World Health Organization

Assistive product specifications and how to use them

Global Disability Innovation Hub

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Introduction

This document was developed to guide procurement of assistive products. It is intended primarily for procurement teams working in less resourced settings. It should be read alongside the World Health Organization (WHO) and United Nations Children's Fund (UNICEF) publication *A manual for public procurement of assistive products, accessories, spare parts and related services*, which sets out the procurement process in detail, including key steps and good practice *(1)*.

These two publications come in response to the 2018 World Health Assembly resolution WHA71.8 on improving access to assistive technology *(2)*. This resolution requests WHO to provide Member States with technical and capacity-building support for procurement of good-quality and affordable assistive products.

Assistive products are any external products, including devices, equipment, instruments and software, especially produced or generally available, the primary purpose of which is to maintain or improve an individual's functioning and independence and thereby promote their well-being. Assistive products are also used to prevent impairments and secondary health conditions *(3)*.

Wheelchairs, spectacles and hearing aids are among the many assistive products that enable people with functional difficulties to participate meaningfully in daily life. Without them, people are often excluded and isolated, while the progression of their disease or functional difficulties may be exacerbated.

Determining the assistive product and service requirements at the planning stage of a procurement process is essential to its success. These requirements will be expressed in a procurement specification that forms the basis of a tender announcement, which suppliers use to formulate bids and the procurement team uses to evaluate bids received. It is crucial for adequate planning and resourcing, and for selecting the right assistive products, suppliers and follow-up services.

Procurement is a specialized professional activity that requires a combination of knowledge, skills and experience. The field of assistive products is specialized, and a multidisciplinary procurement team is recommended to develop procurement specifications. This should bring together expertise in procurement; assistive product service provision, including assessment of a person's needs, product selection, fitting and user training; user experience of assistive products; and repair, maintenance and refurbishment of assistive products.

A ***procurement specification*** is a document that clearly describes what is required in terms of delivery of assistive products and services. The specification should reflect the needs of the purchaser and user groups.

A ***tender*** is an invitation to bid for a project with the objective of entering into an agreement for large volumes of assistive products, accessories, spare parts or related services. Tendering usually refers to the process whereby governments or their representatives invite bids, based on product specifications, that must be submitted within a definite deadline.

Assistive product specifications

This document includes 26 assistive product specifications (APS). The assistive products have been chosen from the World Health Organization (WHO) Priority Assistive Products List (WHO APL) published in 2016 as a model list to guide countries when making decisions related to assistive product procurement and provision *(3)*.

Assistive product specifications (APS) are model specifications developed by WHO to guide procurement teams in developing their own procurement specifications for their context.

The APS addresses six key areas of functional difficulties, with products to assist mobility, hearing, vision, cognition, communication and self-care. The APS describes the minimum requirements related to technical performance and function that the products should meet for safe and effective use.

Of the 50 products in the WHO APL, the 26 selected for APS development were chosen because they are commonly and widely used to address the functional needs of the population; they can be procured in bulk; and they can be provided through primary or community health services, particularly in less-resourced settings.

The APS is targeted at anyone involved in assistive product planning or procurement and related services. The APS may also be informative for product manufacturers, service providers, users and user organizations.

The APS template is presented in three sections: product description; product requirements; and supply and service requirements. Table 1 provides an overview of the information described in each section. This template can be used by procurement teams when developing their own context-specific procurement specifications.

Table 1. The APS template

SECTION 1: PRODUCT DESCRIPTION		
This section provides key information about the group of assistive products included in the specification so they can be easily identified.		
1.1	Name of product	Provides the name of the product, as described in the national assistive product list (if available), or refers to a commonly used product name.
1.2	International Organization of Standardization (ISO) 9999 code	If applicable, provides the ISO classification and terminology for the product (or group of products), as described in ISO 9999:2016 *(4)*.

1.3	Description and intended use	Gives a general description of the product and how a person may use the product to address their needs.
1.4	General features	Summarizes the key characteristics of the product.
1.5	Inclusion	Lists the products included in the APS.
1.6	Exclusion	Lists the products not included in the APS.
1.7	Keywords	Lists important searchable words related to the product(s).

SECTION 2: PRODUCT REQUIREMENTS

This section details the requirements for each assistive product included in the specification. Each requirement is mandatory. This means a supplier must ensure the product meets all requirements.

2.1	Functional requirements	Describes the functional requirements of each product, including the typical user or typical use (e.g. body function, daily activities, living environment), specific characteristics of the product (in addition to the general features in 1.4), and the standard configuration.
2.2	General design requirements	Describes general product performance requirements and overall qualities (e.g. stability, strength, durability, water resistance).
2.3	Standards	States the standards with which the product must comply, including international standards (e.g. ISO and International Electrotechnical Commission (IEC)), and relevant national and regional standards.
2.4	Certificate of conformity	Refers to a certificate of conformity – a legal document signed by the supplier to confirm a product conforms to applicable national or international regulations in the country where it is procured or to the procurement specification.
2.5	Size and weight	Describes information the supplier should provide about the dimensions of the product in its standard configuration, when folded (for storage) and any adjustment range. Information about adjustment should include the minimum and maximum adjusted dimensions, and the adjustment increments. Typical dimensions include overall width, height, length and weight of the assistive product. Wherever necessary, an instruction on how to measure the width, height, length and weight should be provided to the supplier.

2.6	Technical information (for service providers)	Describes the minimum information the supplier should provide about how to maintain, repair or refurbish the product.
2.7	Instructions for use (for users and caregivers)	Describes the minimum user instructions the supplier should provide.
2.8	Environment of use	Describes the weather and other environmental conditions that the assistive product should be able to withstand. This information typically includes acceptable lower and upper limits for temperature and humidity, and whether the product can be used in rain, snow or direct sunshine.
2.9	Warranty	Specifies the duration and details of the product warranty.
2.10	Lifespan	Specifies the expected lifespan in years of the assistive product.
2.11	Packaging, labelling and state of assembly	Describes packaging requirements, including how products should be packaged, the state of assembly, and package labelling.
2.12	Accessories and spare parts	Lists the required accessories and spare parts that should be procured to ensure the assistive product can be maintained and, if necessary, repaired.
2.13	Other product requirements	States any additional product requirements not covered in previous subsections.

SECTION 3: SUPPLY AND SERVICE REQUIREMENTS

This section describes the supply and service requirements the supplier must meet.

3.1	Transportation	Specifies the information the supplier must provide about how the assistive product will be transported to the place of delivery.
3.2	Delivery time	Specifies the time between placing an order and receiving delivery of the assistive product (e.g. that it should not exceed 30 days for internal domestic orders).
3.3	Maintenance	If applicable, describes required maintenance services the supplier should provide, including timeframe and frequency.
3.4	Repair	If applicable, describes required repair services the supplier should provide, including timeframe and frequency.

3.5	Refurbishing	If applicable, describes required refurbishing services the supplier should provide, including timeframe and frequency.
3.6	Training for service providers	Specifies whether training is required for service providers, who needs to be trained, and what training the supplier should provide. Indicates key elements included in the training (e.g. selection, assembly, fitting, user training, maintenance and repair of the assistive product). Refers to detailed training materials, if applicable and available.
3.7	Training for users	Specifies whether training is required for users and, if so, what the supplier should provide. Indicates key elements included in the training (e.g. use, care and maintenance of the assistive product). Refers to detailed training materials, if applicable and available.
3.8	Other supply and service requirements	Describes any other information about supply and service requirements.

How to use the APS

This section provides guidance on using the template. To develop a procurement specification, this guidance should be read alongside the product-specific information in each APS.

Identifying the product

Product description

In Section 1.1, the name of the product should refer to the product name as described in the national assistive product list or following commonly used terminology. The APS refers to the WHO APL.

In Section 1.2, the classification ISO 9999:2016 Assistive Products for Persons with Disability – Classification and Terminology is provided for reference so the product can be easily identified.[1] The extra six digits given in each APS complete the ISO 9999 code for a category of product (e.g. 18 30 15 for portable ramps).

The section on description and intended use should describe the product clearly and what it should be able to do. The general features should give enough detail to identify the product's function and characteristics, but also be generic and not biased towards a brand or design. A generic specification encourages competition and gives suppliers the opportunity to offer innovative assistive products that may be new to the market *(1)*.

One product category (as defined in the WHO APL) can have a large product range. The APS includes a focused product range (selected as described in the introduction above). Each individual APS lists the product range included or excluded in Sections 1.5 and 1.6.

Choosing the right product to meet the user's needs

Product functional and design requirements

A range of products may be included. For example, wheelchairs can be assistant-controlled or self-propelled and come with additional postural support. There are further variations for use in different contexts (e.g. urban, dual-terrain and rough-terrain wheelchairs). The product range should include options to meet the different functional and environmental needs of a wide group of users. The capacity of local services to provide the product range is an important factor in decision-making (see Sections 3.6 and 3.7).

1 This ISO classification is currently being updated. Please refer to the latest publication once available.

Special considerations for products based on software applications

With the advancement of digital technology and increased use of devices such as smartphones, some products are migrating from dedicated hardware design to software applications that operate on mobile and portable devices. Examples include communication boards and books and alarm signallers. For assistive products based on software applications, the procurement team should consider the following:

- availability of the device (hardware) and its requirements to run a software application;
- range and availability of methods for users to access digital content for a software application;
- ease of distribution (by service providers) and use (by users);
- relevant security and privacy standards applied to any form of technology;
- availability of technical support and training for local service providers and local users.

For each product, the typical user or use should be described, including product characteristics (in addition to the general features given in Section 1.4) and standard configuration requirements. A description of the typical user is helpful when selecting the product range quantities to be procured; however, identification and selection of the best product to meet an individual's needs are part of the service provision process.

A clear description of the typical user is essential (e.g. relevant health conditions, functional difficulties, age, size range). If applicable, the context of typical and intended use should also be described (e.g. indoor or outdoor use, noisy environments).

The characteristics and standard configuration should give enough detail to differentiate between products. The description of the product should focus on function and performance without prescribing a specific (hardware and software) design. This encourages suppliers to seek out appropriate product improvements and innovations. The procurement specification should not require specific materials to be used, mechanisms of functioning, size or weight of the product. Where relevant, however, information that is important to achieve certain quality standards or functions may be required.

The procurement team should adapt each APS for the population and context. For example, maximum weight load and dimensions for mobility and self-care products (e.g. wheelchairs, rollators, shower and toilet chairs), and frame size for products to assist low vision (e.g. spectacle magnifiers), should be specified according to the size range of local users.

Design requirements generally apply to all product variations, which need to be safe and durable and work effectively. Additional design requirements to allow for adjustment and customization are useful considerations for certain products (see examples below).

Specifying function and design requirements for complex products

For technically complex products, the procurement team should try to find a minimum product range to meet the needs of as many users as possible. Taking wheelchairs as an example, the team should consider the following function and design requirements:

- Is the wheelchair available in a range of options (e.g. seat width, seat depth, frame length, back-support height).
- Does the wheelchair have adjustment options (e.g. seat, back, arm and foot support) to fit the size and proportions of local users (children, adults, people with bariatric needs)?
- Is it possible to customize the wheelchair for individual needs (e.g. to give posture support and accommodate postural deviations) by interchanging and adjusting parts (e.g. height of arm, foot and back supports and seat depth; configuration of seat or backrest)?
- Is it easy to store and transport (e.g. can the frame be folded or dismantled), and does it have removable arm- and footrests for easy transfer in and out of the wheelchair?
- Is the wheelchair appropriate to the user's environmental and functional needs (e.g. do its design and features allow the user to optimally carry out daily tasks in their chosen environments)?

Some of these considerations also apply to other products, such as rollators, walking frames, and shower and toilet chairs.

Additional product features to enhance function

When procuring hearing aids, for example, the following can improve the user's experience:

- incorporating controls or interfaces that adjust to individual amplification needs;
- compatibility with additional features (e.g. telecoils, directional microphones, feedback management) that assist hearing in unique situations.

Ensuring quality and safety

Standards and certificate of conformity

Standards exist to ensure products are fit for purpose. In some countries, standards are part of existing regulations. The procurement team should identify and select the appropriate national, regional or international standards to be used in the procurement process. The APS provides reference to any relevant existing ISO, IEC or other international standards.[2]

Products should be tested by accredited test laboratories according to relevant national or international standards. For some national standards, certain technical requirements are adapted from international standards to fit the local context better – for example, by modifying the temperature and humidity ranges to the environment where the products will be used.

2 A new ISO standard on quality assurance requirements and procedures for assistive products – ISO 21856: Assistive Products – General Requirements and Test Methods – is in development. Once published, it can be a reference for assistive product quality assurance where no specific product standard has been developed. It could also be partly referred to where applicable.

Procurement of assistive products and related services should be carried out in accordance with national policies, laws, rules and regulations. For instance, within the European Union (EU), public procurement must comply with EU rules and regulations for the region. It is important to conduct thorough research into local regulations that may be in place.

A certificate or declaration of conformity is a legal document signed by the supplier that confirms a product conforms to applicable national or international regulations in the country where it is procured. For instance, a CE (European Conformity) certificate is required for products sold within the EU; a COC (Certificate of Conformity) for Japan; and a GCC (General Certificate of Conformity) for the United States of America. Such certificates attest that the product complies with regulations or standards required in the country where the procurement takes place.

The supplier should be required to provide a certificate that clearly states the product complies with the terms of the procurement specification (which should reflect applicable regulations and standards), and state that it is safe and effective for the intended use. The certificate should be signed by an authorized representative of the supplier.

If products do not comply or are not tested according to relevant standards, or if they deviate from the procurement specification, the supplier should provide an explanation to the procurement team.

More product requirements to be specified

Information on weight and size of the product is needed for planning on transportation, storage and service provision. The procurement specification can also describe which measurements to use, and how measurements should be taken to avoid misunderstandings and ensure all suppliers provide measurements in the same way so they can be compared. For products whose size can be changeable (e.g. wheelchairs with a foldable frame), it is useful to have the dimensions in different modes for transportation or storage. Overall weight and dimensions (width, length, height) of the product in its operation mode and in transportation (with packaging) should be required. Wherever applicable, additional measurements can be specified.

Suppliers should be required to supply technical information for service providers, including instructions on how to select, assemble, fit and adapt the assistive product. If applicable, the supplier should provide instructions on how to maintain, repair and refurbish the product.

Instructions for use for users and caregivers should be required. These should be supplied with each product in the form of a product user manual. Instructions usually include how to use, maintain and clean the assistive product safely and effectively.

The technical information and instructions for use should be provided in the language of the country being supplied. Information in English or other languages can also be required. This information should be available in print or electronic format and be accessible for differently abled users (e.g. in Braille or audio for people with visual impairment).

The products need to withstand the various weather and other environmental conditions they are intended to be used in (e.g. temperature, humidity, rain, snow, direct sunshine). Products mostly used indoors should be required to withstand room temperature and humidity.

Products for outdoor environments should withstand a wider temperature range between –30 and +50 °C and humidity range between 15% and 90%, or as specified in the APS.

The procurement specification should adapt or further specify the requirement considering the local climate; for example, the product may not need to be tested in extreme low or high temperatures that are not relevant to the country. Additional requirements should be specified for the local environment (e.g. terrain for some outdoor mobility products).

The procurement specification should require the duration and details of the warranty from the supplier. This should include the accessories and spare parts procured with the product. The supplier should be required to repair parts that break during the warranty period without expense to the user (provided the product is used and maintained as intended). This includes all spare parts and labour but does not apply to repairs due to normal wear and tear.

Knowing the lifespan of the product is useful for planning the procurement and service provision. The lifespan of the assistive product should be at least five years if the instructions for intended use are followed.

The procurement specification should require information on how products, accessories and spare parts are packaged (e.g. together or separately). The packaging should protect the product from damage and clearly state its contents. Each product should be delivered fully assembled or partly assembled so the remaining work can be carried out with the use of commonly available hand tools. If any special tool is required, it should be included within the package. If applicable, full information on software installation and use should be provided. Requirements on packaging and labelling should take service provision into account.

Accessories and spare parts are items that are removable or replaceable or optional extras. It is important they are procured with the assistive product as they are essential for the product to fully function and meet the user's needs. The procurement specification should require the supplier to offer a range of accessories and spare parts, wherever applicable. All parts of the product that may need replacing during its lifespan should be supplied as spare parts. Accessories and spare parts for the full product range should be procured. The procurement specification should include the required quantity of accessories and spare parts considering the product lifespan, warranty and service provision.

Ensuring successful service provision

Delivery of products

Transportation and delivery time can vary according to the procurement budget, timeline for provision, order size, supplier's inventory and manufacturing lead time. International delivery can be affected by shipment method and customs clearance procedures. Delivery time should be specified by the procurement team based on local knowledge.

Maintenance, repair and refurbishing

Regular maintenance, repair and refurbishing are essential to prolong the life of assistive products. The APS recommends including these services as part of the procurement specification for product manufacturers or suppliers where feasible and cost-effective.

This is particularly recommended for technically complex products and where skilled staff are needed to carry out the work. The procurement team should base its decision on the context and availability of existing service provision.

The procurement team should identify the need for services and define the scope of what is to be provided by suppliers, including the timeframe and frequency, and require suppliers to provide a cost estimate in the bidding. This could include details of payment (per hour), travel expenses (e.g. fuel charges, hotel bills), rules to cover several services completed on the same route, and cost of spare parts (if not covered under warranty).

Suppliers must indicate how these services will be provided. If services are to be subcontracted, they must provide information on the subcontractor, including terms and conditions. The scope of services listed above should also apply to the subcontractor.

Training for service providers and users

Suppliers can play a role in training service providers, and this requirement should be included in the supplier's contract.

This is particularly important for technically complex products. The scope of training should be clearly defined in the procurement specification and may include training on assessment and selection, fitting, adjustments and adaptations, user training, and maintenance, repair and refurbishment. For example, suppliers may be asked to include training on how to assess and fit programmable hearing aids or custom earmoulds for individual users. This passes on product-related knowledge and skills to support safe and effective service provision.

User training on use and care of assistive products should be given by local service providers. Where user training services are not available or lack capacity, the procurement specification may request suppliers to include user training as part of their bids.

The supplier should also be required to provide a product user manual (as outlined in product requirements), giving clear instructions on using and maintaining the product.

Strengthening local capacity of assistive product provision

In many settings there is a lack of personnel with the knowledge and skills to safely and effectively provide assistive products. Training by suppliers should not be relied on as the main approach towards strengthening the capacity of personnel. It should be a complementary activity to wider system-level activities to strengthen the workforce for provision of assistive products, such as inclusion of competencies on assistive products provision into existing pre- and post-service education programmes; and in-service training on provision of assistive products (counting towards continuing professional development credits).

There are further reading materials at the end of this document with relevant materials to support capacity-building of personnel in assistive products service provision.

Environmental impact

Procurement teams should consider the environmental impact of the products they are seeking to purchase and stress the importance of this to potential suppliers. Product specifications should highlight designs that can be economically maintained, repaired and refurbished.

Suppliers should consider whether a product is biodegradable or whether there is potential for recycling at the end of its use. When products reach the end of their lifespan, disposal must be safe and effective. This is particularly important when considering the disposal of single-use products such as incontinence pads, batteries and e-waste from electronic products.

Compilation of assistive product specifications

The individual APS provides product-specific information only. To develop a procurement specification, both the general guidance provided above and the product-specific information in the APS should be used.

