For side rails, see [13.2](#).

13.2 Protection against inadvertent user falls in relation to side rails

Side rails intended to prevent users from falling out from a lying support surface shall be designed with minimum height/length requirements as indicated by G in [Figure 1](#) and [Table 3](#).

Protection side rails presenting a barrier for small children up to 2 years able to stand up shall be designed with minimum height requirements as indicated by G2 in [Figure 1](#). Protection side rails shall cover the full length of the sides of the lying support surface.

Conformity is checked by measurement of G or G2 and inspection of the risk management file.



Key

- 1 lying support surface
- 2 foot board
- 3 head board
- 4 mattress/padding

G, G2 height of the top edge of the protection side rail above the lying support surface/mattress, if any.

Figure 1 — Height of side rail/protection side rail

Table 3 — Protection against inadvertent falls and climbing out of an assistive product

Designator	Description	Requirement/ Conformity method
G Side rail	Height of the top edge of the side rail above the lying support surface/ padding or mattress without compression in at least 50 % of the length of the lying support surface. Other raised and locked positions not meeting the height of 220 mm or length at least 50 % for side rails and specified for purposes other than side rail application (e.g. mobilization bar or grab handles) shall be covered in the manufacturer's risk management file. When side rails cover less than the full length of the lying support surface, those parts that are above 220 mm shall be placed strategically to help prevent accidental falls from the assistive product. NOTE Placement of the 220 mm portions of the rail might need to be placed next to those parts of the body that are highest (e.g. shoulder for a user lying on their side) and the parts that could lead to slipping out of the assistive product (legs) in order to prevent accidental rollout or sliding out.	≥220 mm Conformance is checked by measurement.
G2 Protection side rail	Height of the top edge of a protection side rail above the lying support surface/ padding/ mattress without compression or above the top of any foothold, tested as specified in EN 716-2:2017, in the full length of the lying support surface. Height of the top edge of end panel, if any, designed with protection side rails above the lying support surface/padding/mattress without compression or above the top of any foothold, tested as specified in EN 716-2:2017, in the full width of the lying support surface. Other raised and locked positions not meeting the height of 600 mm for side rails and specified for purposes other than side rail application shall be covered in the manufacturer's risk management file.	≥600 mm Conformity is checked by measurement NOTE The requirement of ≥600 mm is only sufficient for children with height up to 93 cm. A risk assessment shall be carried out in the actual situation, as it might not be able to design a protection side rail with a sufficient height for all children.

NOTE See [A.13.2](#).

14 Prevention of traps for parts of the human body

14.1 Holes and clearances

Holes in, and clearances between stationary parts that are accessible to the user and/or assistant during the intended use of an assistive product shall be as specified in [Table 4](#).

Table 4 — Safe distances between stationary parts

To avoid	Safe distances for adults	Safe distances for children ^a
Finger traps	Less than 8 mm or more than 25 mm	Less than 5 mm or more than 12 mm
Foot traps	Less than 35 mm or more than 100 mm	Less than 25 mm or more than 45 mm
Head traps	Less than 120 mm or more than 250 mm	Less than 60 mm or more than 250 mm
Genitalia traps	Less than 8 mm or more than 75 mm	Less than 8 mm or more than 75 mm
^a According to ISO 17966:2016, it also includes adults with a height of less than 146 cm, or a mass of less than 40 kg, or BMI of less than 17.		

If the intended purpose of an assistive product cannot be met without a hazard caused by the size of holes and the clearance between stationary parts, a warning and instructions on how to operate the assistive product safely shall be provided in the instructions for use.

For stationary parts that can cause a trap, manufacturers shall take into consideration what part/parts of the body that are at risk. The user/user group shall be specified, so that correct safety distances can be applied.

A product intended to be used by a child may also be operated by an adult.

The design of parts that confine a hole or clearance shall take into consideration the forces that can be applied in normal use.

NOTE A force might cause a hole/clearance to widen. This can then cause a failure, as specified in [Table 4](#).

On holes with the shape of a keyhole or V-shaped openings, the lower limit shall not apply. When inspecting the assistive product for traps for body parts any flexibility/elasticity of adjacent parts shall be taken into account.

14.2 V-shaped openings

The risk of entrapment in V-shaped openings shall be assessed by the manufacturer. Particular guidance can be found in [A.14.2](#).

15 Folding and locking mechanisms

15.1 General

Folding and adjusting mechanisms can cause a hazard if parts of the body can enter a gap between parts and be trapped when the gap is closed.

If an assistive product incorporates folding mechanisms, it shall conform to requirements specified in [15.2](#) and [15.3](#).

15.2 Locking mechanisms

The mechanisms shall be capable of being securely locked when the assistive product is in any fixed working configuration. It shall also be capable of being securely locked when folded if it constitutes a risk for the user or assistant. The product shall fold in a safe manner.

15.3 Prevention of trap and squeeze hazards

If there is a risk of trapping or squeezing when an assistive product is folded/unfolded, one of the following solutions is required:

- a) the assistive product shall incorporate means to protect the user from trap and/or squeeze hazards; or
- b) the gap between exposed parts of an assistive product that move relative to each other shall be maintained throughout the range of movement at less than the minimum value or more than the maximum value set out in [Table 2](#); or
- c) if the intended purpose of an assistive product cannot be met without a hazard such as squeezing, a warning and instructions on how to operate the assistive product safely shall be provided in the instructions for use.

The design of a guard shall take into consideration the forces that can be applied in normal use.

16 Carrying handles

16.1 General

Manufacturers should note that national and other requirements might demand mass limits in excess of the following.

If an assistive product or a part of an assistive product is intended by the manufacturer to be portable and it has a mass of more than 10 kg, it shall either:

- a) be provided with one or more suitably placed and suitable handling devices (e.g. handles, lifting eyes) enabling the assistive product to be carried by two or more persons; or
- b) the instructions for use shall indicate the points where assistive products can be lifted safely and describe how they should be handled during lifting, assembly and/or while carrying. If practical, the component parts shall be labelled to indicate where the assistive product can be lifted safely and/or how it can be handled during assembly and/or while carrying.