Accessible book players with audio capability

Name of product

Audioplayers with DAISY capability

ISO 9999 code

22 18 03 Sound recording and playing devices

Description and intended use

Accessible book players with audio capability (hereafter called "players") record, play and display audio and visual information, including sound, text and pictures. They are commonly known as DAISY (Digital Accessible Information System)[3] players to play audio books.

Players are intended for use by children and adults who are blind, have very low vision or are unable to read for other reasons. They include standalone players and software on a computer.

General features

Players enable users to listen to audiobooks and digital text documents, navigating easily by section, subsection, chapter or page. They can be used with or without headphones. They have in-built text-to-speech function, providing digital text as audio. They include functions to bookmark, resume playback from last position (for up to 10 books), set a sleep timer, use variable speed playback, and use voice recording; they may enable connectivity to online libraries.

Inclusion

Table standalone players

Pocket-sized standalone players

Software-based players

Exclusion

CD players for audiobooks

Keywords

Accessible book reader, audio device, blindness, book player, DAISY book reader, DAISY player, EPUB player, low vision, visually impaired, voice recorder

3 See www.daisy.org for more information.

Functional requirements

1. Table standalone player

Typical user	Child or adult who cannot read due to blindness, low vision or other reading impairment and who needs an accessible book player to listen to accessible books and other publications
Specific characteristics	Used primarily in home, work and library settings, placed on a flat surface, with or without headphones The player has a simple alpha or numeric keyboard, and may or may not have internet connectivity
Requirements for standard configuration	Supports one or more of following audio formats: AAC, AMR-WB+, FLAC, MP3, Ogg Vorbis, Speex, WAV Supports one or more of following digital document formats: • DAISY 3.0 and EPUB 3 text-only books • DAISY 2.02 TOC only audiobooks • DAISY 2.02 and DAISY 3.0 full-text full audio synchronized books • docx, doc, htm and txt files Built-in text-to-speech function in preferred languages to enable speech output of text documents and menu Variable speed for playback: • Slow down speed to 75% or less • Increase speed to 200% or more Built-in speakers Headphone connectivity Simple alpha or numeric keyboard Cable power supply Integrated CD/DVD player, memory card reader, USB reader or internet connectivity for content transfer and firmware updates Unique ID/serial number to be printed on each device Optional: power supply with battery or rechargeable battery

2. Pocket-sized standalone player

Typical user	Child or adult who cannot read due to blindness, low vision or other reading impairment and who needs an accessible book player to listen to accessible books and other publications
Specific characteristics	Pocket size enables use of product outdoors or when travelling, with or without headphones The player has a simple alpha or numeric keyboard, and may or may not have internet connectivity
Requirements for standard configuration	Supports one or more of following audio formats: AAC, AMR-WB+, FLAC, MP3, Ogg Vorbis, Speex, WAV Supports one or more of following digital document formats: • DAISY 3.0 and EPUB 3 text-only books • DAISY 2.02 TOC only audiobooks • DAISY 2.02 and DAISY 3.0 full-text full audio synchronized books • docx, doc, htm and txt files Built-in text-to-speech function in preferred languages to enable speech output of text documents and menu Variable speed for playback: • Slow down speed to 75% or less • Increase speed to 200% or more Built-in speakers Headphone connectivity Simple alpha or numeric keyboard Power supply with battery or rechargeable battery Memory card reader, USB reader or internet connectivity for content transfer and firmware update Unique ID/serial number to be printed on each device Optional: built-in camera or compatible with external camera and built-in optical character recognition (OCR)

3. Software-based player

Typical user	Child or adult who cannot read due to blindness, low vision or other reading impairment and needs an accessible book player to listen to accessible books and other publications For users with access to a computer, tablet or smartphone
Specific characteristics	Software to run on a consumer electronic device such as a smartphone, tablet or computer
Requirements for standard configuration	Supports audio formats: AAC, AMR-WB+, FLAC, MP3, Ogg Vorbis, Speex, WAV Supports digital document formats: • DAISY 2.02 TOC only audiobooks • DAISY 3.0 and EPUB 3 text-only books • DAISY 2.02 and DAISY 3.0 full-text full audio synchronized books • docx, doc, htm and txt files Built-in text-to-speech function in preferred languages to enable speech output of text documents and menu Variable speed for playback: • Slow down speed to 75% or less • Increase speed to 200% or more

General design requirements

Players should be easy to operate by most users independently, be fully accessible to users, and have parts that are replaceable, strong and durable. Players should be compatible with online libraries available within the country. Players with a rechargeable battery should last for at least eight hours on a full recharge. The player (hardware) should withstand ordinary cleaning with a wet cloth.

Standards

IEC 60601 Medical Electrical Equipment is applicable for parts of the hardware

Size and weight

Product weight, including battery, should be specified

Environment of use

The product is required to function within heat, cold, humidity, bright light, dark environments, and environments with high levels of dust in the air.

Accessories and spare parts

The following accessories are required:

- headphones;
- data and charging cable;
- connector for charging via main electricity outlet;
- headphones;
- on-the-go (OTG) cable if memory stick connectivity is supported;
- case for carrying.

Alarm signallers with light/ vibration alert

Name of product

Alarm signallers with light/sound/vibration

ISO 9999 code

22 27 04 Signalling devices

22 27 21 Environmental emergency alarm systems

Description and intended use

Alarm signallers alert children and adults to imminent danger (e.g. smoke, fire, security breach). They can also draw attention to everyday events (e.g. doorbell, baby's cry). Alarm signallers are intended for use by children and adults who are deaf or hard of hearing about changes within their environment.

General features

Alarm signallers contain a sensing unit such as a smoke sensor, heat sensor, sound sensor, carbon monoxide sensor or push-button and an alerting system such as a vibrating device or built-in or external flashing or strobe light. The device is powered by electrical supply or battery.

Inclusion

Standalone alarm signallers with smoke, heat, carbon monoxide or sound sensors, and light or vibration alerts

Push-buttons with light or vibration alerts

Exclusion

Alarm signallers with amplified sound alerts

Alarms with direct Bluetooth or proprietary manufacturer connective capabilities

Keywords

Deaf or hard of hearing, fire alarm, flash light alert, smoke alarm, strobe light alert, vibration alert

Functional requirements

1. Alarm signaller with heat or smoke sensor and vibrating pad

Typical user	Child or adult who is deaf or hard of hearing and unable to hear warning signals from traditional fire alarm systems
Specific characteristics	Sensor detects heat or smoke from a fire and triggers vibration device Vibration device can be on the user's body or placed on their seat or bed
Requirements for standard configuration	Heat or smoke sensor with wireless transmitter Vibration device with wireless receiver that can be worn on belt or wrist, or placed on seat or bed (e.g. under pillow)

2. Alarm signaller with heat or smoke sensor and flashing light

Typical user	Child or adult who is deaf or hard of hearing and unable to hear warning signals from traditional fire alarm systems
Specific characteristics	Sensor detects heat or smoke from a fire; bright light flashes when sensor is activated
Requirements for standard configuration	Heat or smoke sensor with wireless transmitter Flashing or strobe light with wireless receiver

3. Alarm signaller with carbon monoxide sensor and vibrating pad

Typical user	Child or adult who is deaf or hard of hearing and unable to hear warning signals from traditional carbon monoxide alarm systems
Specific characteristics	Sensor detects carbon monoxide levels (potential leak) and triggers vibration device Vibration device can be on user's body or placed on their seat or bed
Requirements for standard configuration	Carbon monoxide sensor with wireless transmitter Vibration device with wireless receiver that can be worn on belt or wrist, or placed on seat or bed (e.g. under pillow)

4. Alarm signaller with carbon monoxide sensor and flashing light

Typical user	Child or adult who is deaf or hard of hearing and unable to hear warning signals from traditional carbon monoxide alarm systems
Specific characteristics	Sensor detects carbon monoxide levels (potential leak); bright light flashes when sensor is activated
Requirements for standard configuration	Carbon monoxide sensor with wireless transmitter Flashing or strobe light with wireless receiver

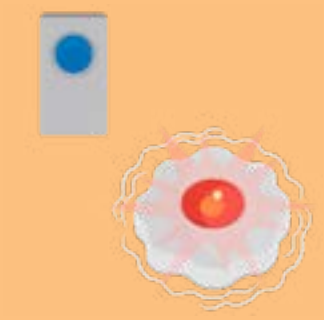
5. Alarm signaller with sound sensor and vibrating pad

Typical user	Child or adult who is deaf or hard of hearing and unable to hear alarm sounds or everyday alerts such as baby crying or doorbell ringing
Specific characteristics	Sensor picks up alarm and alerting sounds (e.g. fire alarm) and triggers vibration device Vibration device can be on user's body or placed on their seat or bed
Requirements for standard configuration	Sound sensor with wireless transmitter Vibration device with wireless receiver that can be worn on belt or wrist, or placed on seat or bed (e.g. under pillow)

6. Alarm signaller with sound sensor and flashing light

Typical user	Child or adult who is deaf or hard of hearing and unable to hear alarm sounds or everyday alerts such as baby crying or doorbell ringing
Specific characteristics	Sensor picks up alarm and alerting sounds (e.g. fire alarm); bright light flashes when sensor is activated
Requirements for standard configuration	Sound sensor with wireless transmitter Flashing or strobe light with wireless receiver

7. Push-button alarm signaller with vibration and flashing light



Typical user	Child or adult who is deaf or hard of hearing and needs to be alerted by another person
Specific characteristics	Pressing push-button triggers vibration device; bright light flashes to alert user
Requirements for standard configuration	Push-button with wireless transmitter Device with vibration function and flashing or strobe light with wireless receiver

General design requirements

The alarm signaller should not cause harmful interference to nearby devices, products or electrical equipment. The device should have an accessible and easy-to-use test button so it can be checked regularly. There should be a battery backup in the event of a power failure or if the system is unplugged from the mains to ensure it will be powered sufficiently for another 72 hours. An alert should sound when the battery power is low and needs to be replaced.

Design requirements for components of the alarm signaller include the following:

- A smoke, fire or carbon monoxide sensor should have enough range to cover all sections of the home or occupied space.
- The vibrating pad should be difficult to unplug or disconnect, and a warning light should come on if it accidentally does so. The pad should be manufactured from a non-slip material so it remains in place under the pillow, mattress or bedpost.
- The power of the vibrating pads should be 2.0–4.0 V.
- Alarm signallers with flashing lights should be suitable for indoor and outdoor use.
- The frequency of the light flashes is generally 0.9 Hz.

Standards

ISO 16201:2006 Technical Aids for Disabled Persons – Environmental Control Systems for Daily Living specifies the functional and technical requirements and test methods for environmental control systems intended for use to alleviate or compensate for a disability. Such systems are also known as electronic aids to daily living.

Environment of use

The product should operate in a temperature range of +15 to +35 °C and relative humidity (non-condensing) range of 5% to 95%.

Body-worn absorbent products, single-use

Name of product

Incontinence products, absorbent

ISO 9999 code

09 30 12 Single-use incontinence products for children

09 30 18 Single-use inserts for adults

09 30 21 Single-use diapers for adults

09 30 24 Single-use protective or disposable underwear for adults

09 30 30 Single-use incontinence products without barrier to liquid for adults

09 30 33 Single-use products for faecal incontinence for adults

09 30 39 Assistive products for fixation of body-worn products for absorbing urine and faeces

Description and intended use

Body-worn absorbent products (single-use) move moisture away from the skin and absorb and contain moderate or heavy urine loss or faeces. They are intended to protect the user's clothes and nearby environment, thereby preserving the user's dignity, comfort and quality of life, and if applicable, that of their caregiver(s), to promote social inclusion.

General features

A single-use body-worn absorbent product generally comprises:

- a topsheet, which lies against the wearer's skin; this is made from a water-permeable material that allows urine to pass readily through to the absorbent core beneath;
- an acquisition layer, which lies between the topsheet (above) and the absorbent core (below); this is designed to allow urine to enter the pad readily and spread over a large area of absorbent core. It does not absorb urine;
- an absorbent core, where urine is captured, spread and stored; this is made from material(s) that absorb(s) and spread(s) urine readily and retain(s) it under pressure;
- a backsheet, which is a layer of waterproof material that forms the outside surface of the pad, away from the wearer's body; this may be breathable;
- a fastening system (all-in-one and belted pads only) self-adhesive or hook-and-loop tabs to secure the products if a separate supporting product (e.g. underwear or fixation pants) is not used; pants/briefs (fixation underwear) can be used to secure single-use absorbent pads.

Inclusion

Single-use pads

Pull-on pads

Belted pads

All-in-ones (wraparound pads)

Exclusion

Washable absorbent products

Single-use/washable absorbent products that are not body-worn (e.g. bedpads)

Products that capture urine and transfer it to a bag or other receptacle (e.g. urinary catheter, sheath drainage system) or occlusive devices that prevent urine from leaving the body

Incontinence-related products that neither absorb nor contain urine or faeces, nor help secure products that do (e.g. urine-detecting sensors)

Keywords

Absorbents, all-in-one, body-worn, incontinence, pads, single-use

Functional requirements

1. Single-use pad for urine	
	
Typical user	Child or adult with light to heavy urine loss
Specific characteristics	Rectangular or shaped pads held in place with user's own close-fitting underwear or with fixation underwear (first part of two-piece system)
Requirements for standard configuration	Range of male and female adult and child pad sizes Light to heavy absorption capacity

2. Male pad for urine

Typical user	Boy or man with light to moderate urine loss
Specific characteristics	Shaped pads designed to cover penis and scrotum and held in place with user's own closely fitting underwear or with fixation underwear (first part of two-piece system)
Requirements for standard configuration	Range of sizes Light to moderate absorption capacity

3. Single-use belted pad for absorbing urine or containing faeces

Typical user	Child or adult with moderate to heavy urine loss or loose stool (diarrhoea)
Specific characteristics	With built-in fastener system
Requirements for standard configuration	Built-in fastening system includes belt (e.g. with tapes and tape landing zone/ hook and loop) Includes elastication around legs Range of male and female adult and child pad sizes Moderate to heavy absorption capacity

4. Single-use pull-on pad for absorbing urine or containing faeces

Typical user	Child or adult with moderate to heavy loss of urine or faeces, who can stand and change product without help from caregiver
Specific characteristics	Resembles ordinary close-fitting underwear
Requirements for standard configuration	Underwear with elasticized waist and legs Range of adult and child sizes Light to heavy absorption capacity

5. Single-use all-in-one (wraparound pad) for absorbing urine or containing faeces

Typical user	Child or adult with moderate to heavy loss of urine or faeces who is not able to stand and needs help from caregiver
Specific characteristics	With built-in fastener system
Requirements for standard configuration	Built-in fastening system (e.g. tapes and tape landing zone/hook and loop) Includes elastication around legs Range of male and female adult and child pad sizes Moderate to heavy absorption capacity

General design requirements

Body-worn absorbent products must achieve a close and secure fit to the body to prevent or minimize leakage. The design should ensure optimal skin protection and absorbency; the user should not need to change the product more than three to four times a day.

Standards*(5)*

ISO 15621:2017 Absorbent Incontinence Aids for Urine and Faeces – General Guidelines on Evaluation

ISO 11498–1 (total absorption capacity)

Size and weight

Size range for different adult and child body sizes

Body measurements required to select appropriate size and fit

Range of absorbency levels for all products

Lifespan

The product within an unopened packet should have a lifespan of at least three years

Accessories and spare parts

The following accessories may be required:[4] washable fixation underwear (pants/briefs) designed to hold pad in position (second part of two-piece system) that resembles male and female styles, adult and child sizes.

4 Standards for fixation pants can be found in Bursting strength (D3787, ASTM method) and Crotch strength (D1424–83, ASTM method).

Body-worn absorbent products, washable

Name of product

Incontinence products, absorbent

ISO 9999 code

09 30 15 Washable incontinence products for children

09 30 36 Washable incontinence pants for adults

09 30 39 Assistive products for fixation of body-worn products for absorbing urine and faeces

Description and intended use

Body-worn absorbent products (washable) move moisture away from skin and absorb urine or (with liner) contain faeces. They are intended to protect the user's clothes and nearby environment, thereby preserving the user's dignity, comfort and quality of life, and (if applicable) that of their caregiver(s), to promote social inclusion.

General features

A washable body-worn absorbent product generally comprises:

- a washable waterproof-backed pad worn with fixation pants, or a waterproof-backed pull-on pad;
- a washable absorbent unbacked fabric pad (usually shaped) or a fabric square folded for use and opened out flat for washing and drying; these are typically made from cotton towelling, but they may also be made from other absorbent fabrics, such as bamboo, rayon or polyester fibres. It is worn with a separate waterproof component (usually a plastic pant (underwear) but can be a plastic sheet folded to fit and secured by tying) to prevent urine or faeces leaking on to clothing and bedding. The waterproof component can provide additional security. A fixation device can be a safety pin or clip.

Inclusion

Washable absorbent products (pads, pants/briefs and all-in-ones (wraparound pads)) to be used for urinary or faecal incontinence; waterproof layer may be integrated or separate

Exclusion

Single-use, disposable absorbent products

Single-use/washable absorbent products that are not body-worn

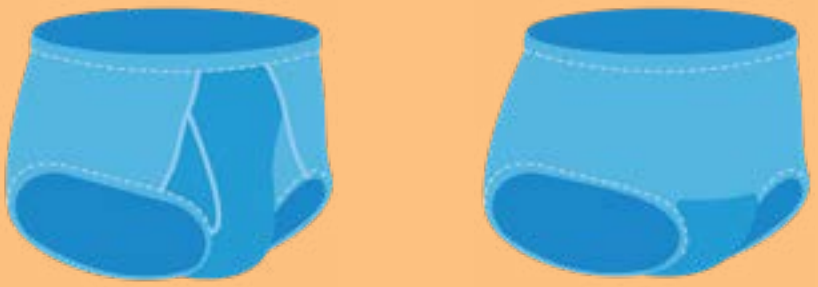
Products that capture urine and transfer it to a bag or other receptacle (e.g. urinary catheter, sheath drainage system) or occlusive devices that prevent urine leaving the body

Incontinence-related products that neither absorb or contain urine or faeces, nor help secure products that do (e.g. urine-detecting sensors)

Keywords

Absorbent products/pants/diapers/wraparounds/pads, body-worn, incontinence, washable, waterproof pants/sheets

Functional requirements

1. Washable, absorbent products	
1.1 Washable incontinence pull-on pad	
	
Typical user	Child or adult with very light to moderate urinary incontinence
Specific characteristics	Similar in appearance to standard underwear with integrated waterproof-backed absorbent pad
Requirements for standard configuration	Range of briefs/pants in male and female adult and child sizes Very light to moderate absorption capacity

1.2 Washable absorbent pad

Typical user	Child or adult with moderate to heavy loss of urine
Specific characteristics	Waterproof-backed pad worn with fixation pants
Requirements for standard configuration	Range of male and female adult and child pad sizes Natural or synthetic absorbent fabric Moderate to high absorption capacity

1.3 Washable all-in-one (wraparound) pad

Typical user	Child or adult with moderate to heavy loss of urine or faeces
Specific characteristics	Unbacked fabric pad (square or shaped) for urine or faeces, shaped to fit around the legs and fasten in the front or at the sides Held in place with integrated or separate fastening device (e.g. pins or clips) Worn with washable waterproof product (e.g. pants (underwear) or folded waterproof sheet)
Requirements for standard configuration	Range of adult and child pad sizes Natural or synthetic absorbent fabric Moderate to heavy absorption

General design requirements

The body-worn absorbent product should be made from non-irritant materials and must achieve a close and secure fit to the body to prevent or minimize leakage when used as intended.