16.2 Requirement

If an assistive product incorporates carrying handles or grips, they shall not become detached from the assistive product and there shall not be any permanent distortion, cracking or other evidence of failure when tested as specified in [16.3](#).

After the completion of the test, the assistive product shall operate as intended by the manufacturer.

16.3 Test method

If an assistive product has one handle or grip, or if an assistive product can be readily carried or lifted by one of a number of handles or grips, determine the force on each handle or grip when it is carried or lifted.

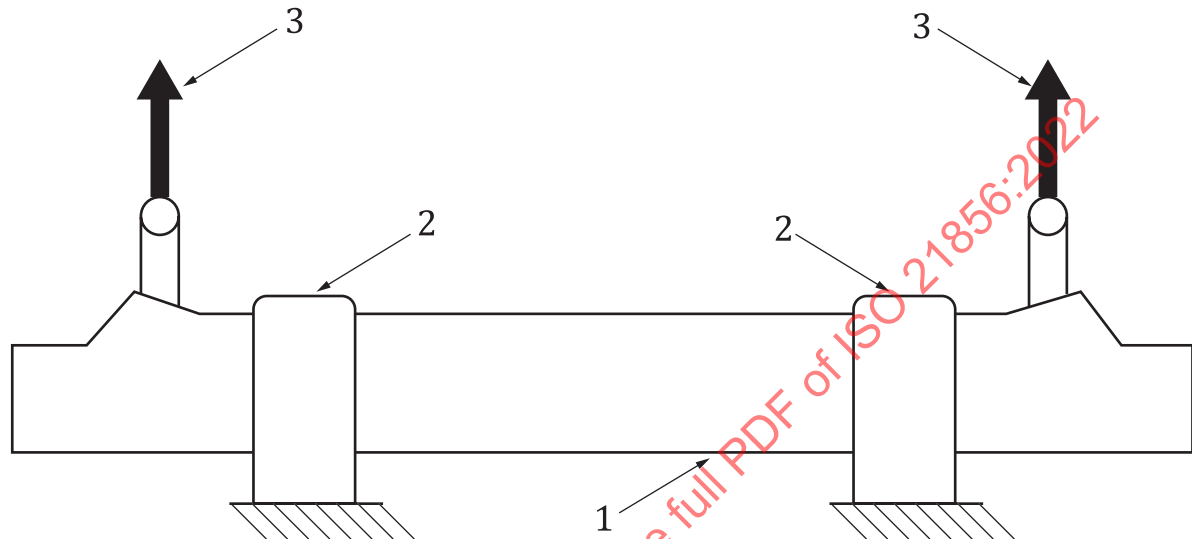
If an assistive product has more than one handle or grip, determine the force on each handle or grip when the assistive product is carried or lifted in the intended manner.

On each handle or grip determine the force necessary to carry the assistive product in the intended manner with a tolerance of force $\begin{smallmatrix} +5\% \\ -0\% \end{smallmatrix}$. If there is more than one intended manner, determine the highest force.

Restrain the assistive product from being lifted or moved during the following test. Apply a force to each handle or grip, equal to twice that determined above with a tolerance of $\pm 5\%$ uniformly distributed over a $70 \text{ mm} \pm 5 \text{ mm}$ length in the centre of the handle or grip, avoiding shock (see [Figure 2](#)).

Maintain the force for between 60s and 70s.

Remove the force and the restraints and inspect the assistive product for damage and satisfactory operation.



Key

- 1 assistive product
- 2 restraints
- 3 test force

Figure 2 — Carrying handle test (example)

17 Assistive products that support or suspend users

17.1 General

If an assistive product is intended to support or suspend persons with disability and/or an assistant or load, no part of the assistive product shall become detached, exhibit cracking, permanent deformation, loss of stability or unacceptable risk inhibiting basic safety and essential performance when tested as specified in [17.2](#) and [17.3](#). After the test, the assistive product shall operate as intended by the manufacturer.

If an assistive product is intended to fold for transport and/or storage, it shall not fold when tested as specified in [17.2](#) and [17.3](#).

NOTE The inspection depends on the type of product as per the risk assessment.

17.2 Static forces

17.2.1 Assistive products that support users

Position the supported system in the least favourable position of intended use. Apply a test load to the support surface in a manner that ensures that there is negligible dynamic loading. The test load is equal

to the maximum load specified by the manufacturer, with a tolerance of $\begin{smallmatrix} +5\% \\ -0\% \end{smallmatrix}$, multiplied by safety factor of 1,5.

Maintain the test load for 60 s to 70s.

17.2.2 Assistive products that suspend users

Position the suspended system in the least favourable position of intended use. Apply a test load to the support surface in a manner that ensures that there is negligible dynamic loading. The test load is equal to the maximum load specified by the manufacturer, with a tolerance of $\begin{smallmatrix} +5\% \\ -0\% \end{smallmatrix}$, multiplied by safety factor as specified in [Table 5](#).

Table 5 — Safety factors on suspended systems

Lifting accessories	Safety factors
Wire-rope	5 times
Chains	4 times
Textile ropes or slings	7 times
Metallic components	4 times
Manually operated machinery	1,5 times

17.3 Dynamic forces

Where dynamic forces (due to sitting down, standing up, user handling process or the like) can be exerted on assistive products parts intended to support or suspend an user or operator in normal use, the assistive products shall maintain basic safety and essential performance.

Conformity is checked by applying a test load equal to the maximum load intended by the manufacturer for a supported and suspended system with a tolerance of $\begin{smallmatrix} +5\% \\ -0\% \end{smallmatrix}$, to the support surface in the worst case position (in a manner that ensures that there is negligible dynamic loading). The test cycle shall be calculated based on normal use, intended environment and life time of the product.

17.4 Requirements and test method for tips

17.4.1 General

If the assistive product is provided with a tip that carries or supports the user, it shall be safe in its use and environment.

EXAMPLES A shower chair, a crutch, vertical support poles.

The number of test cycles shall be calculated based on the intended use and expected service and/or lifetime specified by the manufacturer.

17.4.2 Friction of tips

For safety of friction of tips for any assistive product, using a tip, intended to be placed on a floor, table or on the ground, the applicable clauses of ISO 24415-1 shall be used.

17.4.3 Durability of tips

For durability of tips for any assistive product, using a tip, intended to be placed on a floor, table or on the ground, the applicable clauses of ISO 24415-2 shall be used.

18 Portable and mobile assistive products

18.1 Portable assistive products

A portable assistive product or any of its parts, that is portable, shall withstand the stresses caused by a free fall from the height indicated in [Table 6](#) onto a hard surface.

NOTE For requirements and test methods for a pendant control, see [8.5](#).

Conformity is checked by the following test:

The sample to be tested, with the maximum load in place, is lifted to a height as indicated in [Table 6](#) above a 50 mm ± 5 mm thick hardwood board (for example, >600 kg/m) that lies flat on a concrete floor or a similar rigid base. The dimensions of the board shall be at least those of the footprint of the sample tested. The sample is dropped three times from each orientation in which it may be placed during the intended use.

Table 6 — Drop height

Mass (<i>m</i>) of portable assistive product or its parts kg	Drop height cm
$m < 0,2$	100
$0,2 < m < 1$	20
$1 < m < 10$	5
$10 < m < 50$	3
$m > 50$	2

After the test, any damage sustained which results in an unacceptable risk as determined by inspection of the risk management file and inspection of the assistive product parts that are portable, constitutes a failure.

18.2 Mobile assistive products

A mobile assistive product and any of its parts that is mobile shall withstand the stresses caused by rough handling and movement and shall not result in an unacceptable risk or loss of function.

Conformity is checked by the following tests.

The sample is tested in the intended transport position with maximum rated load in place and in the most adverse condition permitted for the intended use. During the test, suitable precautions shall be taken to prevent over-balance caused by the rough handling stress/shock.

a) Ascending step shock

The sample is pushed three times in its intended direction of travel at a speed of 0,8 m/s ± 0,1 m/s or, for a motor driven mobile assistive product, the maximum speed capable of being maintained, against a solid hardwood plane with vertical face of 40 mm that is rigidly attached to an otherwise flat floor. The direction of movement is perpendicular to the face of the obstacle. The sample need not go over the 40 mm obstruction.

b) Descending step shock

The sample is pushed three times in its intended direction of travel at a speed of 0,8 m/s ± 0,1 m/s or, for a motor driven mobile assistive product, the maximum speed capable of being maintained, in order to fall over a descending vertical step having a height of 40 mm affixed flat on a rigid base (e.g. concrete).

The direction of movement is perpendicular to the face of the descending step.

During performance of the descending step shock test, if a part other than the castor comes in contact with the obstruction before the castor touches the ground, the assistive product continues to be pushed until it has fully descended.

c) Door frame shock

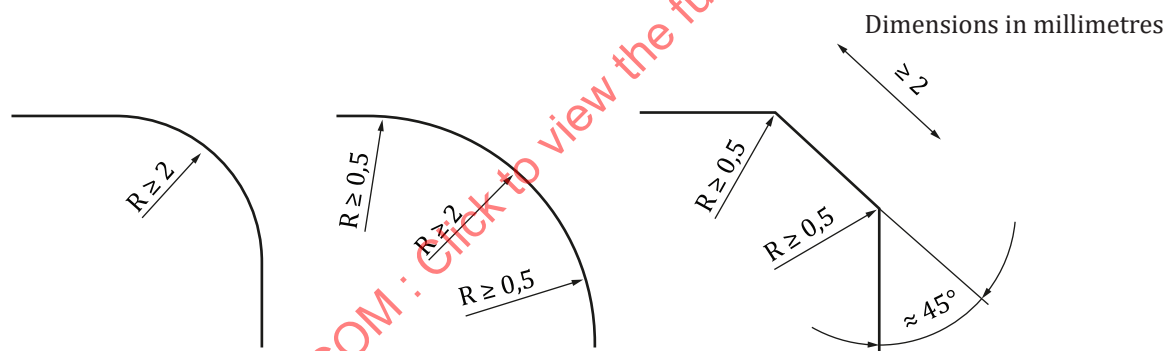
The sample is moved three times in its normal direction of travel at a speed of $0,8 \text{ m/s} \pm 0,1 \text{ m/s}$, or, for a motor driven mobile assistive product, the maximum speed capable of being maintained, against a hardwood vertical obstacle having a width and thickness of 40 mm affixed to a vertical rigid support (e.g. concrete). The height of the vertical obstacle shall be higher than the contact point(s) of the assistive product.

The direction of movement is perpendicular to the face of the obstacle.

After each test, the sample shall be inspected for any damage, which results in an unacceptable risk or loss of function. Any such damage constitutes a failure.

19 Surfaces, corners, edges and protruding parts

If not required for the intended function of an assistive product, all accessible edges, corners and surfaces shall be smooth and be free from burrs and protruding parts and sharp edges shall be rounded or chamfered. Conformity is checked by measurement as indicated in Figure 3. Alternatively, the risk management process shall consider surfaces, corners and edges and the associated materials and components used.



Reproduced with permission from EN 50637:2017, Figure 201.119.

Figure 3 — Required minimum radii of edges and corners

NOTE For guidance, see [A.19](#).

20 Hand-held assistive products

An assistive product and any of its parts that is hand-held during its intended use shall not result in an unacceptable risk or loss of function as a result of a free fall.

NOTE 1 For requirements and test methods for a pendant control, see [8.5](#).

Conformity is checked by the following tests:

The sample to be tested, with the maximum rated load in place, is allowed to fall freely once from each of three different starting orientations encountered during the intended use from the height at which the assistive product, accessory or assistive product parts are used (as defined by the manufacturer specified in the accompanying documents), or from a height of 1 m, whichever is greater, onto a $50 \text{ mm} \pm 5 \text{ mm}$ thick hardwood board (hardwood $> 600 \text{ kg/m}^3$) lying flat on a concrete or a similar rigid base.