Washable pads and pants or briefs should be suitable for hand or machine washing with soap or laundry detergent a minimum of 200 times at temperature up to 60 °C without using bleaching agents or fabric conditioner, and should be suitable for line or tumble drying at a low temperature.

Standards

ISO 15621:2017 Absorbent Incontinence Aids for Urine and/or Faeces – General Guidelines on Evaluation

Size and weight

The following sizes should be required:

- size range for adults and children
- body measurements required to select appropriate size and fit

Environment of use

Washable absorbent products should withstand room temperature and humid conditions.

Lifespan

Lifespan varies depending on how the product is used and laundered

Although waterproof components can be used multiple times, they are less durable than the fabric components, which can last for at least 200 uses; in integrated products, the lifetime of the waterproof component is likely to be the limitation.

Accessories and spare parts

The following accessories should be procured:

- washable fixation underwear (pants/briefs) designed to hold pad in position (second part of two-piece system) resembling regular male and female styles but made from stretchy fabric with a more generous design for comfortable fit and to secure the pad, in adult and child sizes;

- washable waterproof pants (underwear) with elasticated waistband and leg openings, breathable waterproof material that withstands multiple washes, and large enough to cover all areas of the pad, and used in conjunction with non-waterproof-backed products such as washable absorbent pads or all-in-ones (wraparound pads);

- washable waterproof sheets to be tied around the pad for a close fit and as a fixation mechanism, large enough to cover all areas of the pad, and used in conjunction with washable absorbent pads or all-in-ones (wraparound pads).

Washable waterproof pants or sheets should be suitable for hand or machine washing multiple times at low temperatures with soap or laundry detergent without using bleaching agents or fabric conditioner, and should be suitable for line drying away from direct heat sources or tumble drying at a low temperature.

Optional disposable liners (biodegradable and flushable) can be used to contain faeces when used with washable absorbent pads or all-in-one (wraparound) pads. They are provided in multi-product dispensers or can be torn from a roll.

Clubfoot braces

Name of product

Clubfoot braces

ISO 9999 code

None

Description and intended use

Clubfoot braces are used as part of the overall management of infants and children born with congenital talipes equinovarus (CTEV, idiopathic clubfoot). The braces position the child's feet to maintain a position after the use of a series of plaster casts (serial casts) to correct the foot.

Clubfoot braces are worn almost all the time in infants. Once the child is of walking age, clubfoot braces are generally used overnight until the condition is resolved. Clubfoot braces are used for children with CTEV affecting one or both feet.[5]

General features

A clubfoot brace is comprised of two boots that attach to a bar. The boots attach to the bar with a clip or screw and hold the feet in abduction (apart), dorsiflexion (up) and external rotation (rotated outward). The main components are the boots and bar. All boots have a heel cup or well-rounded heel counter. Many boots have an inspection hole at the back to check the child's heel is flat on the bottom of the boot. Boot fastenings may be straps and buckles, hook-and-loop (Velcro) or laces.

Inclusion

Clubfoot braces that hold both feet in a position of abduction, dorsiflexion and external rotation in boots attached to a bar

Exclusion

Single-leg clubfoot braces

Ankle–foot orthoses

5 As clubfoot braces are an integral part of the overall management of clubfoot, it is important to ensure the procurement team includes representation from those implementing clubfoot management programmes.

Keywords

Clubfoot orthosis, CTEV, Dennis Brown splint, foot-abduction brace, foot-abduction orthosis, Ponseti

Functional requirements

1. Clubfoot brace with two boots attached to a bar	
	
Typical user	Infant or child up to age five years who has completed the corrective phase of clubfoot treatment
Specific characteristics	Fixed bar (width adjustment is an optional feature) Boots that hold feet at shoulder width apart in position of abduction and dorsiflexion (angle adjustment is an optional feature)
Requirements for standard configuration	Standard configuration should allow for following adjustments: • Length of bar: size range to accommodate infants (0–12 months) and children (1–5 years) (e.g. bar width 12–38 cm) • Bilateral boots: size range to accommodate infants (0–12 months) and children (1–5 years) (e.g. foot bed length 6.4–20.4 cm) • Abduction angle of boot 30–70 ° (allows for unaffected foot) • Dorsiflexion angle of boot 10–15 ° • Smallest assembled size weight range 110–320 g • Largest assembled size weight range 270–650 g

General design requirements

The clubfoot brace should be designed for ease of use and be strong and durable:

- easy for the child's parents or carers to put the boots on and off the child;
- Velcro or laces on the boots that are easy to fasten firmly enough to keep the child's heels down within the boots;
- easy to clean.

The bar should be lightweight but strong enough to maintain the child's feet in a position of abduction and dorsiflexion (outward and upward angulation respectively). The design should include:

- a straight medial (inside) border on boot, or medial reinforcement of the boot material to prevent front of child's foot from angling inwards (forefoot adductus);
- features to prevent heel slipping up inside boot;
- features to prevent or reduce friction on skin;
- large shoelace holes or eyelets if laces are used;
- open-toed design, because child's toes should not be covered in the brace.

Standards

None

Size and weight

The following measurements should be provided:

- minimum, maximum and increments for adjustable bar or between fixed bar sizes
- boot size
- overall assembled weight of clubfoot braces

Lifespan

The product should have a lifespan of at least one year

Accessories and spare parts

The following spare parts should be procured:

- spare bars
- boots
- bar and boot connectors
- screws and other assembly parts.

The following optional accessories may also be procured:

- padding for bar
- strap saddles (to prevent pressure sores on skin)
- shoelace.

Other technical requirements

Information should be provided in the user manual on how to avoid and check for friction on the skin, how to check and ensure the heel stays down within the boot, and how to put the brace on and take it off.

Communication boards and books

Name of product

Communication boards, books and cards

ISO 9999 code

22 21 03 Letter and symbol sets and boards

Description and intended use

Communication boards and books enable the user to communicate using symbols, words, pictures or objects. The user looks at, points to, or otherwise selects items on the communication board or book. The communication board or book adds to or replaces spoken communication.

Communication boards and books are intended for use by children and adults with limited or no spoken communication, such as due to a neurological problem, hearing loss or intellectual disability.

General features

Communication boards are printed boards incorporating a grid of communication resources such as a set of symbols, paintings, icons, real-life pictures, letters, words or objects to represent ideas when communicating with others.

Communication boards or books are made from durable materials or laminated paper or card. They can be fixed to a shelf, wheelchair tray, table or wall. Communication boards and books can be designed and printed using dedicated computer software.

Inclusion

Universal communication boards (multi-layer static communication boards)

Customized (personalized) communication boards

Eye-pointing communication frames

Communication books

Exclusion

Products designed as visual infographics or schedules primarily for organization and management/ marketing rather than communication

Therapy aids for speech or language using printed boards for training, therapy and intervention but not communication

Keywords

Communication symbol, eye-pointing, multi-layer static communication board

Functional requirements

1. Universal communication board

Typical user	Child or adult with limited or no spoken communication and who has complex communication needs
Specific characteristics	Communication symbols and board layouts produced in accordance with common standards or user's needs
Requirements for standard configuration	Vocabulary can be varied to reflect user's needs and culture

2. Customized (personalized) communication board

Typical user	Child or adult with limited or no spoken communication and who wants to build on and extend the vocabulary of the universal communication board
Specific characteristics	Communication symbols and board layouts reflect user's needs
Requirements for standard configuration	In addition to following the general principles of communication board design, specific communication symbols or usage methods can be set according to user's needs[6]

3. Eye-pointing communication frame

Typical user	Child or adult with limited or no spoken communication and with severely restricted limb movement, relying on the eye to look at symbols to communicate
Specific characteristics	Symbols and words from available range are attached around a frame, which is held vertically during communication
Requirements for standard configuration	The frame is usually rectangular with a gap in the middle where communication partners can see each other Symbols and words are attached around the frame in consistent format so they can be easily found and pointed at by the eye

6 This product is usually designed and printed using dedicated software.

4. Communication book

Typical user	Child or adult with limited or no spoken communication and who uses a wider vocabulary
Specific characteristics	Collection of symbols related to common theme or setting is displayed as individual pages reflecting interests
Requirements for standard configuration	According to user's communication needs, pages are produced in different categories and bound into a book

General design requirements

The communication board or book should be easy to carry and suitable for use. The materials must be appropriate and safe (e.g. non-toxic laminate) and can protect the board or book from damage. The print should be clear and easy to read, with good contrast, and use permanent ink. Software for designing and printing the board or book should be available on CD or through direct download; availability of backup media should be identified. The grid and symbol layout should be adjustable with the software.

Standards

Board size: ISO 19027:2016(E)3.1a

Board materials (paper or plastic): ISO 19027:2016(E)3.1b

Design of the symbol on the board: ISO 19027:2016(E)3.2

Layout of display item on board: ISO 19027:2016(E)3.2

Clarity and contrast of print: ISO 19027:2016(E)3.2

Environment of use

The product should withstand heat, dust, humid and dry environments.

Lifespan

The product should have a lifespan of at least three years

Other product requirements

Information on tactile printers and their compatibility with tactile symbols should be provided

Information on whether both colour and black-and-white versions of symbols should be used on the board should be provided

Crutches

Name of product

Crutches, axillary/elbow

ISO 9999 code

12 03 06 Elbow crutches

12 03 12 Axilla crutches

12 03 09 Forearm crutches

Description and intended use

Crutches are walking aids with elbow, underarm or forearm support and a single shaft fitted with a tip (ferrule). A single crutch or pair of crutches is intended for use by children and adults to support balance or weightbearing through the leg(s).

General features

A crutch has a straight or offset handle with an ergonomically shaped handgrip and a height-adjustable shaft fitted with a tip.

Inclusion

Elbow, axilla and forearm crutches

Exclusion

Walking sticks with or without seat

Multi-tip walking sticks (e.g. tripods, quadripods)

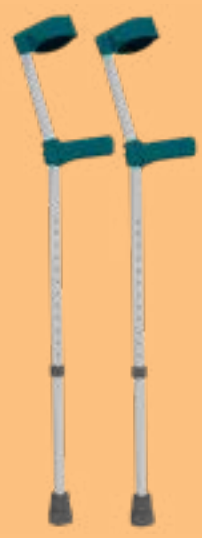
Lateral support frames

Keywords

Arthritis crutches, axillary crutches, axilla crutches, elbow crutches, ferrules, forearm crutches, gutter crutches, platform crutches, tips

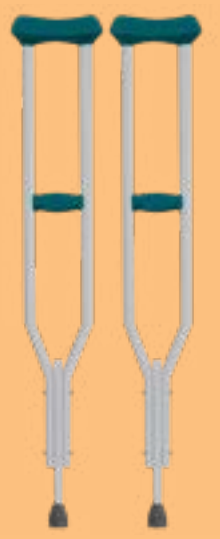
Functional requirements

1. Elbow crutch



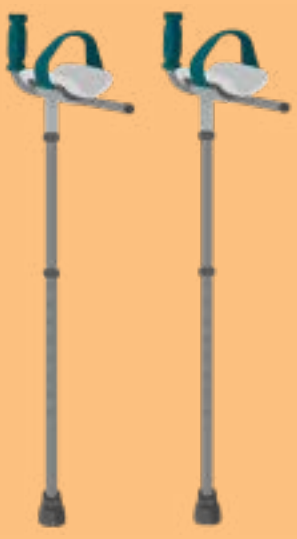
Typical user	Short- or long-term use for child or adult who needs support to balance or bear weight through their legs
Specific characteristics	Cuff: • closed/semi-circle • hinged/fixed attachment • Ergonomically moulded handgrip Shaft: • height-adjustable • fitted with tip Height-adjustment mechanism: • quick-release • single height adjustment (shaft only) • double height adjustment (cuff and shaft)
Requirements for standard configuration	Complete assembly with appropriate tip for environment Tips securely fitted and made from durable rubber Three to four different sizes to fit children and adults (e.g. child, youth, adult, tall adult) Bariatric range for users over 120 kg

2. Axilla crutch



Typical user	Short-term use for child or adult who needs support to balance or bear weight through their legs
Specific characteristics	Cushioned underarm support Ergonomically moulded handgrip Shaft: • height-adjustable • fitted with tip Height-adjustment mechanism: • double height adjustment (handgrip and shaft)
Requirements for standard configuration	Complete assembly with appropriate tip for environment Shaft: • adjustable height • commonly made from aluminium or wood Height adjustment of handgrip independent of shaft (total height) adjustment Handgrip commonly made from plastic Tips securely fitted and made from durable rubber Three to four different sizes to fit children and adults (e.g. child, youth, adult, tall adult) Bariatric range for users over 120 kg

3. Forearm crutch



Typical user	Short- or long-term use for child or adult who needs support to balance or bear weight through their legs and is unable to use standard handgrip due to hand or arm impairment
Specific characteristics	Forearm support: • horizontal support • moulded • cushioned • hook-and-loop fastener Handgrip: • telescopic handle rotates through 360 ° Shaft: • height-adjustable • fitted with tip Height-adjustment mechanism: • quick-release • single height adjustment (shaft only)
Requirements for standard configuration	Complete assembly with appropriate tip for environment Tips securely fitted and made from durable rubber Three to four different sizes to fit children and adults (e.g. child, youth, adult, tall adult) Bariatric range for users over 120 kg

General design requirements

The crutch should be easy to adjust, strong and durable; have low deformation risk and high abrasion resistance; and be made from lightweight material. The tips of the crutch should be durable, non-slip and replaceable. A variety of types are available for different environmental contexts.

Parts must be replaceable and made from materials that withstand the environment of use.

Standards

Specific tests for elbow crutches:

- ISO 11334–1:2007 specifies requirements and test methods for elbow crutches fully equipped with handgrip and tip; the methods specify testing of separation, static load capacity, fatigue and resistance to low temperature embrittlement
- ISO 11334–1:2007 gives requirements relating to safety, ergonomics and performance, together with information to be supplied by the manufacturer, including marking and labelling

Tests for axilla and forearm crutches:

- In the absence of an ISO standard, use EN 1985:1999 Walking Aids – General Requirements and Test Methods; appropriate parts of this standard may be applied to the above products and other walking aids beyond this APS
- ISO 24415–2: 2011 Tips for Assistive Products for Walking – Requirements and Test Methods – Part 2: Durability of Tips of Crutches (excludes tips manufactured for special purposes such as ice and snow)

Size and weight

The following information should be provided for all products across all size ranges as specified:

- overall length
- height-adjustment range(s)
- maximum user weight
- unit weight
- handle height (axilla and elbow crutches)
- length of forearm support (forearm crutches)
- underarm pad (axilla crutches) or cuff (elbow crutches) to handle length

Environment of use

The crutches should be appropriate for local terrain and conditions such as sand, mud, rocky ground, rain, snow, ice and sleet.[7]

7 This will affect the materials used in the shaft and the specifications of the type of tips for the product.

Lifespan

At least five years, provided the crutches are maintained and correctly used in their intended environment, in line with the product instructions; this period may be adjusted based on local conditions and context of use

Accessories and spare parts

The following spare parts are required:

- tips for different environmental conditions;
- height-adjustment mechanisms;
- individual components as spare parts.

The following optional accessories can be required:

- padded handgrip covers;
- cuff protectors.

Other product requirement

Appropriate tips suitable for the local environment to fit the shafts.

Filters

Name of product

Spectacles; low vision, short distance, long distance, filters and protection

ISO 9999 code

22 03 03 Light filters (absorption filters)

Description and intended use

Filters are glare control lenses that absorb harmful ultraviolet (UV) light and enhance contrast. More commonly referred to as sunglasses. They are intended for use by children and adults with various ocular conditions causing visual impairment.

General features

Filters are available in various designs (e.g. wraparound, fit-over, side-shields, clip-on) and in various lens colours for different ocular conditions at specific percentages of light transmittance.

Inclusion

Filters in various designs and lens colours

Exclusion

None

Keywords

Glare, light, sunglasses

Functional requirements

1. Filters	
	
Typical user	Child or adult experiencing glare due to various ocular conditions
Specific characteristics	None
Requirements for standard configuration	Should have almost 100% UV absorption up to 400 nm wavelength Significant percentage of frames are made from materials that do not cause irritation to skin Polarized lens Lens colours for various ocular conditions include grey, amber, amber-orange, red-orange, plum, yellow, red, green, grey-green, orange, topaz, polarized grey and polarized amber

General design requirements

The filter should be durable and lightweight. The lens should be scratch- and impact-resistant.

Standards

BS EN 170:2002 Personal Eye Protection: Ultraviolet Filters: Transmittance Requirements and Recommended Use

ISO 12312–1:2013 Eye and Face Protection – Sunglasses and Related Eyewear – Part 1: Sunglasses for General Use

Size and weight

Information about eye size, bridge width, temple length, lens diameters and overall weight should be provided

Environment of use

Filters should function in wet and dry environments and be able to withstand a temperature range of –30 to +50 °C (e.g. lens materials made from CR-39 and crown [borosilicate] glass). Lenses made from polycarbonate material should withstand up to +124 °C.

Accessories and spare parts

The supplier should make available the following accessories:

- boxes, cases and pouches;
- velvet cleaning cloths.

The supplier should make available the following spare parts:

- temples
- nose pads
- screws.

Handrails and grab-bars

Name of product

Handrails and grab-bars

ISO 9999 code

18 18 03 Hand rails and support rails

18 18 06 Fixed grab bars and handgrips

18 18 10 Removable grab rails and handgrips

18 18 11 Hinged rails and arm supports

Description and intended use

Handrails or grab-bars are cylindrical rails or bars attached to a wall, floor or other stable structure that a person can hold for support. They are intended for use by children and adults who need support when moving between lying, sitting or standing, and while standing or moving around in indoor and outdoor environments.

General features

A handrail or grab-bar is circular in shape, has a continuous construction with no joins or obstruction along the passage of the bar or rail, and has both ends permanently attached to a wall, floor or ceiling.

Inclusion

Short grab-bars and handrails

Long handrails

Exclusion

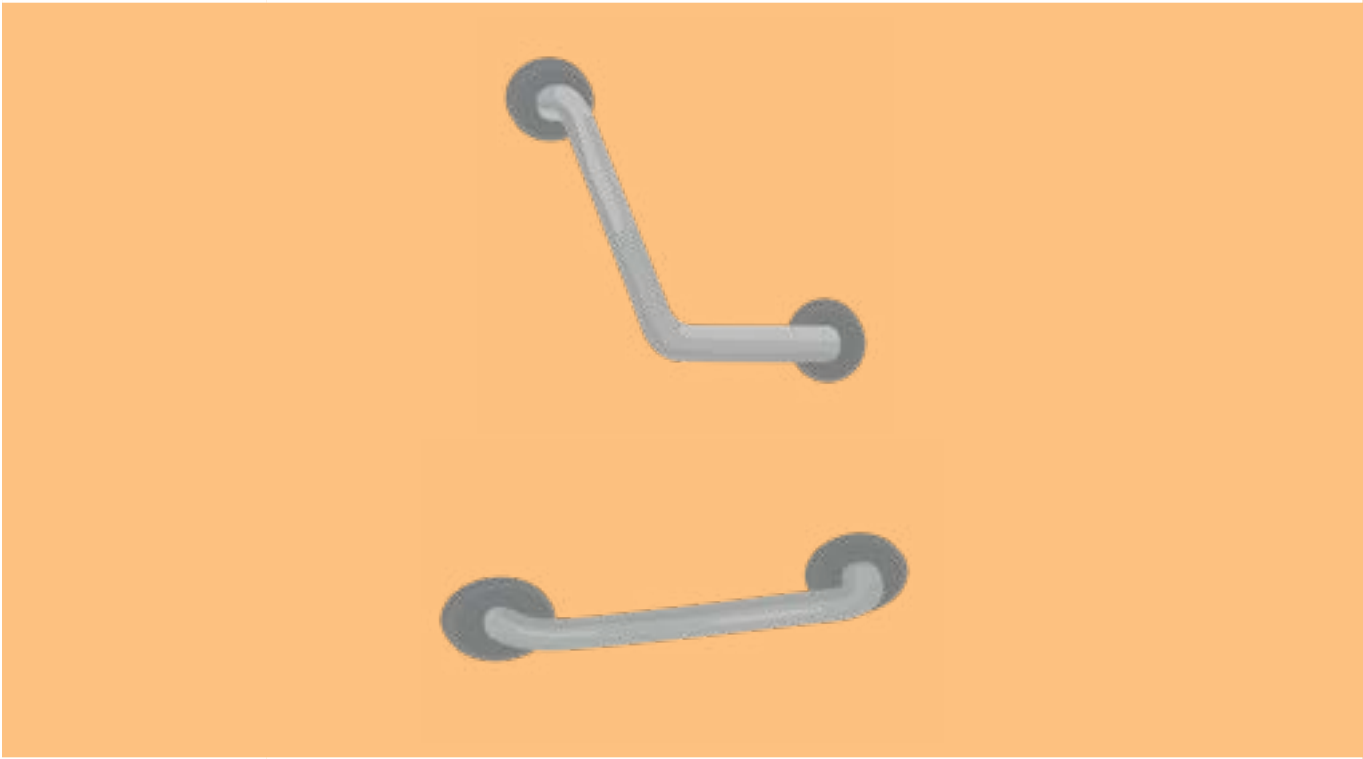
Suction rails

Keywords

Grab-bars, handrails, home modification, support

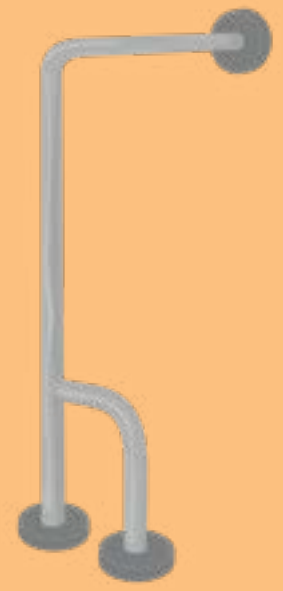
Functional requirements

1. Wall-mounted straight or angled grab bar



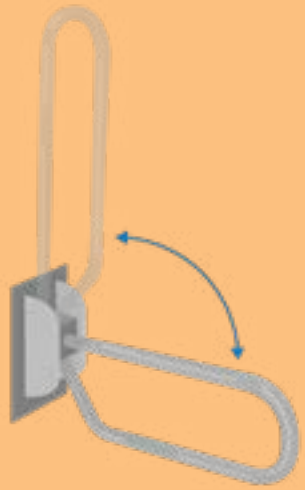
Typical user	Child or adult who needs support when moving between lying, sitting or standing, while standing, or when going up and down steps
Specific characteristics	Both ends permanently attached to wall in horizontal, vertical or diagonal position
Requirements for standard configuration	Stainless-steel, aluminium, brass, wood, plastic or galvanized tubing with diameter 30–50 mm. Clearance from wall should be approximately 50 mm to ensure sufficient space for finger clearance Minimum load 150 kg for wide platform Fixed or customized length with effective grab length not less than 230 mm Adequate contrast visually with background wall Satin, power-coated, epoxy-coated, enamel-coated or polished finishing

2. Floor-to-wall/floor-to-ceiling grab bar



Typical user	Child or adult who needs support when moving between lying, sitting or standing, while standing, or when going up and down steps; and where it is not possible to attach the bar to a wall
Specific characteristics	Fixed between wall and floor, or from floor to ceiling
Requirements for standard configuration	Stainless-steel, aluminium, brass, wood, plastic or galvanized tubing with diameter 30–50 mm Clearance from wall should be approximately 50 mm to ensure sufficient space for finger clearance Minimum load 150 kg for wide platform Fixed or customized length with effective grab length not less than 230 mm Adequate contrast visually with background wall Satin, power-coated, epoxy-coated, enamel-coated or polished finishing

3. Fold-down/drop-down rail



Typical user	Child or adult who needs support to sit down or to stand up from sitting, or to go up or down a step; and where it is not possible to attach the bar to a wall or where space is limited
Specific characteristics	Has extra vertical support leg to floor or looped rail that provides two alternative gripping positions
Requirements for standard configuration	Stainless-steel, aluminium, brass, wood, plastic or galvanized tubing with diameter 30–50 mm Clearance from wall should be approximately 50 mm to ensure sufficient space for finger clearance Minimum load 150 kg for wide platform Fixed or customized length with effective grab length not less than 230 mm Adequate contrast visually with background wall Satin, power-coated, epoxy-coated, enamel-coated or polished finishing

4. Wall-mounted banister rail

Typical user	Child or adult who needs support to walk up or down stairs or along a corridor

Specific characteristics	Both ends permanently attached to wall in diagonal or horizontal position
Requirements for standard configuration	Stainless-steel, aluminium, brass, wood, plastic or galvanized tubing with diameter 30–50 mm Clearance from wall should be approximately 50 mm to ensure sufficient space for finger clearance Adequate contrast visually with background wall Satin, power-coated, epoxy-coated, enamel-coated or polished finishing Available in standardized lengths of 300 mm, 450 mm, 600 mm and 900 mm

General design requirements

The hand rail or grab bar should be made with strong material, durable and safe for use in the environment of use. The finish should be slip- and rust-resistant. If used in wet areas (e.g. bathrooms), every component of the grab bar or hand rail needs to be waterproof.

The option of a coloured finish should be available for children and adults with visual impairments.

The grab bar or hand rail should allow the user's hand to encircle and be in complete contact with the rail when gripping.

Standards

ISO 17966:2016 specifies requirements and associated test methods for assistive products for personal hygiene that support users and that are intended by the manufacturer to alleviate or compensate for disability. The work environment and safety aspects for assistants are also included. It specifies safety and performance requirements that apply during normal use and foreseeable misuse and failure. It also specifies methods of measurement of the forces necessary to operate controls and specifies limits on the forces needed for some operations.

EN 12182 Assistive Products for Persons with Disability – General Requirements and Test Methods could be considered, and some specifications can be found in ISO 21542 Building Construction – Accessibility and Usability of the Built Environment, Chapter 14.

Size and weight

Information about overall width, length and safe working load of grab-bars and handrails is required

Environment of use

The product should withstand a relative humidity range of 15% to 100%.

Hearing aids

Name of product

Hearing aids (digital) and batteries

ISO 9999 code

22 06 15 Behind-the-ear hearing aids

22 06 27 Accessories for assistive products for hearing

Description and intended use

Hearing aids are electronic devices attached to the ear that amplify sound and direct that sound into the ear. They are intended to assist children and adults who experience varying degrees of hearing loss, from deaf to hard of hearing, in the perception of environmental sounds and to hear and understand oral language.

General features

A hearing aid typically incorporates microphone(s), receiver, amplification unit and power supply and works with an ear coupling system such as tubing (standard or slim) and an earmould or ear insert. It is powered by conventional or rechargeable batteries inside the device. Hearing aids vary in power and pattern of amplification depending on the degree, configuration and type of hearing loss. Hearing aids may include compatibility with additional features such as telecoils (T-coils), directional microphones and direct audio input (DAI) to assist hearing in unique situations.[8]

Inclusion

Behind-the-ear hearing aids with preconfigured ear inserts or custom earmoulds

Preprogramed behind-the-ear hearing aids

Exclusion

Analogue hearing aids

In-the-ear, spectacle and body-worn hearing aids

Bone conduction hearing aids

Other assistive listening or amplification devices

Cochlear implant processors

8 T-coil or DAI is required in the design to be compatible with personal remote microphone systems (see APS Personal remote microphone systems for more information).

Keywords

Communication, DAI, deaf, hard of hearing, hearing loss, preprogramed, T-coil

Functional requirements

1. Behind-the-ear hearing aid with preconfigured ear inserts

Typical user *(6)*	Adult with mild to severe hearing loss in most environments
Specific characteristics	Meets amplification needs of users with specific hearing loss configurations in mild to severe range Device may incorporate controls or interface that allow it to be programmed to meet individual amplification needs
Requirements for standard configuration	Amplification frequency response and maximum output (OSPL) that meet requirements of standard prescription formulae (e.g. Desired Sensation Level v.5 or National Acoustics Laboratories NL2) Frequency range should be 200–4500 Hz (minimum) Preconfigured (stock or disposable) ear inserts in variety of sizes

2. Behind-the-ear hearing aid with custom earmoulds

Typical user	Child or adult with mild to profound hearing loss in most environments[9]

9 More selective fitting may be necessary in children with congenital deafness, and children or adults with developmental disabilities.

Specific characteristics	Meets amplification needs of users with specific hearing loss configurations in mild to profound range Device may incorporate controls or interface that allow it to be programmed to meet individual amplification needs
Requirements for standard configuration	Amplification frequency response and maximum output (OSPL) that meet requirements of standard prescription formulae (e.g. Desired Sensation Level v.5 or National Acoustics Laboratories NL2) Frequency range should be 200–4500 Hz (minimum) Coupling system for custom-made earmoulds

3. Preprogramed behind-the-ear hearing aid with either custom earmoulds or preconfigured ear inserts

Typical user	Adult with targeted common hearing loss configurations
Specific characteristics	Meets generic amplification needs of targeted hearing loss configurations in mild to severe range Device incorporates controls or interface that allows selection of hearing programme
Requirements for standard configuration	Amplification frequency response and maximum output (OSPL) that meets requirements of standard prescription formulae (e.g. Desired Sensation Level v.5 or National Acoustics Laboratories NL2) Frequency range should be 200–4500 Hz (minimum) At least three preset hearing programmes Preconfigured (stock or disposable) ear inserts in variety of sizes or custom-made earmoulds

General design requirements

The hearing aid should meet the parameters given by WHO *(7)*. It should be comfortable, easy to wear, and practical to manipulate; fit a range of hearing loss configurations; permit measurement of sound output; and be reliable and packaged in robust containers. To ensure durability when exposed to water, humidity or dust, the ingress protection (IP) rating (a measure of device tolerance for such environments) should be considered if available, and hearing aids with ratings appropriate to the user's environment selected. A minimum IP rating for dirt/dust and water resistance of 5/6 or greater is desirable.

Standards

IEC 60118 Electroacoustics – Hearing Aids (several parts in this series may be applicable)

Environment of use

Hearing aids should be able to withstand various weather conditions, including light rain, snow and dust. Hearing aids need to function in an ambient temperature range of–20 to +45 °C and relative humidity range of 0% to 80%

Accessories and spare parts

The following accessories are required:

- hearing-aid storage containers for users
- hearing-aid cleaning tools (e.g. small brushes and wires);
- batteries.[10]

Other product requirements

Battery life for the typical use should be specified.

10 The procurement team should ensure users will be able to access a regular supply of batteries for their devices.

Manual Braille writing equipment

Name of product

Braille writing equipment/Brailler

ISO 9999 code

22 12 12 Manual Braille writing equipment

Description and intended use

Braille writing equipment is used to produce embossed Braille characters on paper. They are intended for use by children and adults with blindness or low vision.

General features

The equipment consists of a manually operated slate or frame with Braille cells and a special-tipped object called a stylus.

The slate or frame is usually metal or plastic, with two plates hinged together on the top or side to hold papers for writing Braille. A stylus consists of a short rod with a blunted point to emboss Braille dots. It is typically about 5 cm long with a metal tip and a small handle gripped by the index finger and thumb for embossing the Braille dot into the page.

Inclusion

Braille slates/frames

Interline Braille writing slates/frames

Interpoint Braille writing slates/frames

Small pocket frames

Stylus of different types

Exclusion

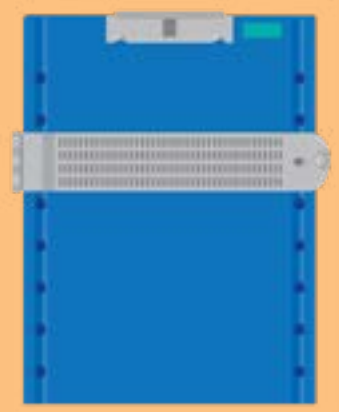
Electric/electronic/digital Braille writing devices

Keywords

Braille writing, interline, interpoint, slate/frame, stylus

Functional requirements

1. Braille slate/frame with a board and marker

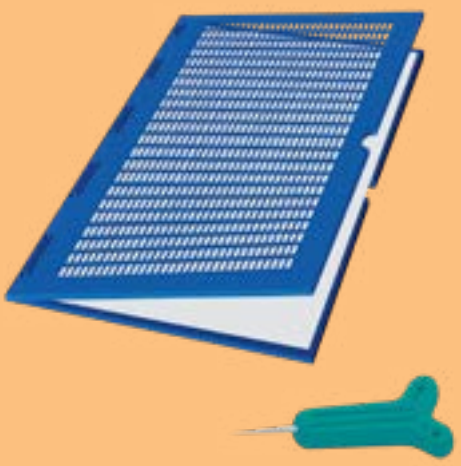


Typical user	Child or adult with blindness or low vision
Specific characteristics	None
Requirements for standard configuration	Board/frame of A4 size with 30 cells x 27 lines Marker after every 5 cells Metal guide and board with up to 9 holes for fitting guide

2. Interline Braille slate/frame

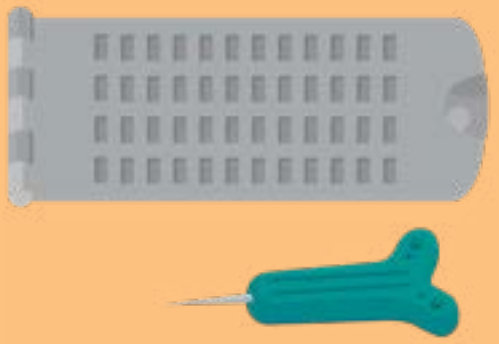
Typical user	Child or adult with blindness or low vision
Specific characteristics	Capacity to emboss Braille on both sides of paper, where alternate lines are embossed front and back
Requirements for standard configuration	30 cells x 27 lines Marker after every 5 cells

3. Interpoint Braille slate/frame



Typical user	Child or adult with blindness or low vision
Specific characteristics	Capacity to emboss Braille on both sides of paper, where space between dots on front side is used when embossed on back
Requirements for standard configuration	Up to 30 cells x 27 lines Marker after every 5 cells

4. Small pocket frame



Typical user	Child or adult with blindness or low vision
Specific characteristics	Much smaller and extremely portable
Requirements for standard configuration	Up to 8 or 10 lines with maximum 20 cells per line

5. Stylus of knob, flat or saddle type

Typical user	Child or adult with blindness or low vision
Specific characteristics	None
Requirements for standard configuration	Plastic head with metal rod at bottom 5.72 cm long with 27.94–40.64 cm metal tip

General design requirements

The dots of each cell must be easily discernible by touch. The height of the dots must be sufficient to be easily distinguished from the background. The board or frame should be lightweight, easy to open and close to hold the paper in place, and self-locking to hold the paper. The stylus should be lightweight and able to be firmly and comfortably gripped by the index finger and thumb for embossing.

Standards

None *(8)*

Size and weight

Weight, length and width of frame, slate or board should be provided

Accessories and spare parts

The following accessories should be required:

- case for stylus.

Mechanical Braille typewriters

Name of product

Braille writing equipment/Braillers

ISO 9999 code

22 12 15 Typewriters

Description and intended use

Braille typewriters (Braillers) are mechanical (hand-operated) devices used for writing Braille by pressing related keys on to paper. Braillers are intended to support communication for children and adults with blindness or low vision and for Braille transcribers to write in Braille.

General features

A Brailler has a hard casing and a keypad. Braille letters are indented into Braille paper by pressing on one of the six Braille keys.

Inclusion

Mechanical Perkin Braillers

Exclusion

Eurotype Braillers

Tatrapoint Braillers

Electric/electronic Braillers

Unimanual Braillers

Large cell Braillers

Smart Braillers

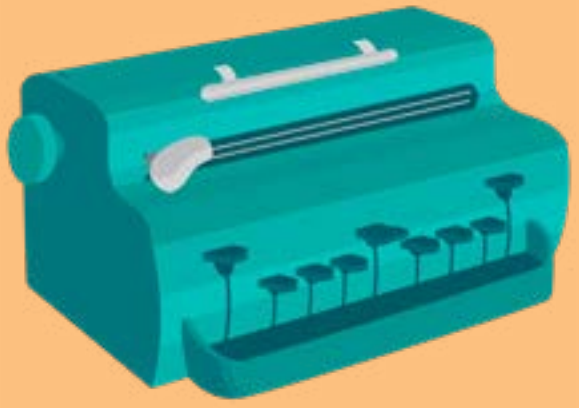
Extension keys are excluded

Keywords

Brailler, Braille reading, Braille writing

Functional requirements

1. Standard Perkins Brailler



Typical user	Child or adult with blindness or low vision
Specific characteristics	None
Requirements for standard configuration	Closed body architecture (to prevent dust accumulation) Braille dots to be even 42 cells per line with up to 30 lines per page Brailler functions: • keypad – six Braille keys, one space key, one backspace key and one line-changing key • margins – full right and left margin adjustment to accommodate given paper size and line centring • bell – audible bell sounds, 7 spaces before end of line • carriage – carriage release, full horizontal movement between margin stops Dot specification: • dot height 0.048 cm • dot diameter 0.144 cm • dot spacing 0.228 cm • character spacing 0.609 cm • line spacing 1.016 cm

General design requirements

The Brailler must be durable, easy to operate, and be upward writing (dots on the same side of the paper). The Brailler should have an ergonomically designed keypad and be much less fatigue-inducing (compared with slate and stylus). Parts of the Brailler should be easy to replace when required. The Brailler is compatible with standard Braille paper.

Standards

None

Lifespan

The product should have a lifespan of at least 10 years

Accessories and spare parts

The following accessories should be procured:

- dust covers.

Medication organizers

Name of product

Medication organizers

ISO 9999 code

04 19 04 Assistive products for measuring, dispensing or modifying medication to ensure its proper use

22 27 16 Memory support products

Description and intended use

Medication organizers help people take their medicines in the correct dosages at the correct time and help to prevent adverse effects such as missed doses or overdoses. They are intended for use by children and adults to store prescribed medications. Some medication organizers notify the user when the medicines are due to be taken and can monitor whether the user has taken their medicines.

General features

A medication organizer comprises a container with compartments to store medicines for each day of the week. There are usually sub-compartments for doses to be taken at different times in one day. Medication organizers are available in different shapes and sizes. They are usually made of transparent plastic for easy identification of medicines, with different colours or printed marks used to distinguish time. Multiple medicines can be managed. Some medication organizers have functions or compatible with software to manage intake of medicines.