After the test, the hand-held assistive product and any of its parts that are hand-held during their intended use shall not result in an unacceptable risk or loss of function.

NOTE 2 There might be a hand-held assistive product that might need more drops due to its intended use or user group.

NOTE 3 For guidance on assistive products used in combination with hand-held consumer products, see [A.20](#).

21 Assistive products for children

If an assistive products is intended to be used by children, it shall fulfil the following requirements in order to prevent choking hazards.

Any part that can be detached without the use of a tool shall be of a size where it cannot create a choking hazard to small children (under the age of 36 months).

Conformity is checked by the following test:

The part shall not fit wholly within the cylinder in [Figure 4](#) (reproduced from ISO 31110:2020, Figure 22).

Dimensions in millimetres

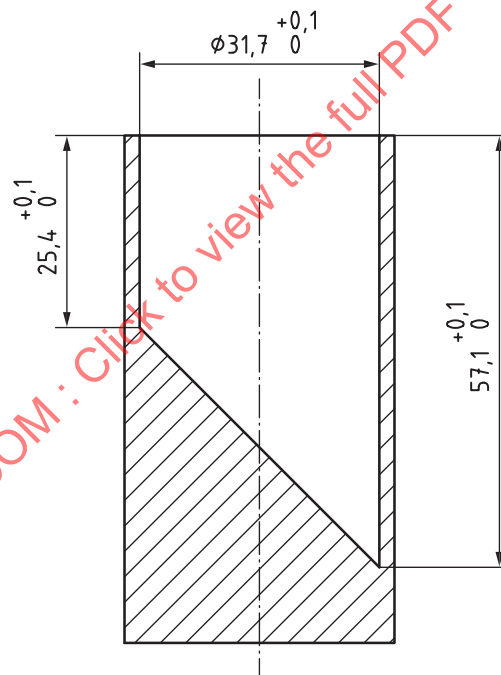


Figure 4 — Small parts cylinder

22 Stability

For safety of stability of any assistive product, other than fixed or hand-held, intended to be placed on a floor, table or on the ground, the relevant parts of Clause 9.4.1, 9.4.2, 9.4.3 of IEC 60601-1:2005+AMD1:2012+AMD2:2020, shall be used.

NOTE Relevant parts are dependent on the intended use of the product.

23 Forces in soft tissues of the human body

The hazards that can be caused by forces applied to the soft tissues of the body shall be assessed in the risk analysis and management (see [4.1](#)).

NOTE For guidance, see [A.23](#).

24 Ergonomic principles

An assistive product shall be designed to the ergonomic principles set out in EN 614-1, taking into account the special needs of the person with a disability for whom the assistive product is intended.

An assistive product may be used not only by whom it is primarily intended for, but also by an assistant. The ergonomic principles set out in EN 614-1 shall apply to all involved persons.

Grips, handles and pedals shall suit the functional anatomy of the user, according to the intended use and meet with the following requirements:

- a) the distance between any handle (part intended to be grabbed) requiring an operating force of more than 10 N and any construction part of the assistive product shall not be less than 35 mm;
- b) the distance between any upper surface of a pedal (in its operating position) and any other part of the assistive product shall have a vertical toe clearance of not less than 75 mm;
- c) the diameter of any operating handles and/or knobs requiring an operating force of more than 10 N shall be between 19 mm and 43 mm;
- d) for assistive products operated from a standing position, pedals shall be placed not more than 300 mm above the surface of the floor;
- e) for assistive products operated from a standing position, hand operated controls shall be placed at a height of 800 mm to 1200 mm above the surface of the floor;
- f) handles for pushing and/or pulling shall be placed at a minimum height of 900 mm.

NOTE 1 For guidance on operating forces, see [A.24](#).

NOTE 2 Some operating controls might need other positions depending of the use of the assistive product.

25 Requirements for information supplied by the manufacturer

25.1 General

The information supplied by the manufacturer comprises the data in the instructions for use and on the label. All information shall, as far as possible, be available in Pictogram.

The information applied to, and supplied with, assistive products shall conform to ISO 20417.

Any means of provision of information with assistive products shall take into account the intended users, the conditions of use and any issues specific to individual assistive product type that are necessary for the safe and effective use of the product.

Special attention shall be paid to accessibility of the user information, particularly the instructions for use and the design of labels and the design and presentation of warnings.

Further guidance on the preparation of instructions can be found in IEC/IEEE 82079-1.

Information on how to obtain the user information in a format appropriate for use by people with visual, reading or cognitive disabilities shall be considered.

NOTE 1 Further guidance can be found in [Annex C](#).

NOTE 2 Further guidance in relation to cognitive accessibility can be found in ISO 21801-1.

25.2 Instructions for use

25.2.1 General

The manufacturer should provide the information in the instructions for use in three separate sections: pre-sale, user and service information as specified in [25.2.2](#), [25.2.3](#) and [25.2.4](#) respectively. These may be provided as separate printed documents or in other forms of media to meet the needs of individual users or their assistants.

25.2.2 Pre-sale information

In addition to the requirements of [25.1](#), pre-sale information shall include the following:

- a) information on how to obtain the user information in a format appropriate for use by people with visual, reading or cognitive disabilities;
- b) as far as possible, a description of the intended use, the intended user group and the intended environment;
- c) maximum and minimum user mass and maximum load;
- d) maintenance instructions, if applicable;
- e) if an assistive product is intended to be cleaned, a description of the method and suitable cleaning materials, including precautions needed to avoid corrosion, if applicable;
- f) if an assistive product is intended to be disinfected, a description of the method and suitable materials, including any precautions needed to avoid corrosion, if applicable;
- g) the overall dimensions (width, length and height) of the assistive product, expressed in millimetres, and its mass, expressed in kilograms, when it is ready for use and, if applicable, when it is folded or dismantled;
- h) if the assistive product can be dismantled or has any removable parts, the mass expressed in kilograms of each part that has a mass of more than 10 kg;
- i) if the assistive product is supposed to be used in combination with other products, the manufacturer shall state to which products, and how this can be done in a safe way;
- j) warning about dangerous combinations of devices (e.g. cushions for the prevention of decubitus ulcers often only work on correct seat surface) and combinations of flame resistant and non-flame-resistant material;
- k) a list of accessories, detachable parts and materials that the manufacturer has determined as being intended for use with the assistive product;
- l) if a programmable controller is fitted, information on the method of programming, the competence required to carry out the programming and the effects on performance;
- m) operator control adjustments;
- n) whether and how the assistive product can be folded or dismantled to assist in storage or transport;
- o) instructions regarding transport of the assistive product (e.g. in a car or aeroplane);
- p) measured sound power level.