Inclusion

Medication organizers without automated functions

Medication organizers with automated functions

Medication organizers compatible with software

Exclusion

Single-use medication organizers

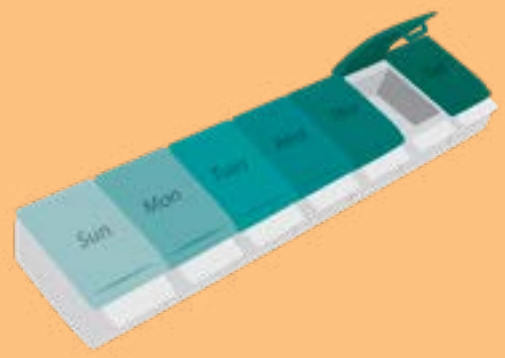
Medication organizers for suppositories, liquids, injections and inhalers

Keywords

Alarm function, communication function, lock function, pill organizer, pill dispenser, remote monitoring, timed reminder

Functional requirements

1. Medication organizer (without automated functions)



Typical user	Child or adult who takes medicines, or their caregiver
Specific characteristics	Rectangular or fan-shaped Medicines accessed by flipping or rotating lid
Requirements for standard configuration	Rectangular, with separate flip-top box, grid inside box, and small box within main box Fan-shaped with subdivided container Sections in different colours or printed marks for different times Can be lockable and tamperproof

2. Medication organizer with timed reminder function

Typical user	Child or adult who takes medicines, or their caregiver, and who may need to be reminded to take medicines

Specific characteristics	Various shapes and sizes (e.g. rectangular or fan-shaped) and with range of time reminders and other automated features, such as: • small grid with sensory information for signalling time; time reminders may be audio, visual or tactile (e.g. vibration) • additional features include a locking function for users and environments where the safe taking or storage of medicines is a priority
Requirements for standard configuration	Medication organizer with timed reminder features (light-, vibration-, sound- or voice-based) Must be lockable and tamperproof

3. Medication organizer with timed reminder medication software

Typical user	Child or adult who takes medicines, or their caregiver; who may need to be reminded to take their medicines; and who uses a mobile phone
Specific characteristics	Various shapes and sizes (e.g. rectangular or fan-shaped) and with range of time reminders and other automated features, including supporting software and mobile or email reporting and reminding prompts, such as: • display with sensory information for signalling time; time reminders may be audio, visual or vibration • reminders or reports sent to the user's or caregiver's mobile phone or email Additional features include locking function for users or environments where the safe taking or storage of medicines is a priority
Requirements for standard configuration	Medication organizer with software with function to send timed reminders; software can be downloaded and installed from manufacturer's website; instructions for use should be supplied by seller Must be lockable and tamperproof

General design requirements

The medication organizer should be made from good-grade plastic with no bisphenol A (BPA). The material must be durable and not easily damaged. The lid must be easy to open, but it must not open accidentally when being carried or if there is vibration. The lid must close tightly to prevent moisture and ensure the medication is kept safely. It can be used in a variety of everyday environments. Different colours or print marks can be used to identify and differentiate the time to take the medicines in each compartment. Clearly printed marks meet the standard for erasure resistance. Optional Braille marks.

Standards

No current product standards exist for medication organizers. Relevant standards may include standards governing the safe handling of medicines when being removed from packaging, and standards for the automated dispensing of foodstuffs such as pet food:

IEC 60335-2-75 Ed. 3.1 Household and Similar Electrical Appliances – Safety Part 2-75: Particular Requirements for Commercial Dispensing Appliances and Vending Machines

ISO/IEEE 11073-10471:2010 Health Informatics – Personal Health Device Communication. Part 10471: Device Specialization – Independent Living Activity Hub

ISO/IEEE 11073-10472:2012 Health Informatics – Personal Health Device Communication. Part 10472: Device Specialization – Medication Monitor

EN 15823:2010 Packaging. Braille on Packaging for Medicinal Products

Size and weight

Dimensions of operable compartments and lids should be required

Environment of use

The product should withstand safe temperatures that the medication can tolerate.

Lifespan

The product should have a lifespan of at least two years.

Accessories and spare parts

The following spare parts should be required:

- any moving, removeable or replaceable parts of the medication organizer (e.g. lids, compartments, dividers).

Optical magnifiers

Name of product

Magnifiers, optical

ISO 9999 code

ISO 22 03 09 Magnifier glasses, lenses and lens systems for magnification

Description and intended use

Optical magnifiers can produce magnified (enlarged) images of close objects and print. They are intended for use by children and adults with low vision that cannot be fully corrected with spectacles or other treatment such as surgery.

General features

An optical magnifier uses positive power lens to produce a magnifying effect. It comprises a single lens or more than one lens (lens system). Most lenses or lens systems are mounted into a frame, with the exception of a dome magnifier. Different frame types suit different tasks.

The range of magnifying power (magnification) is measured in dioptres (D). Magnifiers most commonly have a lens power range from +4D to +76D. Some magnifiers include a built-in light source and are described as illuminated magnifiers.

Inclusion

Handheld, stand magnifiers, pocket, dome, sheet, spectacle and other portable magnifiers

Magnifiers with or without illumination

Exclusion

Magnifiers or magnifying systems for specialist occupations (e.g. watchmaking, dentistry)

Electronic, digital or video magnifiers

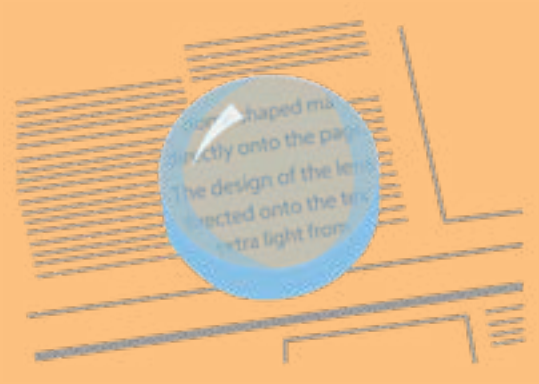
Telescopes

Keywords

Low vision, visual impairment, sight enhancement

Functional requirements

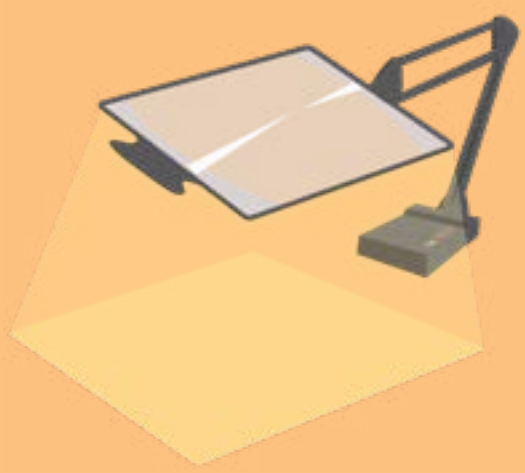
1. Non-illuminated stand magnifier



Typical user	Child or adult with near vision impairment even after treatment or correction of any refractive error
Specific characteristics	Supports around lens mount should be small or transparent to avoid blocking light from area being viewed Smaller supporting stands can expose more area for better spot-writing function Some stand magnifiers have adjustable lens to compensate for user's uncorrected refractive error
Requirements for standard configuration	Lens power range +6D to +76D Lens diameter:[11] minimum lens diameter is described below, as greater than or equal to (≥): ≤ +8D: ≥ 90 mm > +8D to +12D: ≥ 80 mm > +12D to +16D: ≥ 60 mm > +16D to +20D: ≥ 45 mm > +20D to +26D: ≥ 35 mm > +26D to +40D: ≥ 30 mm ≥ +40D: ≥ 26 mm Lens: plastic Frame (mount): high-grade plastic

11 As magnification increases, lens diameter reduces, which reduces the area of magnification for the user.

2. Illuminated stand magnifier



Typical user	Child or adult with near vision impairment even after treatment or correction of any refractive error
Specific characteristics	Same as non-illuminated stand magnifier with in-built illumination distributed evenly across area being viewed
Requirements for standard configuration	Lens power range +6D to +76D Minimum lens diameter is described below, as greater than or equal to (≥): ≤ +8D: ≥ 90 mm > +8D to +12D: ≥ 80 mm > +12D to +16D: ≥ 60 mm > +16D to +20D: ≥ 45 mm > +20D to +26D: ≥ 35 mm > +26D to +40D: ≥ 30 mm ≥ 40D: ≥ 26 mm Lens: plastic Frame (mount):high-grade plastic Illumination options for illuminated magnifiers: light-emitting diode (LED), surface-mounted diode (SMD) LED or incandescent bulbs

3. Non-illuminated handheld magnifier

Typical user	Child or adult with near vision impairment even after treatment or correction of any refractive error
Specific characteristics	Magnification can be adjusted by changing distance between magnifier and object being viewed; this can also help to compensate for uncorrected refractive error Available as lens held in round frame with handle, pocket magnifiers, chest-support magnifiers and pendant magnifiers
Requirements for standard configuration	Lens power range: +4D to +56D Minimum lens diameter is described below, as greater than or equal to (≥): ≤ +8D: ≥ 90 mm > +8D to +12D: ≥ 80 mm > +12D to +16D: ≥ 60 mm > +16D to +20D: ≥ 45 mm > +20D to +26D: ≥ 35 mm > +26D to +40D: ≥ 30 mm ≥ +40D: ≥ 26 mm Lens: plastic Frame (mount) and handle: high-grade plastic

4. Illuminated handheld magnifier

Typical user	Child or adult with near vision impairment even after treatment or correction of any refractive error
Specific characteristics	Same as non-illuminated handheld magnifier with in-built illumination distributed evenly across area being viewed
Requirements for standard configuration	Lens power range: +4D to +56D Minimum lens diameter is described below, as greater than or equal to (≥): ≤ +8D: ≥ 90 mm > +8D to +12D: ≥ 80 mm > +12D to +16D: ≥ 60 mm > +16D to +20D: ≥ 45 mm > +20D to +26D: ≥ 35 mm > +26D to +40D: ≥ 30 mm ≥ 40D: ≥ 26 mm Lens: plastic Frame (mount) and handle: high-grade plastic Illumination options for illuminated magnifiers: LED, SMD LED or incandescent bulbs

5. Spectacle magnifier

Typical user	Child or adult with near vision impairment even after treatment or correction of any refractive error
Specific characteristics	Lens or lens system mounted into spectacle frames Enables binocularity when base-in prisms are incorporated, to offer better field of view
Requirements for standard configuration	Lens power: • single-vision lens power range +4D to +24D • single-vision lens with prismatic power for binocular viewing range +4D to +10D Frame: high-grade plastic Solar UV transmittance: UV absorption should be 95% and above close to 400 nm

General design requirements

The magnifier lenses should be lightweight, have a protective coating against scratches, and be impact-resistant. Lenses are preferably aspheric for better image quality without spherical aberrations. The lens mount and body of the magnifier should be made of high-quality, durable material.

Built-in illumination could be an option to provide adequate light to suit the task. The battery compartment of the illuminated magnifiers should allow easy battery changes. Regular and rechargeable battery options should be available (e.g. high-capacity nickel metal hydride batteries). LED or SMD LED bulbs are preferred over incandescent bulbs as they provide a brighter, longer-lasting light. The bulb should be shock-resistant and non-heat-generating.

The magnifier should be ergonomic for use or wear, and the overall design should be user-friendly.

Standards

ISO 11.040.70 Ophthalmic Equipment Including Ophthalmic Implants, Glasses, Contact Lenses and Other Cleaning Products

ISO 15253: 2000 Ophthalmic Optics and Instruments – Optical Devices for Enhancing Low Vision

Environment of use

The product should withstand room temperature.

Lifespan

The product should have a lifespan of at least three years

Accessories and spare parts

The following accessories are required:

- pouches for magnifiers.

Personal remote microphone systems

Name of product

Hearing loops/FM systems

ISO 9999 code

22 18 24 Radio frequency transmission systems

22 18 30 Induction loop devices

Description and intended use

Personal remote microphone systems improve the signal-to-noise ratio (SNR) for children and adults with hearing difficulties to overcome the negative effects of talker distance, ambient noise and reverberation in an environment (e.g. in a school classroom).

General features

The system comprises a wireless transmitting microphone worn by the speaker and personal receiver(s) worn by the listener. The system sends signals directly from the microphone and transmitter to the receiver. The system operates on frequency modulation (FM) or digital modulation (DM).

Inclusion

Radio transmitters with built-in or external microphone

Receivers for compatible hearing aids and cochlear implants

Exclusion

Hardwired microphone/receiver systems

AM, shortwave radio and infrared-based systems

Keywords

Ambient noise, digital modulation (DM), direct audio input (DAI), frequency modulation (FM), induction loop, reverberation, signal-to-noise-ratio (SNR), talker distance, T-coil

Functional requirements

1. Transmitter with microphone

Typical user	Speaker who communicates with a child or adult with compatible hearing aids and cochlear implants in certain environments (e.g. classroom)
Specific characteristics	Worn by speaker
Requirements for standard configuration	Internal or external microphone that allows placement near speaker's mouth or clipped at the chest Operated by rechargeable or disposable battery

2. Receiver with direct audio input (DAI)

Typical user	Child or adult with compatible hearing aid or cochlear implant
Specific characteristics	Plugged into hearing aid or external part of cochlear implant
Requirements for standard configuration	Compatible with transmitter frequency Universal design for behind-the-ear (BTE) hearing aids or cochlear implants with DAI

3. Receiver with induction loop (T-coil)

Typical user	Child or adult with compatible hearing aid or cochlear implant
Specific characteristics	Worn around neck of the user of hearing aid or cochlear implant
Requirements for standard configuration	Compatible with transmitter frequency For behind-the-ear (BTE) hearing aids or cochlear implants with T-coil Loop design with breakaway capabilities

General design requirements

The system should be lightweight, small, wearable and user-friendly. It should be robust and appropriate for use by people of all age groups. The system should operate within regionally authorized frequency bands for the FM system or 2.4–2.5 GHz frequency bands as specified in the industrial, scientific and medical (ISM) radio bands for the DM system. The FM system should be designed to achieve high-frequency (HF) characteristics SNR > 45 dB.

Standards

Standards for wireless communication technologies for potential hazardous effects associated with electromagnetic (non-ionizing) radiation interaction with human tissue.

IEC 62209-2 Ed. 1.0 Human Exposure to Radiofrequency Fields from Handheld and Body-mounted Wireless Communications Devices – Human Models, Instrumentation and Procedures – Part 2: Procedure to Determine the Specific Absorption Rate for Wireless Communication Devices Used in Close Proximity to the Human Body (Frequency Range of 3 MHz to 6 GHz).

Electromagnetic compatibility (EMC) and electrical safety assessments for all electronic equipment including medical devices

IEC 60601-1 Medical Electrical Equipment – General Requirements for Basic Safety and Essential Performance (several parts may apply)

ETSI EN 300 328 Wideband Transmission Systems

Environment of use

The product should function in an ambient temperature range of –20 to +45 °C and relative humidity range of 0% to 80% *(6)*.

Accessories and spare parts

The following accessories should be required:

- transmitters and receiver(s) storage containers.

The following spare parts should be required:

- external microphones
- batteries
- audio shoes for universal receivers.

Other product requirement

The following additional information should be required:

- operating frequency
- battery life for typical use

Portable ramps

Name of product

Portable ramps

ISO 9999 code

18 30 15 Portable ramps

Description and intended use

Portable ramps are moveable sloping surfaces that bridge a gap or difference in levels (over a maximum of two steps). They are intended for children and adults who use wheeled mobility devices (e.g. a wheelchair or rollator) to go up and down one or two steps to access a home or other building, or to access a vehicle or public transport.

General features

A portable ramp is a moveable, flat, non-slip, supporting surface. When used to bridge two levels, it is tilted at an angle with one end higher than the other (inclined plane). Ramp ends are shaped to prevent the ramp from sliding during use and angled for smooth transition on to and off the ramp. Edges are raised for the safety of the user. A portable ramp may be fitted with carrying handles or supplied with a carrying bag for transportation.

Inclusion

Wide-platform portable ramps

Twin-track portable ramps

Exclusion

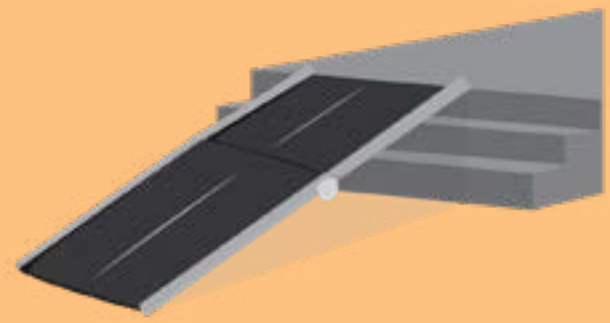
Permanent ramps

Keywords

Access ramp, accessibility, bridge, inclined plane surface, non-slip, ramp

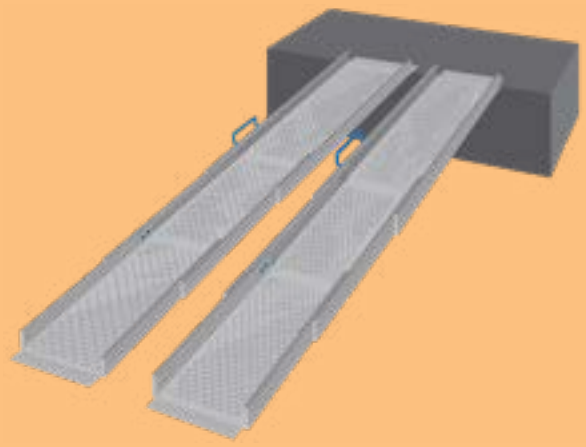
Functional requirements

1. Wide-platform portable ramp



Typical user	Child or adult with difficulties going up or down steps or who uses mobility products
Specific characteristics	One wide platform Can be folded for transportation
Requirements for standard configuration	Platform made from aluminium, fibreglass or graphite fibre, with non-slip surface made from textured aluminium or rubber Length 100–350 cm Width 72–107 cm Minimum load 270 kg Must have raised edges of height 2–4 cm Fitted with carrying handle

2. Twin track portable ramp (two driving tracks)



Typical user	Child or adult who uses a wheelchair, stroller or other three- or four-wheeled mobility product
Specific characteristics	Two separate tracks Can collapse telescopically for transportation

Requirements for standard configuration	Platform made from aluminium, fibreglass or graphite fibre, with non-slip surface using deck grip, textured aluminium or rubber Length 100–350 cm Minimum width of each track 15.5 cm Minimum load 175 kg Must have raised edges of height 2–4 cm Fitted with carrying handle

General design requirements

The portable ramp should be made with materials that are waterproof, strong, durable and lightweight. Its surface should be non-slip, even in wet conditions. It should be easy to set up and move. It should be safe for repeated use considering the weight of the user, the user's assistive product(s) (e.g. wheelchair) and the carer or assistant (as needed). There should be no risk of trapping fingers when operating the ramp's folding or telescopic mechanism.

The portable ramp should be foldable or adjustable for transportation. It should not unfold or move during transport. It should be possible to position and install the ramp without using tools.

Transportation length should be a maximum of 150 cm to be easily transported in a standard car.

Standards

None

Size and weight

Information about overall width, height, length and weight of portable ramps, including usable surface width and length, and height of side edges, should be required

Dimensions in operating and folded modes should be provided

Environment of use

The product should withstand various weather conditions, including rain, dust, snow, ice and sleet, and be appropriate for local temperatures. The product should withstand an ambient temperature range of –30 to +50 °C and a relative humidity range of 15% to 100%.

Lifespan

The product should have a lifespan of at least three years[12]

Accessories and spare parts

The following accessories should be required:

- carrying bags.

12 Friction of the surface of the ramps should be considered.

Ready-to-wear spectacles for near vision (reading glasses)

Name of product

Spectacles; low vision, short distance, long distance, filters and protection

ISO 9999 code

22 03 06 Spectacles and contact lenses

Description and intended use

Ready-to-wear spectacles for near vision are plus-powered lenses mounted into a spectacle frame. They are commonly known as reading glasses. They are intended for use by adults with presbyopia, helping them to visually focus on near tasks such as reading, writing, sewing or cooking.

General features

Reading glasses comprise lenses with a power in the range +0.75D to +4.00D. Left and right lenses have the same plus power and are single-vision lenses (distribute focus evenly across the lens surface). Reading glasses are available in different frame sizes and styles, with no adjustability or customizing.

Inclusion

Near-vision ready-to-wear spectacles (reading glasses)

Exclusion

All other types of spectacles, including spectacles for people with myopia, hyperopia, astigmatism and low vision

Keywords

Visual impairment, presbyopia, near tasks

Functional requirements

1. Near vision ready-to-wear spectacles	
	
Typical user	Adult with presbyopia needing plus-powered lenses for near-vision tasks such as reading, writing, sewing or cooking
Specific characteristics	Full-field and half-eye frames
Requirements for standard configuration	Lens power range +0.75D to +4D with 0.25D interval Lens material: plastic or glass Solar UV transmittance: UV absorption should be 95% and above close to 400 nm

General design requirements

The frame of the reading glasses should be durable and lightweight. The lens should be impact- and scratch-resistant. The lens diameter should depend on the lens design and frame size.

Standards

ISO 16034:2002 Ophthalmic Optics – Specifications for Single Vision Ready-to-wear Near-vision Spectacles

EN 14139:2002 Ophthalmic Optics – Specifications for Single Vision Ready-to-wear Near-vision Spectacles

US ANSI standard: Z80.31–2017 Specifications for Ready-to-wear Near-vision Spectacles

Size and weight

The supplier should provide the following information:

- frame dimensions, including eye size (lens width), bridge width, temple (arm) length and lens height
- optical centration distance
- overall weight

Accessories and spare parts

The following accessories should be supplied as standards:

- individual box, case or pouch for each pair of reading glasses;
- cleaning cloth for each pair of reading glasses.

Other product requirements

The lens power should be labelled on each pair of glasses

The following additional information should also be provided by the supplier:

- Lens type and material
- Lens coating
- Frame material and colour
- Frame colour

Rollators

Name of product

Rollators

ISO 9999 code

12 06 06 Rollators

Description and intended use

Rollators are walking aids that can be moved by pushing or pulling. They are intended for use by children and adults to support balance or weightbearing through the leg(s).

General features

A rollator has a frame with built-in handgrips, three or four wheels, and brakes for parking and slowing down. A rollator may have a seat or basket and may be foldable.

Inclusion

Regular, heavy-duty and small four-wheeled rollators

Posterior or reverse rollators (also called posterior walkers)

Exclusion

Walking frames with two tips and two wheels

Keywords

Anterior walker, posterior/reverse walker, walking aid

Functional requirements

1. Rollator for indoor and limited outdoor use	
	
Typical user	Short- or long-term use for adult who is frail or needs support to balance or bear weight through their legs
Specific characteristics	Pushed in front of user Frame: • folding or rigid • height-adjustable handgrips • four wheels Height-adjustment mechanism: • telescopic • quick-release Handgrips: • moulded grips
Requirements for standard configuration	Two handgrips Four wheels with diameter 100 mm Driving and parking brakes Fold-down seat May include basket Size range to fit all adults Bariatric range for users over 120 kg

2. Rollator for outdoor use

Typical user	As above
Specific characteristics	Pushed in front of user Frame: • folding or rigid • height-adjustable handgrips • Four large wheels Height-adjustment mechanism: • telescopic • quick-release Handgrips: • moulded grips
Requirements for standard configuration	Two handgrips Four large wheels with diameter from 200 mm; or two large wheels with diameter from 200 mm and two small wheels with diameter from 100 mm Driving and parking brakes Fold-down seat May include basket Size range to fit all adults Bariatric range for users over 120 kg

3. Posterior rollator for indoor use

Typical user	Child or young adult, commonly with a neurological disorder, who needs support to walk short distances indoors
Specific characteristics	Pulled from behind by user Can only move forwards (one-directional) Frame: • folding or rigid • height-adjustable • four wheels Height-adjustment mechanism: • telescopic • quick-release Handgrips: • moulded grips
Requirements for standard configuration	Two handgrips Four wheels with diameter from 100 mm; one-directional rear wheels Brakes, directional and reversing block

General design requirements

Easy to operate and adjust. Strong, durable, low deformation risk, high abrasion resistance, and lightweight material used.

Parts (including wheels) must be replaceable. Made of materials that withstand the environment of use.

Standards

ISO 11199–2:2006 Walking Aids Manipulated by Both Arms – Requirements and Test Methods – Part 2: Rollators (or more recent version or equivalent)

Size and weight

The following product dimensions should be provided:

- overall length
- overall width
- width between handles
- overall height and adjustment range(s)
- maximum user weight
- unit weight
- dimensions in operating and folding modes

Environment of use

The rollator should withstand heavy use on local terrain and in weather conditions such as rain, dust, snow, ice and sleet. A variety of tyre types in different diameters should be made available, suitable to the specific environmental needs of each country.

Lifespan

At least five years, provided the rollator is maintained and used correctly in its intended environment, in line with the product instructions; this period may be adjusted based on the influence of local conditions and context

Accessories and spare parts

The following spare parts are required:

- height-adjustment mechanisms;
- individual components as spare parts.

The following optional accessories can be required:

- seats;
- baskets;
- forearm supports (for posterior rollators);
- wheels for different environmental conditions (for rollators).

Other product requirements

Product should be completely assembled

Talking/touching watches

Name of product

Talking/touching watches

ISO 9999 code

22 27 12 Clocks and timepieces

Description and intended use

Talking/touching watches are timekeeping devices that give the time verbally or enable users to know the time by touching the watch face. They are intended for use by children and adults who are blind or deaf-blind or who have low vision.

General features

A talking/touching watch is battery-operated (e.g. one or two lithium batteries) that can be recharged via USB or a solar panel on the dial. It may also have additional characteristics such as vibration beeps or other embossed tactile features. Talking/touching watches are available in atomic and quartz versions.

Inclusion

Talking watches

Touching watches

Exclusion

Talking clocks

Conventional watches without voice generation and Braille features

Touchscreen watches

Keywords

Blind, deaf-blind, low vision, personal organization, time management

Functional requirements

1. Talking watch (atomic or quartz)

Typical user	Child or adult with blindness or low vision
Specific characteristics	Voice announcement of time activated by pushing button on watch
Requirements for standard configuration	Analogue/digital dial that tells time in 12- or 24-hour format Large-dial/LED light for low vision and button for self-illumination Has night light Push-button to active voice that reads out time Possibility for hourly alarm setting and date/month/year announcement (calendar announcement/talking calendar) Plastic/stainless-steel body

2. Touching watch (atomic or quartz)

Typical user	Child or adult who is blind or deaf-blind
Specific characteristics	Time expressed in Braille numbers or in analogue format on watch face User finds out time by touching watch face

Requirements for standard configuration	Analogue face with hour and minute hands or Braille numbers embossed 12-hour format Possibility for hourly alarm setting and date/year announcement Large dial Braille or raised tactile markings Vibration function

General design requirements

Talking/touching watches should be easy to use, be water-resistant, have automatic or manual daylight saving and international time zone adjustment mechanisms, and have power-saving mode. Touching watches should be made from durable materials and have sturdy hour and minute hands resistant to damage from frequent touching.

Standards

ISO standard catalogue on watches ISO ICS39.040.10

Size and weight

The radius of the dial for different sizes of watch (male, female, child) should be provided

For touching watches, the height of the tactile dot and numbers should be mentioned

The size and weight of the case should be given

Environment of use

Talking/touching watches should be able to absorb shock.

Accessories and spare parts

The following accessories are required:

- batteries (lithium)
- microfibre cleaning cloths
- watch cases.

Therapeutic footwear

Name of product

Therapeutic footwear

ISO 9999 code

09 03 42 Shoes and boots

09 06 21 Assistive products for heel protection, toe protection or foot protection

Description and intended use

Therapeutic footwear takes the pressure off problem areas and prevents secondary problems that may lead to amputation. It is intended for use by children and adults with neuropathic or diabetic feet or ankles.

General features

Therapeutic footwear is a pair of shoes or sandals with a removable insole that adds extra depth and cushioning, or footwear that allows the use of custom-made insoles. They usually have adjustable closures to ensure a snug-fitting upper to hold the foot in place on the insole preventing restriction and shear forces on the skin; wide and deep toe boxes; a wide heel base; a cuff around the ankle with rolled seams to prevent friction; built-in forefoot rocker; rocker bottom soles; and adjustable straps or shoelaces.

Inclusion

Prefabricated therapeutic footwear

Exclusion

Custom-made orthopaedic shoes and sandals

Keywords

Diabetic footwear, neuropathic footwear, therapeutic footwear

Functional requirements

1. Therapeutic footwear

Typical user	Child or adult with diabetic or neuropathic at-risk feet, or foot or ankle deformities, who needs shoes that protect and support feet structure or to take pressure off areas with existing or healed ulcers
Specific characteristics	Prefabricated shoes or sandals with removable insoles to allow insertion of custom-made alternative to contain deformed or at-risk feet
Requirements for standard configuration	Shape: broad deep toe boxes, wide in midfoot, in-flared (forefoot wider on the inside) and out-flared (forefoot wider on the outside), extra depth to accommodate insertion of orthotic or insole Upper design: natural, synthetic materials or materials from renewable sources Types of closure: laces, hook-and-loop fastener, buckles or combination Heel design: wide heel base, either closed with heel counter or open a width-adjustable backstrap Toe design: may be closed (fully covering toes) or open (leaving toes uncovered); in closed-toe design, other features include vamp/shoe tongue, which provides additional adjustability and protection for foot Outsole design: built-in forefoot rocker sole or toe-spring to assist in toe-off Sizes: range of child and adult sizes to meet local population needs Extra depth or removable insole of at least 5 mm thickness Footwear to be supplied complete with fasteners and insoles

General design requirements

Therapeutic footwear must fit properly and fasten snuggly to prevent movement of the foot. It must provide support and accommodate the shape of the foot and any bony deformities and orthotics or insoles. Footwear should provide comfort and must be easy to put on and take off.

Upper materials should be breathable, not allow moisture to be trapped, be fast drying and be available in colours appropriate to the region's climate and conditions. Shoe uppers should be easily adjustable for people with poor or weak hand function and allow evenly distributed pressure.

The cuff or topline around the ankle should be well-fitting and have rolled seams to prevent friction and blistering (particularly over the Achilles tendon. It can extend over the malleoli (bony projections on either side of the ankle) to add medial and lateral stability if needed.

Extra depth/removable insoles allow for the insertion of custom-made orthotics/insoles that provide good heel control to ensure sideways stability.

Insoles should redistribute pressure, provide support and cushioning, and be made of materials that are durable, mouldable and washable.

The outer sole and soling materials should be appropriate for the local climate and terrain, be durable and lightweight, provide support and control/traction, and be repaired easily with adhesives.

Standards

None

Size and weight

Weight, size, width and shape of the footwear should be specified

Environment of use

The product should be appropriate for the local terrain (e.g. mud, rock), conditions (e.g. rain, snow, ice, sleet), and local temperature and humidity ranges.

Lifespan

At least two years, provided the product is maintained and used correctly in its intended environment, in line with the product instructions; this period may be adjusted based on the environment, use, and size and weight of the person and existing foot deformity

Toilet and shower chairs

Name of product

Chairs for shower/bath/toilet

ISO 9999 code

09 12 03 Commode chairs

09 12 12 Raised toilet seats mounted on frame

09 33 07 Shower chairs with and without wheels

Description and intended use

Toilet and shower chairs provide solutions for children and adults who find it difficult or impossible to use a standard toilet or shower. Users may need support to transfer on or off the chair and when washing and drying themselves.

General features

A toilet or shower chair comprises a chair or stool with a seat, and is either static or mobile with wheels or castors. It may have armrests or footrests.

Inclusion

Static toilet or shower chairs or stools

Mobile shower commode chairs

Foldable mobile shower commode chairs

Exclusion

Tub transfer benches

Bathtub seats/benches

Toilet seats and seat inserts

Keywords

Commode, commode chair with wheels, over-toilet shower commode, sanichair, shower chair, toilet wheelchair

Functional requirements

1. Static toilet chair

Typical user	Child or adult who cannot access or safely use their existing toilet
Specific characteristics	Static chair with backrest that can be placed over toilet or used away from toilet with removable collection bucket
Requirements for standard configuration	Fixed or removable backrest Seat with aperture Removeable collection bucket (pan) Height-adjustable legs fitted with non-slip tips; minimum height should be sufficient to clear the toilet it will be placed over (for pedestal toilet) Sizes to fit children and adults Bariatric range for users over 120 kg May include toilet splash guard and fixed or removeable armrests

2. Static shower stool

Typical user	Child or adult unable to stand safely or at all to wash themselves, but with good sitting balance

Specific characteristics	Static stool without backrest
Requirements for standard configuration	Complete seat or with aperture Height-adjustable legs fitted with non-slip tips Sizes to fit children and adults Bariatric range for users over 120 kg May include fixed or removable armrests

3. Static shower chair

Typical user	Child or adult unable to stand safely or at all to wash themselves, and who needs backrest support to sit safely
Specific characteristics	Static chair with backrest
Requirements for standard configuration	Fixed backrest Complete seat or with aperture Height-adjustable legs fitted with non-slip tips Sizes to fit children and adults Bariatric range for users over 120 kg May include fixed or removable armrests

4. Attendant-propelled mobile toilet and shower chair

Typical user	Child or adult who cannot access or safely use their existing toilet and wash area; who requires assistance with transferring and mobility; and who prefers to move in their shower or toilet chair to access wash areas
Specific characteristics	Chair with backrest and wheels to be pushed by carer
Requirements for standard configuration	Fixed backrest with push-handles Seat with aperture Removeable collection bucket (pan) Removable armrests Height-adjustable, flip-up or removable footrests Four swivel castors (at least two lockable); or two rear wheels and two front castors Sizes to fit children and adults Bariatric range for users over 120 kg May include commode with tilt-in-space option (minimum 0–35 °); height-adjustable headrest; or pelvis or trunk straps and supports

5. Self-propelled mobile toilet and shower chair

Typical user	Child or adult who cannot access or safely use their existing toilet and wash area; but who is able to and prefers to self-propel in their shower or toilet chair to access wash areas
Specific characteristics	Chair with backrest and large rear wheels to be propelled by user
Requirements for standard configuration	Fixed backrest with push-handles Seat with aperture Removeable collection receptacle (pan) Removable armrests Height-adjustable, flip-up or removable footrests Two rear wheels with brakes and two front castors Sizes to fit children and adults Bariatric range for users over 120 kg May include commode with tilt-in-space option (minimum 0–35 °); height-adjustable headrest; or pelvis or trunk straps and supports

6. Folding toilet or shower commode chair

Typical user	Child or adult who cannot access or safely use existing toilet and wash areas; who needs backrest support; and who needs a folding chair either to save space or to allow for travel with the device
Specific characteristics	Lightweight chair for toilet and shower Can be folded for transportation
Requirements for standard configuration	Chair with folding or collapsible frame Chair with backrest and push-handles Seat with aperture Removeable collection receptacle (pan) Removable armrests Height-adjustable, flip-up or removable footrests Two large rear wheels with brakes for self-propelling and two front castors Sizes to fit children and adults Bariatric range for users over 120 kg

General design requirements

The chair or stool should be made from a material that is rustproof, waterproof and contamination-resistant, and with a smooth finish to enable easy cleaning and to prevent injury to the bare skin. Each product should have sufficient strength and durability for daily sustained use. Tips, castors and wheels must be replaceable.

For self-propelled chairs, the large rear wheels need to be in an optimal position for the user to reach.

Standards

ISO 17966:2016 Assistive Products for Personal Hygiene that Support Users – Requirements and Test Methods

Size and weight

Information about overall width, width between arms, seat dimension, floor-to-seat height, weight of chair, and safe working load and product capacity of chair should be provided

If applicable, dimensions in operating and folded modes should be provided

Where applicable, height-adjustment ranges should be provided

Environment of use

The product should withstand conditions in a domestic bathroom, such as warm water and humidity.

Accessories and spare parts

The following accessories should be procured if not automatically provided with the product:

- seats
- removable buckets
- splash guards.

Walking frames

Name of product

Walking frames/walkers

ISO 9999 code

12 06 03 Walking frames

Description and intended use

Walking frames are walking aids with four shafts or with two shafts and two small wheels (castors), which are lifted or pushed by the user. They are intended for use by children and adults to support balance or weightbearing through the legs.

General features

A walking frame has two handgrips and four height-adjustable shafts that end in either four tips (ferrules) or two tips and two wheels. A variety of tips and wheels are available for different products and terrains.

Inclusion

Walking frames with four tips

Walking frames with two tips and two wheels

Exclusion

Rollators

Reciprocal walking frames

Keywords

Walker, walker with front wheels

Functional requirements

1. Walking frame with four tips

Typical user	Short- or long-term use for child or adult who needs support to balance or bear weight through their legs
Specific characteristics	Frame: • folding or rigid • four height-adjustable shafts Height-adjustment mechanism: • telescopic • quick-release Handgrips: • two moulded grips Tips: • four removable or replaceable tips
Requirements for standard configuration	Complete assembly with tips for user's environment Tips securely fitted, non-slip, and replaceable or interchangeable Three to four different sizes to fit children and adults (e.g. child, youth, adult, tall adult) Bariatric range for users over 120 kg

2. Walking frame with two tips and two wheels

Typical user	Short- or long-term use for child or adult who needs support to balance or bear weight through their legs
Specific characteristics	Frame: • folding or rigid • four height-adjustable shafts Height-adjustment mechanism: • telescopic • quick-release Handgrips: • two moulded grips Tips: • two fitted with wheels and two fitted with tips
Requirements for standard configuration	Complete assembly with tips for user's environment Tips securely fitted, non-slip, and replaceable or interchangeable Wheels do not swivel and only allow forwards and backwards movement Three to four different sizes to fit children and adults (e.g. child, youth, adult, tall adult) Bariatric range for users over 120 kg

General design requirements

The walking frame should be easy to operate and adjust, be strong and durable, have low deformation risk and high abrasion resistance, be made from lightweight material, and withstand the environment of use. Parts of the walking frame must be replaceable (including wheels).

Standards

ISO 11199–1:1999 Walking aids Manipulated by Both Arms – Requirements and Test Methods – Part 1: Walking Frames

ISO 24415–1 Tips for assistive products for walking – Requirements and test methods – Part 1: Friction of tips

ISO 24415–2:2011: Tips for assistive products for walking – requirements and test methods – Part 2: durability of tips of crutches (excludes tips manufactured for special purposes such as ice and snow)

EN 1985 Walking aids – General requirements and test methods or equivalent

Size and weight

Product dimensions to be provided:

- overall length
- overall width
- width between handgrips
- overall height and adjustment range(s)
- maximum user weight
- unit weight
- if applicable, dimensions in operating and folding modes

Environment of use

The walking frame should withstand heavy use on local terrain and weather conditions (e.g. rain, dust, snow, ice, sleet).[13]

Accessories and spare parts

The following spare parts are required:

- tips for different environments;
- non-swivel wheels for different environments;
- handgrips;
- height-adjustment mechanisms;
- individual components as spare parts.