25.2.3 User information

User information shall be provided by the manufacturer with each assistive product. Information shall contain all pre-sale warnings and information and the following as applicable for each assistive product:

- a) the location and the type of identification number/word on the assistive product shall be given for the unique identification number of the assistive product;
- b) the intended user;
- c) any adjustment or settings required before the assistive product can be used and information on how adjustments or settings affect the assistive product;
- d) information on adjustment possibilities and the competence required to carry out these adjustments;
- e) instructions on operation of all controls;
- f) the battery type and nominal voltage;
- g) instructions for battery maintenance;
- h) instructions for operating the battery charger, including warnings regarding any potential safety hazards (e.g. a possibility of gas accumulating in the charging area);
- i) instructions on dismantling and re-assembly of the assistive product or any removable parts;
- j) the positions of points where the component parts can be gripped for safe moving and handling and/or a method for handling during dismantling, assembly or carrying;
- k) a warning if surface temperatures can increase / decrease when exposed to external sources of heat or cold (e.g. sunlight, outdoor environment);
- l) a warning if the assistive product might disturb the operation of devices in its environment that emit electromagnetic fields (e.g. alarm systems of shops, automatic doors, etc.);
- m) a warning if the performance of the assistive product can be influenced by electromagnetic fields (e.g. those emitted by portable telephones, electricity generators or high-power sources);
- n) if the intended purpose of an assistive product cannot be met without a hazard (e.g. holes, V-shaped opening), a warning and instructions on how to operate the assistive product safely;
- o) if the intended purpose of an assistive product cannot be met without a hazard due to moving parts such as squeezing, a warning and instructions on how to operate the assistive product safely;
- p) the level of resistance to ignition of materials and assemblies;
- q) information on the recycling of used batteries and other parts of the assistive product;
- r) expected lifetime of the assistive product.

It is recommended to include instructions on how to solve simple problems for the ease of use.

25.2.4 Service information

The service information shall contain all the pre-sale information, user information and instructions necessary for the maintenance, adjustment and repair of the assistive product and for their placement of parts.

The service information shall be sufficiently detailed concerning preventive inspection, maintenance and calibration, including the frequency of such maintenance.

The service information shall provide information for the safe performance of such routine maintenance necessary to ensure the continued safe use of the assistive product.

Additionally, the service information shall identify the parts on which preventive inspection and maintenance shall be performed by service personnel, including the periods to be applied and details about the actual performance of such maintenance.

25.3 Labelling

All warnings used as risk control shall be clearly labelled.

Symbols for use in the labelling of medical products shall be in accordance with ISO 15223-1 and ISO 7000.

All operating controls shall be marked for their intended function.

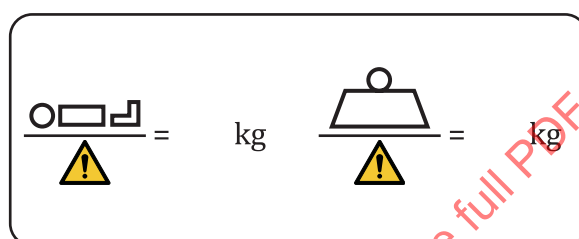
Every assistive product shall be permanently marked with at least the following information, if applicable:

- a) name and address of the manufacturer and, in addition, name and address of the supplier if different from the manufacturer;
- b) model definition;
- c) lot or batch and/or serial number;
NOTE Serial number is preferred for traceability and inspection records.
- d) year and month of manufacture;
- e) Unique Device Identification (UDI);
- f) electrical details in accordance with IEC 60601-1:2005+AMD1:2012+AMD2:2020;
- g) product IP rating;
- h) details of any other energy source used (e.g. water/air operated, operating pressure range);
- i) maximum and minimum user mass, see [Figure 6](#);
- j) maximum load, see [Figure 6](#);
- k) assistive products and detachable parts (intended to be detached without the use of tools) with a mass of more than 10 kilograms shall be marked with an appropriate symbol, see example in [Figure 5](#);

All warnings used as risk control shall be clearly labelled.



Figure 5 — Example of graphical symbol for parts weighing more than 10 kg (application of ISO 7000-1321B)



NOTE 1 In the spacing before "kg" in the symbol of user weight an interval can be marked, e.g. "45 to 120".

NOTE 2 Reproduced with permission from IEC 60601-2-52:2009, Figure 201.105.

Figure 6 — Graphical symbol for maximum/minimum user weight and maximum load

26 Packaging

The hazards that can be caused by inadequate protective packaging shall be assessed in the risk analysis and management (see 4.1).

NOTE For guidance, see 4.26.

27 Test report

The test report shall at least contain the following information:

- unique report number;
- the name, address and the specific accreditation number of the test institute if applicable;
- the date of issue of the test report;
- a reference to this document, i.e. ISO 21856:2022;
- the name and address of the manufacturer of the assistive product;
- a description of the sample including the manufacturer's or vendor's trade mark, model or type, serial number and any variations or accessories fitted;
- the source of the sample;

- h) where the controller is programmable, the settings used while testing;
- i) a photograph of the sample equipped as during the test;
- j) the results of the tests including record of maintenance, if any;
- k) a statement of whether or not the tested sample met all of the applicable requirements of this document and a list of all the failed requirements.
- l) a statement of which alternate, or additional, device-specific standards have been applied.