13 This will affect the materials used in the shaft and the specifications for the tips and wheels required.

Walking sticks, tripods and quadripods

Name of product

Canes/sticks

ISO 9999 code

12 03 03 Walking sticks and canes

12 03 16 Multi-tip walking sticks and canes

Description and intended use

Walking sticks, tripods and quadripods are walking aids with a handgrip and single height-adjustable shaft with one, three or four ends fitted with tips (ferrules). Walking sticks are intended for use by children and adults to support balance or weightbearing through the leg(s). Tripods or quadripods may be used by children and adults who need additional support.

General features

A walking stick has a straight or offset handle with an ergonomically shaped handgrip and a height-adjustable shaft. A tripod has three ends and a quadripod has four ends. Each end is fitted with a tip. A variety of tips are available for different products and terrains.

Inclusion

Walking sticks

Tripods/quadripods

Exclusion

Forearm, elbow and axilla crutches

Keywords

Cane, ferrules, tips, walking aids

Functional requirements

1. Walking stick

Typical user	Short- or long-term use for child or adult who needs support to balance or bear weight through their leg(s)
Specific characteristics	Handgrip: • flat or ergonomically moulded • straight or offset Shaft: • height-adjustable • folding (optional) End: • single end • fitted with tip Height-adjustment mechanism: • telescopic • quick-release
Requirements for standard configuration	Complete assembly with appropriate tip for user's environment Tips securely fitted, non-slip, and replaceable or interchangeable Three or four different sizes to fit children and adults (e.g. child, youth, adult, tall adult)

2. Tripod/quadripod

Typical user	Short- or long-term use for child or adult who needs support to balance or bear weight through their leg(s) For use on level terrain only
Specific characteristics	Handgrip: • flat or ergonomically moulded • offset Height-adjustable shaft Ends: • three or four ends • ends offset • narrow or wide base • fitted with ferrule or tip Height-adjustment mechanism: • telescopic • quick-release
Requirements for standard configuration	Complete assembly with appropriate tips for user's environment Tips securely fitted, non-slip, and replaceable or interchangeable Shaft: height-adjustable via clip or push-button; pin should be made from stainless-steel Three or four different sizes to fit children and adults (e.g. child, youth, adult, tall adult)

General design requirements

The walking stick, tripod or quadripod should be easy to operate, strong and durable, have low deformation risk and high abrasion resistance, and be made from lightweight materials. Parts of the walking stick, tripod or quadripod must be replaceable.

Standards

ISO 11334–4:1999 Walking Aids Manipulated by One Arm – Requirements and Test Methods – Part 4: Walking Sticks with Three or More Legs

ISO 11334–1:2007 Walking Aids Manipulated by One Arm with Three or More Legs

ISO 24415–1 Tips for Assistive Products for Walking – Requirements and Test Methods – Part 1: Friction of Tips

ISO 24415–2:2011 Tips for Assistive Products for Walking – Requirements and Test Methods – Part 2: Durability of Tips of Crutches (excludes tips manufactured for special purposes such as ice and snow)

CNS 15191 (2010)/BS 5181 (1975)/ CPSA 0073 (1996) Static Loading and Junction Strength Test for Wooden Walking Sticks

CNS 15192 (2010) Adjustable Metal Walking Sticks

EN 1985 Walking Aids – General Requirements and Test Methods or Equivalent

Size and weight

The following information should be provided for all products across all size ranges as specified:

- overall dimensions (length, minimum and maximum handgrip height)
- height-adjustment range(s)
- maximum user weight
- unit weight
- dimensions in operating and folded modes (for folding walking sticks)

Environment of use

The walking stick, tripod or quadripod should be appropriate for local terrain and conditions (e.g. sand, mud, rocky ground, rain, snow, ice, sleet).[14]

Accessories and spare parts

The following spare parts are required:

- tips for different environmental conditions;
- height-adjustment mechanisms;
- individual components as spare parts.

14 The conditions likely to be encountered will affect the materials used in the shaft and the tips required.

Wheelchair seat cushions

Name of product

Pressure relief cushions

ISO 9999 code

04 33 03 Seat cushions and underlays for tissue integrity

Description and intended use

Wheelchair cushions provide postural support, redistribute pressure to protect skin and soft tissue, improve sitting comfort, and reduce the heat and moisture generated when the user is sitting on the cushion. Wheelchair cushions are intended for children and adults who use wheelchairs.

General features

A wheelchair cushion comprises the components with the features described below.

There is a pre-seat bone (ischial) shelf (support) at the front of the cushion to prevent sliding. Side supports create a well (pelvic contour) to offload pressure under the seat bones and load the full length of the thighs to optimize pressure distribution. The contour height of the well varies according to the level of postural support and offloading for pressure redistribution. This feature may be preshaped and visible or preshaped in the function of the base with the cushion top appearing flat.

The thigh support area may include inside (medial) or outside (lateral) thigh supports as integral or optional components.

In cushion designs with a base and top layer, the top layer of the cushion varies in thickness according to the cushion function and contributes to the level of immersion (sinking into) and envelopment (conforming to the shape).

The cushion may be constructed in the following forms:

- firm, non-deforming, preshaped base (base with seat bone well), with or without the top layer;
- firm, non-deforming, preshaped base without the top layer, where variances in support capability of different layers or sections will create pre-seat bone well offloading, immersion and envelopment;

- no dedicated, structural base, where the design combined with placement of multiple sections of fluid volume or variances in support capability of different layers or sections to create offloading, immersion and envelopment.

The base may be flat or curved and may have an integral component including inside (medial) or outside (lateral) thigh supports.

A thin rigid board provides rigidity for the cushion with a flat base to be used on a sling seat.

A cover follows the contours of the cushion and body when the user is seated without changing the pressure-distribution properties of the cushion.

Inclusion

Comfort cushions for users with no or low risk of pressure injuries

Postural support cushions for users with low risk of pressure injuries

Pressure redistribution wheelchair seat cushions for users at risk of pressure injuries

Exclusion

Cushions that do not provide immersion or offloading to redistribute pressure

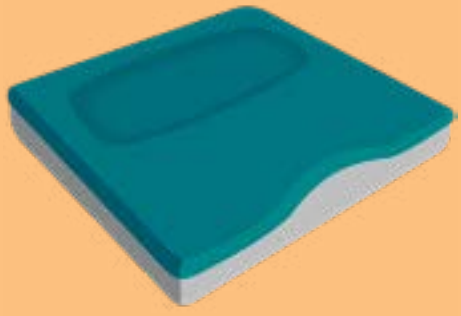
Keywords

Comfort cushion, contoured cushion, moulded cushion, pressure relief/redistribution, rigid seat cushion, seating position, slung seat cushion, wheelchair cushion

Functional requirements

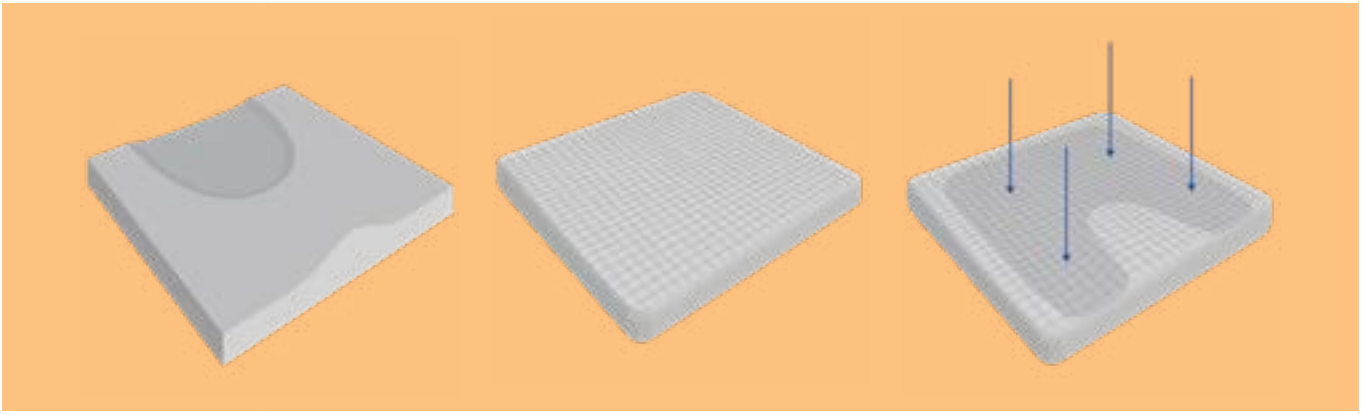
1. Comfort cushion for users with no or low risk of pressure injuries

1.1 Contoured cushion with separate top layer



Typical user	Child or adult who uses a wheelchair; who requires comfort; but who is not at risk of pressure injuries and does not need support to maintain stability or aligned posture
Specific characteristics	Constructed with firm, non-deforming pre-contoured base with shallow-depth seat bone well and thin separate top layer (excludes air, gel and fluid pads)
Requirements for standard configuration	Cushion design: • overall height approximately 40–45 mm • allows limited offloading or immersion and envelopment less than 35 mm Base: • flat base for wheelchairs with rigid seats • curved base for wheelchairs with sling seats to match sling seat shape or supplied with rigid seat insert or sling filler pad if flat-based Size range: • should match wheelchairs provided • available in child, adult and bariatric size and weight ranges • seat width range in 25–50 mm incremental or adjustable options • available in different lengths or can be cut to size Supplied with cover that meets general design requirements; for users with incontinence, a water-resistant cover or lining to protect cushion should be supplied

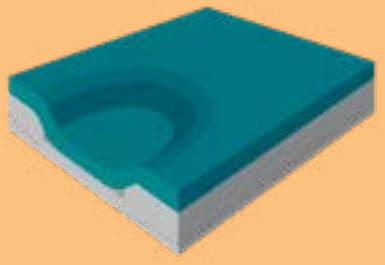
1.2 Contoured cushion without top layer



Typical user	Child or adult who uses a wheelchair and who requires comfort; and who is not at risk of pressure injuries and does not need support to maintain stability or aligned posture
Specific characteristics	Constructed with firm, non-deforming pre-contoured base with shallow-depth seat bone well; or with flat or pre-contoured base with deforming properties, where variations in support from different layers or sections create moderate or partial offloading or immersion
Requirements for standard configuration	Cushion design: • overall height approximately 40–45 mm • allows limited offloading or immersion and envelopment less than 35 mm Base: • flat base for wheelchairs with rigid seats • curved base for wheelchairs with sling seats to match sling seat shape or supplied with rigid seat insert or sling filler pad if flat-based Size range: • should match wheelchairs provided • available in child, adult and bariatric size and weight ranges • seat width range in 25–50 mm incremental or adjustable options • available in different lengths or can be cut to size Supplied with cover that meets general design requirements; for users with incontinence, a water-resistant cover or lining to protect cushion should be supplied

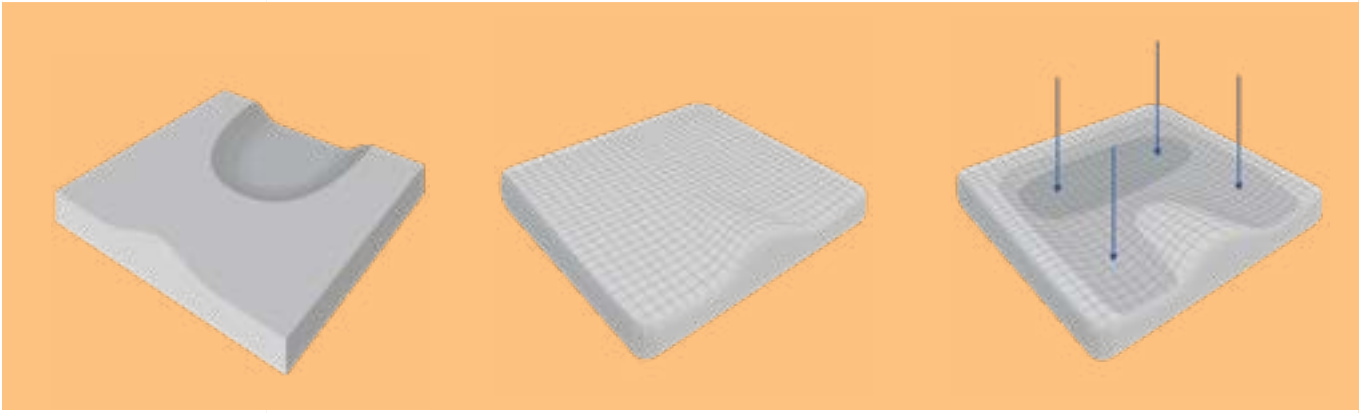
2. Postural-support cushion for users with low risk of pressure injuries

2.1 Contoured cushion with separate top layer



Typical user	Child or adult who uses a wheelchair; who requires comfort and good support to maintain stability and an aligned posture; and who is not at risk, or is at low risk, of pressure injuries
Specific characteristics	Constructed with firm, non-deforming pre-contoured base with medium-depth seat bone well and thin top layer (excludes air, gel and fluid pads) Can be adjusted or modified to optimize posture support for: • height and depth pre-seat bone well • thigh support • postural deviations of pelvis, hips and thighs
Requirements for standard configuration	Cushion design: • overall height approximately 45–60 mm • allows limited offloading or immersion and envelopment less than 35 mm Base: • flat base for wheelchairs with rigid seats • curved base for wheelchairs with sling seats to match sling seat shape or supplied with rigid seat insert or sling filler pad if flat-based Size range: • should match wheelchair provided with cushion • available in child, adult and bariatric size and weight ranges • seat width range 25–50 mm incremental options or adjustable • available in different lengths or can be cut to size Supplied with cover that meets general design requirements; for users with incontinence, a water-resistant cover or lining to protect cushion should be supplied Optional postural-support options for thighs, such as wedge (raised seat front) or inside or outside thigh supports, either as separate supports or integrated into cushion

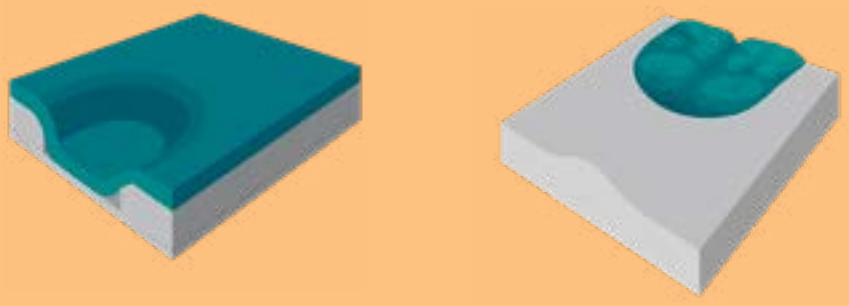
2.2 Contoured cushion without top layer



Typical user	Child or adult who uses a wheelchair; who requires comfort and good support to maintain stability and aligned posture; and who is not at risk, or is at low risk, of pressure injuries
Specific characteristics	Constructed with firm, non-deforming, pre-contoured base with medium-depth seat bone well; or with flat or pre-contoured base with deforming properties, where variations in support from different layers or sections create moderate or partial offloading or immersion
Requirements for standard configuration	Cushion design: • overall height approximately 45–60 mm • allows limited offloading or immersion and envelopment less than 35 mm Base: • flat base for wheelchairs with rigid seats • curved base for wheelchairs with sling seats to match sling seat shape or supplied with rigid seat insert or sling filler pad if flat-based Size range: • should match wheelchair provided • available in child, adult and bariatric size and weight ranges • seat width range 25–50 mm incremental or adjustable • available in different lengths or can be cut to size Supplied with cover that meets general design requirements; for users with incontinence, a water-resistant cover or lining to protect cushion should be supplied Optional postural-support options for thighs, such as wedge (raised seat front) or inside or outside thigh supports, either as separate supports or integrated into cushion

3. Pressure-redistribution wheelchair seat cushion for users at risk of pressure injuries (with moderate/partial immersion and envelopment features)

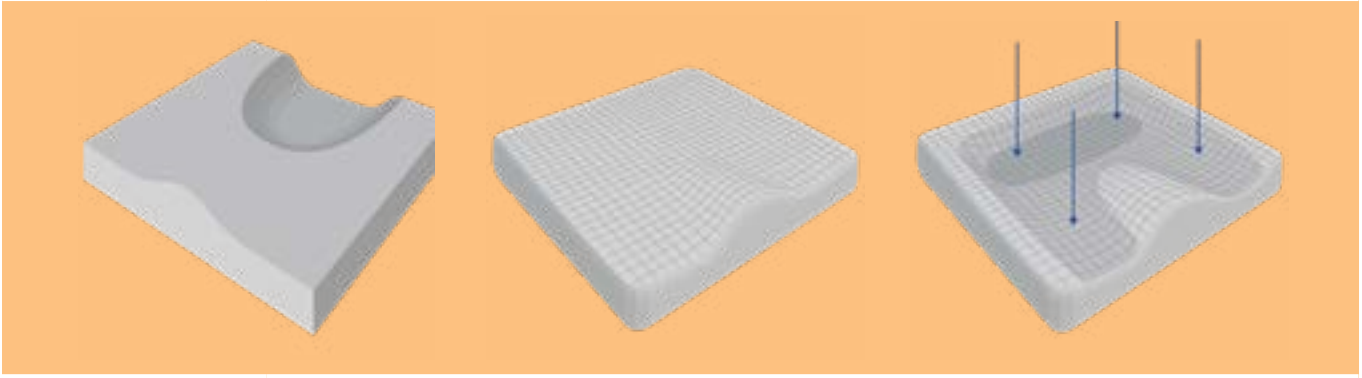
3.1 Contoured cushion with separate top layer or seat bone well pad



Typical user	Child or adult who uses a wheelchair; who is at risk of pressure injuries; and who needs good support to maintain stability and aligned posture
Specific characteristics	Constructed with firm, non-deforming, pre-contoured base with medium-depth seat bone well and separate thick foam top layer or separate removable or medium-volume air-, gel- or fluid-filled seat bone well (pelvic contour) pad Pad may be integrated into top layer Can be adjusted or modified to optimize posture support for: • height and depth of pre-seat bone well • thigh support • postural deviations of pelvis, hips or thighs
Requirements for standard configuration	Cushion design: • overall height approximately 50–70 mm • allows moderate or partial offloading or immersion and envelopment 35–45 mm Base: • flat base for wheelchairs with rigid seats • curved base for wheelchairs with sling seats to match sling seat shape or supplied with rigid seat insert or sling filler pad if flat-based Size range: • should match wheelchairs provided • available in child, adult and bariatric size and weight ranges • seat width range in 25–50 mm incremental options or adjustable • available in different lengths or can be cut to size Supplied with cover that meets general design requirements; for users with incontinence, a water-resistant cover or lining to protect cushion should be supplied Optional postural-support options for thighs, such as wedge (raised seat front) or inside or outside thigh supports, either as separate supports or integrated into cushion