28 Guidelines for accessible information on assistive products

Details are given in [Annex C](#).

STANDARDSISO.COM : Click to view the full PDF of ISO 21856:2022

Annex A (informative)

General recommendations

Basic principles

This annex provides guidelines and recommendations for the manufacturer additional to the clauses in this document.

The numbering of the clauses in this annex corresponds to the numbers of the clauses and subclauses in the main text to which the guidance applies (e.g. A.4.9 refers to 4.9).

An assistive product shall be aimed at improvement of the quality of care of the user, persons with disability and/or older persons in long term care.

- It shall enhance the Quality of Life of the users and the assistants.
- It shall not increase the stigma or impair the dignity of the users and the assistants
- It shall reduce the physical and psychological burden of assistants
- Safety of the users and the assistants shall be prioritized.

In the case of those having an information collecting function, the privacy of the user and/or assistants shall be securely protected.

A.4.9 Sensory and cognitive impairment

Cognitive impairment can affect anyone and can be temporary or permanent. Cognitive impairment can affect a person's ability to

- Perceive information (e.g. reduced visual perception, which can cause problems recognizing words, pictures or other visual input).
- Sustain, focus and divide attention (e.g. reduced ability to filter unwanted stimuli (e.g. light sound) or difficulties multitasking).
- Learn, store and maintain new episodes, knowledge and skills, and retrieve and maintain former episodes, knowledge and skills.
- Communicate, i.e. understand and express oneself both verbally and non-verbally.
- Orientate oneself and navigate spatially and topographically.
- Solve problems, organize, plan, initiate, carry out, and terminate activities appropriately and timely.
- Think and reason in an abstract manner (e.g. understand generalizations and associations).

Hearing impairment is defined as a partial or total inability to hear. Hearing loss is caused by many factors, including genetics, age, exposure to noise, illness, complications at birth, chemicals and physical trauma.

- Loss of hearing in children can affect the development of language.
- Loss of hearing in children can affect their ability to attend social activities.
- Loss of hearing in children will affect their ability to perform well at school and to assimilate knowledge.

- Adults with hearing impairment will experience work related and social difficulties.
- Hearing impaired persons will experience problems when listening to TV, in cinemas, in crowded rooms and in daily conversations.
- The use of hearing aids is often regarded as stigmatizing.
- Age-related hearing loss (presbycusis) generally comes with the loss at higher frequencies.

Hence the consonants in speech - such as 's', 'f' and 't' - end up sounding very similar and will be masked by the more energetic vowels. This means that a person might hear but not always understand.

Hearing impairment can be ranked as mild, moderate, severe or profound. The ranking is defined by the hearing loss (HL) in dB (decibel):

- Mild:
 - for adults: between 26 and 40 dB HL;
 - for children: between 20 and 40 dB HL.
- Moderate: between 41 and 60 dB HL.
- Severe: between 61 and 80 dB HL.
- Profound: 81 dB HL or greater.
- Totally deaf: Have no hearing at all.

A.5.5.2 Cleaning and disinfection

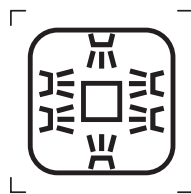
Examples of cleaning symbols are presented in [Figure A.1](#), [A.2](#), [A.3](#) and [A.4](#).



Figure A.1 — Example of graphical symbol for jet stream washing (ISO 7000-3890)



Figure A.2 — Example of graphical symbol for manual washing (ISO 7000-0423)



NOTE Rigid objects include assistive products such as wheelchairs, hoists or beds.

Figure A.3 — Example of graphical symbol for machine washing, rigid objects (ISO 7000-3897)

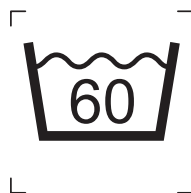


Figure A.4 — Example of graphical symbol for machine washing (ISO 7000-3094)

A.5.5.4 Animal tissue

Manufacturers should be aware that such products can carry infection and microbial contamination and should examine them for signs of disease or contamination. This is of particular importance when there is a possibility of contact with damaged skin.

Typical materials and products affected are the following:

- a) leather (shoes, thigh cuffs, prosthetic sockets);
- b) sheepskin (seating assistive products);
- c) pig bristle (brushes);
- d) human hair (wigs).

A.6.1 Noise and vibration

Manufacturers should evaluate any noise and vibration from powered assistive products in the intended environment(s) of use. Care should be taken of the possible sensitivity of pets.

Where specific standards are not available, manufacturers should determine what appropriate methods of test are available in other standards and supplement these with a panel consisting of users with a disability, carers and appropriate professionals to assess the acceptability of noise and vibration.

Noise levels should be related to the circumstances in which an assistive product is used.

Noise should be reduced as much as possible at its source.

Manufacturers should consider the following International Standards relating to the effects of vibration:

- ISO 2631-1;
- ISO 5349-1;
- ISO 5349-2.

A.7 Electromagnetic compatibility

When specifying the EMC performance of an assistive product, manufacturers are recommended to consider the already widely established environments:

- residential, commercial and light industrial;
- industrial;
- other (typically meaning more harsh environments and some specific places such as surgical theatres or near specific machinery, e.g. transmitters).

A user should be able to use an assistive product in all the manufacturer's intended environments of use for the assistive product with minimum limitation. The manufacturer should make it clear in simple language when limitations exist by describing the circumstances that must be avoided and should explain the consequences of exposing the assistive product to a potentially dangerous environment, e.g. radio transmitters. If possible, any appropriate actions that will offset any hazard should be described.

A.9.4 Ingress of liquids

Assistive products, such as bath assistive products, which are intended to be repeatedly immersed in water or other liquids should be constructed to withstand repeated immersion without causing a safety hazard.

A.13.2 Protection against inadvertent user falls in relation to side rails

The requirement for side rail height to be at least 220 mm above the lying support surface in at least 50 % of the length of the lying support platform is intended to ensure that side rails reduce the risk of the user accidentally slipping or rolling off the lying support surface.

Due to the nature of the side rail entrapment hazard, conformity with the listed dimensional requirements is not in itself considered adequate to address all possible dangers (including entrapment of legs and arms, or the risk of user falling from an attempt to climb over the side rails).

For this reason, an additional requirement to perform a risk assessment (evaluating all issues pertaining to side rails) has been included.

The 220 mm dimension is the minimum height requirement for the top edge of a side rail above the mattress and is based on the midpoint (centre of gravity) of an adult male torso at the 95th percentile lying on the shoulder on a lying support surface/ or compressed mattress.

The minimum height requirement for side rails can increase the risk of injury when a user climbs over and falls. The minimum length requirement on side rails can increase entrapment risk by reducing egress points for the user, and while it can decrease inadvertent fall risk from rolling out of an assistive product, it can increase risk where users might opt to climb over the side rails. The dimensional requirements in this document reflect an attempt to make the best risk trade-offs on the basis of available information. Future data can demonstrate that some of these requirements should be revised at a future date.

[Table A.1](#) provides background information for the dimension G2 in [Table 3](#).

The 600 mm dimension for protection side rails represents a barrier that a child up to 2 years cannot climb over.

The table is an excerpt from CEN/TR 13387-3:2018, Table 5.

Table A.1 — Height according to age (protective barrier)

Age (months)	Body length (mm) P95	Centre of gravity (% of length)	Centre of gravity calculated from the ground (mm)	Recommended height for age ^a (mm)
3 to 6	701	58,5	410	450
6 to 9	750	58,5	439	485
9 to 12	794	58,5	464	510
12 to 18	862	58,5	504	555
18 to 24	930	58,5	544	600

^a Safety factor of 10 % (rounded up or down) added.

A.14.2 V-shaped openings

To reduce neck entrapment with regards to wedging of the neck, angles for V-shaped entry into the openings should be greater than 75°. The 75° angle reflects an understanding that at some point, a narrow angle creates a V-shaped space or geometry that could be conducive to entrapment. The 75° angle was chosen by reviewing the tools to assess entrapment risk for swimming pool equipment (see EN 13451-1) and making changes suitable to application on assistive products by increasing the wedging minimum angle of 60° to 75°. The 75° angle reduces the risk of patient entrapment through hooking of the neck and head in the V-shaped opening the wider angle allows the patient to pull his head free from a vertical opening with less effort. This is essential when considering a weak or confused patient.

A.19 Surfaces, corners, edges and protruding parts

The requirements set in EN 1888-1:2018, Clause 6.1.3, should be applied. For guidance on test methods for protruding parts, see EN 716-2:2017, Clause 5.9.

A.20 Hand-held assistive products

General

This category of assistive products encompasses both products specially designed to be assistive products and consumer products with software (applications) for assistive functionality, i.e. applications for controlling an assistive product running on ordinary smart phones and tablets.

It is recognized that the mechanical design and ruggedness of these different range of products will require different test methods for safety. It can be assumed that a consumer product will not withstand the test procedures and criteria applicable for explicit assistive products.

Hence the focus should be on fail-safe operation in case of mechanical damages and malfunctions in the consumer product itself, rather than the consumer capability to maintain its functionality after mechanical impacts.

Assistive products/ parts of assistive products on consumer products

The application software for the assistive product shall meet the requirements in IEC 62304, the software functions shall also be identified as “primary operating function” or “operating function”.

If the software is used as a primary operating function, the software shall be fail-safe and the assistive product shall have a back-up system to operate the assistive product. This secondary operation could be electrical or manual and could be operated by the user and/or by an assistant.

For instance, if the software is used as an operating function, the software shall be fail-safe however the assistive product does not have to have a back-up system to operate the assistive product.

NOTE For instance, adjusting the positions of head/upper body and legs in a bed.

It is the manufacturer's responsibility to ensure that the application software will always be fail-safe, even when the consumer product itself is malfunctioning.

A.23 Forces on soft tissues of the human body

People with disabilities resulting in impaired mobility and/or sensory loss are particularly susceptible to develop pressure injuries (also referred to as pressure ulcers). In general, there is a high prevalence of pressure injuries among hospital patients, nursing home patients and home care residents. Pressure injuries can cause acute discomfort and suffering, resulting in a severely reduced quality of life. They also add a heavy economic burden to health services and society as a whole.

Overview of causes

Per the 2016 revised definitions published by the NPUAP: A pressure injury is localized damage to the skin and/or underlying soft tissue usually over a bony prominence or related to a medical or other device. The injury can present as intact skin or an open ulcer and may be painful. The injury occurs as a result of intense and/or prolonged pressure or pressure in combination with shear. The tolerance of soft tissue for pressure and shear can also be affected by microclimate, nutrition, perfusion, co-morbidities and condition of the soft tissue.

In general, pressure injuries are caused by the sustained deformation of soft tissues, eventually causing tissue necrosis (death).

“An increasing body of evidence suggests two physiologically relevant deformation thresholds exist. One is a lower threshold leading to occlusion of blood and lymphatic vessels resulting in ischemia-induced damage and the other is a higher threshold leading to direct deformation-induced damage”. (NPUAP/EPUAP/PPPIA 2014)

There are many factors external to the body that contribute to the development of pressure injuries. Pressure, shear and friction have been identified as major contributors, along with temperature, humidity and moisture of the environment immediately next to the skin and subdermal tissues. The time these conditions are maintained also influences the occurrence and severity of the pressure injury.

Pressure injuries develop as a result of the internal response to external mechanical load.

Understanding the aetiology of pressure injuries relies on an awareness of the internal response, and not just what is apparent on the outside of the body or on the skin surface. (NPUAP/EPUAP/PPPIA 2014)

There are several design considerations for assistive products, which have to account for the aforementioned external factors implicated in pressure injury formation. These include:

1) Effects of posture

Pressure injuries occur most frequently where local pressure gradients are highest – that is over the bony prominences of the body that carry body weight. This corresponds, during lying, to the sacrum, greater trochanters, heels and elbows; and during sitting, to the sacrum and ischial tuberosities. Some postures can increase loading over vulnerable sites, for example sitting with elevated feet (high ischial tuberosity pressures), or raising the head of bed in lying.

2) Pressure

Gravity is the major contributor to pressure on body tissues. It is usually considered to act perpendicular to the plane of the tissues.

One way of reducing the pressure over certain parts of the body is to distribute its load over as large an area as possible. Typically, this involves using soft conforming materials, which allows the body to immerse into the material providing envelopment. Foams, air cells, or fluid filled flexible pads are frequently used for this purpose. Alternatively, forces can be redistributed to tissues that can be more

resistant to pressure, for example in cushion designs that cut away areas under the ischial tuberosities and build up surfaces under the thighs.

NOTE Because pressure injuries are caused by a wide variety of factors, there is no one threshold of pressure below which pressure injury will not occur.

3) Time

The time during which tissues are exposed to pressure and shear forces is routinely limited by ensuring that people carry out regular changes of posture and move between different support surfaces at regular intervals. Some support surfaces change their surface profile to limit the time forces are applied to specific tissues. Other support surfaces alter the pressure on parts of the body within short time intervals, e.g. alternating air mattresses. Clinical guidelines recommend repositioning occur every 2 hours to 4 hours. However, this will depend on the aforementioned tolerance of the individual to withstand pressure and shear forces. Those who have impairments, for example poor perfusion, comorbidities and condition of the soft tissue will need to be repositioning more frequently to that of a healthy individual.

4) Shear forces

External shear forces are also considered to be a major contributor to the causes of pressure injuries and, in combination with pressure, will increase the risk of tissue breakdown. Shear forces act in parallel to the planes of the tissues. When pressure and shear forces act upon skin and subdermal tissues they create internal shear stresses and strains, contributing to the occlusion of blood and lymphatic vessels and, where strains are high, direct cellular level deformation damage. This can occur when the skin remains stationary on the supporting surface whilst the underlying body structure moves, such as when a person slides down a tilted bed or chair.

One way of reducing external shear forces is to keep the patient in a horizontal lying position. However, this position might not be tolerated by people with breathing difficulties and might limit their functionality, e.g. eating or reading. Internal shear stresses and strains are still present, even in this position, which is one reason repositioning protocols must be followed.

Another potential method of managing shear forces acting on vulnerable skin sites includes the addition of strategically placed low-friction interface materials. These interface materials can be used in conjunction with devices (e.g. heel boot), or be integrated into support surfaces for the bed and chair environments. An overall low-friction surface is not recommended because it will likely compromise the position, stability and safety of the individual situated on the support surface.

5) Friction

Skin injuries similar to pressure injuries can occur when people are slid over support surfaces, e.g. bed linens. Typically, this occurs when transferring from one support surface to another. Most friction injuries can be avoided by using appropriate techniques when moving individuals so that their skin is lifted clear of the surfaces and never dragged across them. Specialist low friction sliding sheets are also available to minimize the risk of these friction injuries.

Voluntary and involuntary movements by the individuals themselves can lead to friction injuries, especially on elbows and heels. Assistive products can be designed with materials that reduce this contact or that decreases the friction between the skin and the support surface. This could in turn reduce the external shear forces and the internal tissue shear stresses and strains.

6) Temperature

Thermodynamic conditions within and around skin tissues, commonly termed the microclimate, strongly influence the risk of soft tissue breakdown and the development of pressure injuries. Indeed, it is well established that both heat and moisture decrease the resilience of the epidermis and hence increase its susceptibility to damage at the skin-support interface in load-bearing regions of the body. Higher temperatures cause the metabolic rate of tissues to increase along with a corresponding increase in demand for blood supply. They also increase sweating and raise risks from humidity and moisture.

Ideally, support surfaces should conduct heat away from the body to manage temperature at the local skin interface. However, many materials, such as some foams, which can be good pressure distributors, tend to be good insulators and cause increased temperatures.

7) Humidity and moisture

Humidity and moisture in the environment are thought to increase risk of pressure injuries through their effect on the mechanical strength of tissues. These conditions can be exacerbated by sweating caused by high temperatures or by the presence of incontinence. Moisture has also been shown to increase the interfacial frictional forces, which can prove damaging to the skin surface. Some support surface designs include management systems to wick away moisture from the patient interface. Careful design considerations are required to ensure there is a balance between maintaining the low microclimate (temperature and humidity) and not drying out the skin.

8) Risk assessment

The provision and design of any assistive products which are intended to support the body or cause forces to be applied to the body should consider the risks of causing pressure injuries. They should minimize these risks appropriately for the susceptibility of the individuals for whom they are intended and balance them against the risks of other adverse effects of use of the device.

A.24 Ergonomic principles

Guidance on the design and location of control actuators for able people in industry is given in EN 894-3. This guidance should be used with caution as persons with disability can need special features to suit their disability. In most cases, control forces should not exceed the following:

- a) the operating force for levers used to activate or release a feature by hand should not exceed 60 N;
- b) the operating force for levers used to hold or move a feature for a significant time should not exceed 13 N (e.g. the joystick of a wheelchair);
- c) the operating force for levers used to activate or release a feature by foot should not exceed 60 N in a "pulling direction" and 100 N in a "pushing direction";
- d) the operating force for devices used to activate or release a feature by finger action should not exceed 5 N.

Persons with disability are likely to suffer from weakness and lack of control in their limbs. In order to facilitate the operation of a particular feature and also to avoid accidental operations certain ergonomic criteria should be considered: a minimum threshold for the operating force to be applied by the user is advisable; size, position and spacing between control mechanisms should be appropriate. The user should receive feedback from the mechanism (i.e. by light, click, noise, etc.) to make certain that it has actually been operated.

A.26 Packaging

The packaging of an assistive product is intended to provide appropriate protection against damage, deterioration or contamination during storage and transportation to the point of use. The various forms of storage and the types of transportation that might be encountered should be considered, and the effectiveness of the packaging checked.