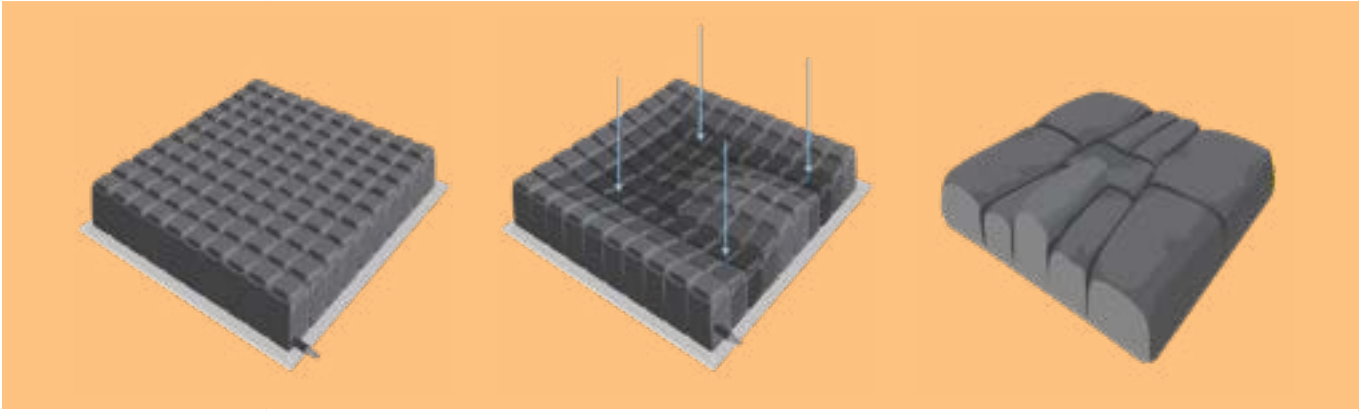
	Accessories: • inflation pump for adjustable air pads • emergency patch kit for air, gel and fluid pads

3.2 Contoured cushion without top layer



Typical user	Child or adult who uses a wheelchair; who is at risk of pressure injuries; and who needs good support to maintain stability and aligned posture
Specific characteristics	Constructed with firm, non-deforming, pre-contoured base with medium-depth seat bone well; or with base with deforming properties, where variations in support from different layers or sections create moderate or partial offloading or immersion and envelopment
Requirements for standard configuration	Cushion design: • overall height approximately 50–70 mm • allows moderate or partial offloading or immersion (sinking into) and envelopment (conforming to shape) 35–45 mm Base: • flat base for wheelchairs with rigid seats • curved base for wheelchairs with sling seats to match sling seat shape or supplied with rigid seat insert or sling filler pad if flat-based Size range: • should match wheelchairs provided • available in child, adult and bariatric size and weight ranges • seat width range in 25–50 mm incremental options or adjustable • available in different lengths or can be cut to size Supplied with cover that meets general design requirements; for users with incontinence, a water-resistant cover or lining to protect cushion should be supplied Optional: postural-support options for thighs, such as wedge (raised seat front) or inside or outside thigh supports, either as separate supports or integrated into cushion

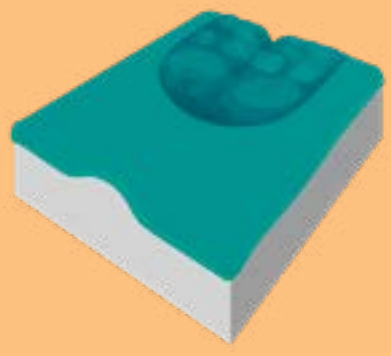
3.3 Cushion without dedicated structural base with multiple sections



Typical user	Child or adult who uses a wheelchair; who is at risk of pressure injuries; and who needs good support to maintain stability and aligned posture
Specific characteristics	Constructed without structural dedicated base but with multiple sections Placement of sections and manipulating air, gel and fluid volume and pressure create moderate or partial offloading, immersion and envelopment Air, gel or fluid volume can be manipulated in different sections by removing or adding cells or changing air, gel or fluid volume or pressure to accommodate small pelvis and hip postural deviations
Requirements for standard configuration	Cushion design: • overall height approximately 50–70 mm • allows moderate or partial offloading or immersion (sinking into) and envelopment (conforming to shape) 35–45 mm Size range: • should match wheelchairs provided • available in child, adult and bariatric size and weight ranges • seat width range in 25–50 mm incremental options • different length options Supplied with cover that meets general design requirements; for users with incontinence, a water-resistant cover or lining to protect cushion should be supplied Optional: postural-support options for thighs, such as wedge (raised seat front) or inside or outside thigh supports, either as separate supports or integrated into cushion Supply with rigid seat insert or sling filter pad for more stability in wheelchairs with sling seat Accessories: • inflation pump (for adjustable air volume) • emergency patch kit for air, gel and fluid cushions

4. Pressure redistribution wheelchair seat cushion for users at risk of pressure injuries (with deep/full immersion and envelopment features)

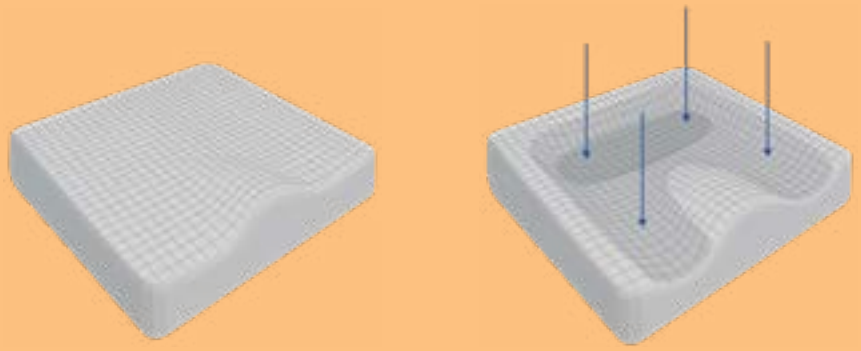
4.1 Contoured cushion with separate top layer or seat bone well pad



Typical user	Child or adult who uses a wheelchair; who is at risk of or has existing or previous pressure injuries; and who needs good support to maintain stability and aligned posture
Specific characteristics	Constructed with firm, non-deforming, pre-contoured base with deep seat bone well and separate removable layer with large-volume air, gel or fluid seat bone well pad Pad may be integrated into top layer Can be adjusted or modified to optimize posture support for: • height and depth pre-seat bone well • thigh support • postural deviations of pelvis, hips or thighs
Requirements for standard configuration	Cushion design: • overall height approximately 70–120 mm • allows full or deep offloading or immersion (sinking into) and envelopment (conforming to shape) 40–45 mm or deeper Base: • flat base for wheelchairs with rigid seats • curved base for wheelchairs with sling seats to match sling seat shape or supplied with rigid seat insert or sling filler pad if flat-based Size range: • should match wheelchair provided • available in child, adult and bariatric size and weight ranges • seat width range in 25–50 mm incremental options • different length options Supplied with cover that meets general design requirements; for users with incontinence, a water-resistant cover or lining to protect cushion should be supplied

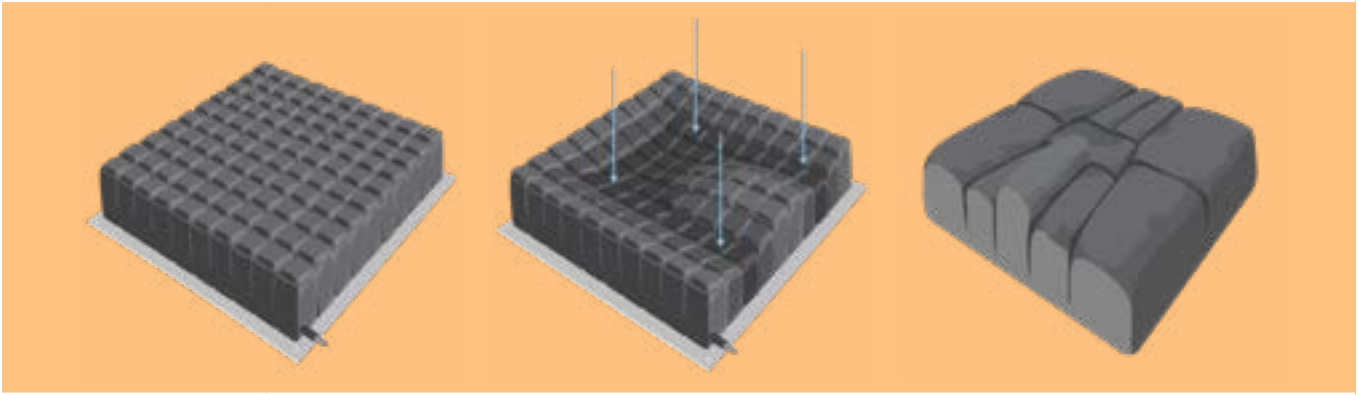
	Optional: postural-support options for thighs, such as wedge (raised seat front) or inside or outside thigh supports, either as separate supports or integrated into cushion Accessories: • inflation pump for adjustable air pads • emergency patch kit for air, gel and fluid pads

4.2 Contoured cushion without top layer



Typical user	Child or adult who uses a wheelchair; who is at risk of or has existing or previous pressure injuries; and who needs good support to maintain stability and aligned posture
Specific characteristics	Constructed with flat or pre-contoured base with conforming properties, where variations in support from different layers or sections create offloading or full or deep immersion and envelopment
Requirements for standard configuration	Cushion design: • overall height approximately 70–120 mm • allows full or deep offloading or immersion (sinking into) and envelopment (conforming to shape) 40–45 mm) or deeper Base: • flat base for wheelchairs with rigid seats • curved base for wheelchair with sling seats to match sling seat shape or supplied with rigid seat insert or sling filler pad if flat-based Size range: • should match wheelchairs provided • available in child, adult and bariatric size and weight ranges • seat width range in 25–50 mm increment options or adjustable • different length options or adjustable in length Supplied with cover that meets general design requirements; for users with incontinence, a water-resistant cover or lining to protect cushion should be supplied Optional: posture-support options for thighs, such as wedge (raised seat front) or inside or outside thigh supports, either as separate supports or integrated into cushion

4.3 Cushion without dedicated structural base with multiple sections



Typical user	Child or adult who uses a wheelchair; who is at risk of or has existing or previous pressure injuries; and who needs good support to maintain stability and aligned posture
Specific characteristics	Constructed without dedicated structural base but with multiple sections. Placement of sections and manipulating air, gel or fluid volume or pressure creates offloading, and full or deep immersion and envelopment Air, gel or fluid volume can be manipulated in different sections by removing or adding cells or changing air, gel or fluid volume or pressure to accommodate small pelvis and hip postural deviations
Requirements for standard configuration	Cushion design: • overall height approximately 70–120 mm • allows full or deep offloading or immersion (sinking into) and envelopment (conforming to shape) 40–45 mm or deeper Size range: • should match wheelchair provided • available in child, adult and bariatric size and weight ranges • seat width range in 25–50 mm incremental options • different length options Supplied with cover that meets general design requirements; for users with incontinence, a water-resistant cover or lining to protect cushion should be supplied Optional: postural-support options for thighs, such as wedge (raised seat front) or inside or outside thigh supports, either as separate supports or integrated into cushion Supply with rigid seat insert or sling filter pad for more stability in wheelchairs with sling seat Accessories: • inflation pump for adjustable air volume • emergency patch kit for air-, gel- or fluid-filled cushions

General design requirements

The cushion and cover must provide the required level of postural support (positioning, stability and reduced sheer), pressure redistribution (protecting skin and reserve soft tissue integrity), improved sitting tolerance (comfort), and reduced heat and moisture (improved microclimate).

The cushion construct should be designed and made from materials that contribute to the microclimate between the skin and the cushion to manage moisture, airflow and heat. The front and rear and the top and bottom of the cushion must be clearly differentiated for correct placement and use.

The cover should be stretchable and breathable to assist with the microclimate between the skin and cushion to manage moisture, airflow and heat. It should be removable and washable. If cushion is adjustable in shape or size, the cover must be adaptable to fit the new size or shape.

Standards

ISO 16840-1:2006 Wheelchair Seating – Part 1: Vocabulary, Reference Axis Convention and Measures for Body Segments, Posture and Postural-Support Surfaces

ISO 16840-2:2018 Wheelchair Seating – Part 2: Determination of Physical and Mechanical Characteristics of Seat Cushions Intended to Manage Tissue Integrity

ISO 16840-3:2014 Wheelchair Seating – Part 3: Determination of Static, Impact and Repetitive Load Strengths for PSDs

ISO 16840-4:2009 Wheelchair Seating – Part 4: Seating Systems for Use in Motor Vehicles

ISO 16840-6:2015 Wheelchair Seating – Part 6: Simulated Use and Determination of the Changes in Properties of Seat Cushions

ISO/TR 16840-9:2015 Wheelchair Seating – Part 9: Clinical Interface Pressure Mapping Guidelines for Seating

ISO 16840-10:2014 Wheelchairs Seating – Part 10: Resistance to Ignition of Non-integrated Seat and Back Support Cushions – Requirements and Test Methods

ISO/TS 16840-11:2014 Wheelchair Seating – Part 11: Determination of Perspiration Dissipation Characteristics of Seat Cushions Intended to Manage Tissue Integrity

ISO/TS 16840-12:2015 Wheelchair Seating – Part 12: Apparatus and Method for Cushion Envelopment Testing

Some parts of ISO 7176 series may also be applicable

Size and weight

Information about overall width, height, length and weight of wheelchair cushion must be provided, including size of the cushion that was weighed (see ISO 16840-1)

If cushion can be cut to size or length, this information must be provided

Maximum user weight capacity should be required for each type of cushion and size

Accessories and spare parts

The following accessories should be procured:

- rigid seat inserts;
- sling filler pads;
- thigh-support options;
- covers;
- inflation pumps for adjustable air volume;
- emergency patch kits for air-, gel- and fluid-filled cushions.

Other product requirements

For all cushions that are not ready to use, the manual should include instructions for setup and use.

Wheelchairs, manual

Name of product

Wheelchairs, manual assistant-controlled

Wheelchairs, manual for active use

Wheelchairs, manual with postural-support devices

ISO 9999 code

12 22 03 Bimanual handrim-drive wheelchairs

12 22 06 Bimanual lever-drive wheelchairs

12 22 09 Single-side manual drive wheelchairs

12 22 15 Foot-propelled wheelchairs

12 22 18 Push wheelchairs

12 27 04 Transportation chairs

12 27 07 Prams and buggies

18 09 39 Modular seating systems

Other relevant codes:

12 24 Wheelchair accessories

09 07 Assistive products for body stabilization (belts, harnesses)

18 10 Accessories for posture-support wheelchairs

Description and intended use

Wheelchairs provide wheeled mobility with an appropriate seating system and rely on the user or an assistant to move around. Wheelchairs are intended for children and adults with limited mobility.

General features

A wheelchair usually has three or four wheels with rear wheel locks or brakes for parking, footrests (foot supports), seat and backrest (back support), armrests (arm supports) and clothing guards. It has push rims or levers for self-propelling and may have push-handles for assistant-propelling. It can be foldable or can be dismantled into smaller, separate parts for transportation and storage. A wheelchair can be used with a range of postural-support devices (PSDs) and add-on mobility components for achieving its full function.

Inclusion

Wheelchairs, manual assistant-controlled

Wheelchairs, manual for active use

Wheelchairs, manual with postural-support devices

Exclusion

Wheelchairs, electrically powered

Wheelchairs, standing

Trikes (dedicated)

Keywords

Active wheelchair, adaptive stroller, buggy, manual wheelchair, PSD, postural-support wheelchair, transport/push wheelchair, wheelchair with PSDs, wheelchair with recline, wheelchair with tilt

Basic-level posture support needs Children and adults who use wheelchairs, and who can sit upright and balanced without any postural deviations or tendencies. They use manual wheelchairs with an appropriate seat depth, seat width, backrest height, armrests and footrests. They do not need modifications or additional postural supports.

Intermediate-level posture support needs Children and adults who use wheelchairs, with mild to moderate postural deviations and tendencies and who need additional support to sit upright or balanced. These users need modifications or postural supports added to an appropriate manual wheelchair or may need a postural-support wheelchair.

Advanced-level posture support needs Children and adults who use wheelchairs, with complex, fixed postural deviations. Depending on the deviation, these users may need modifications or postural supports added to an appropriate manual wheelchair or may need a postural-support wheelchair.

Basic-level services Wheelchair services delivered to users with basic-level posture support needs.

Intermediate-level services Wheelchair services delivered to users with intermediate-level posture support needs.

Advanced-level services Wheelchair services delivered to users with advanced-level posture support needs.

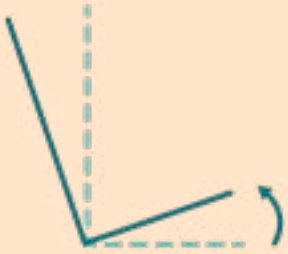
Functional requirements

1. Wheelchairs, manual assistant-controlled

1.1 Transport wheelchair

Typical user	Child or adult who can sit upright and balanced without additional support For intermittent use for short-duration transportation indoors and outdoors
Specific characteristics	Wheelchair with folding or rigid frame, four wheels, push-handles, seat and backrest, armrests, footrests, tipping lever, and rear wheels and front castors appropriate for indoor and outdoor use
Requirements for standard configuration	Frame: • frame with mechanism(s) to fold or dismantle • fixed seat or seat frame depth • backrest with fixed height, at least at mid-thoracic height of user • two flip-up, swing-away or removable footrests with adjustable height • flip-up or removable armrests Rear wheels: • diameter from 305 mm (assistant-propelled) to 660 mm (self-propelled) • rear wheel in line with backrest tubes (back posts) or further to rear Front castors: • diameter 203 mm • width 25–50 mm Puncture-proof rear tyres and front castors Seat width range: minimum four sizes

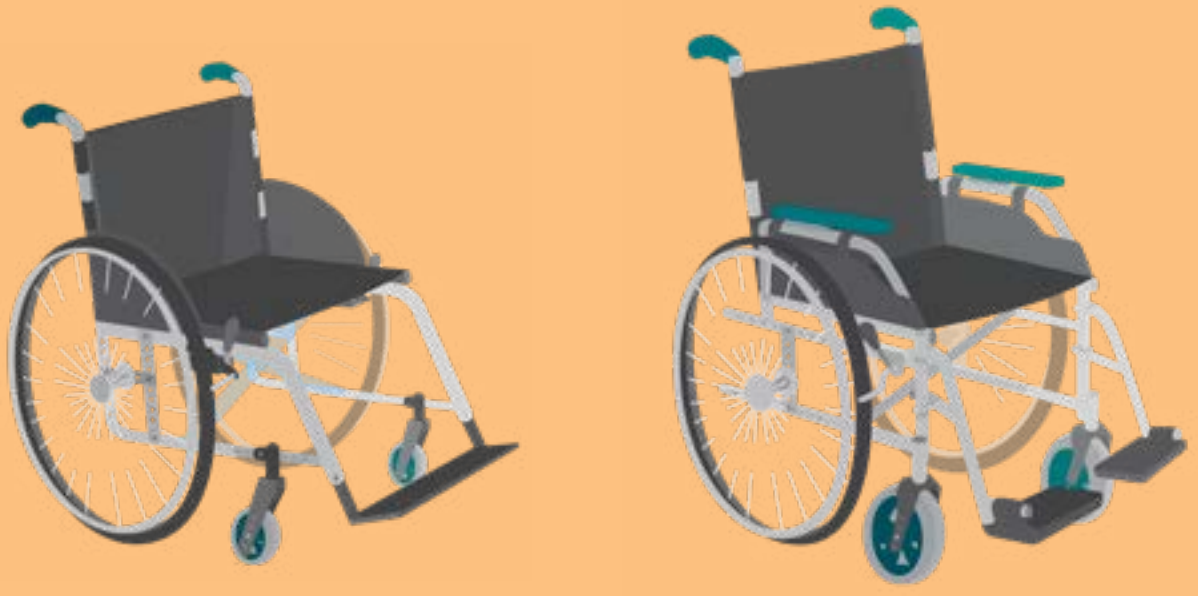
1.2 Adaptive stroller

Typical user	Child or adult who cannot sit safely in an upright posture and requires additional postural support For intermittent use for short-duration transportation indoors and outdoors
Specific characteristics	Wheelchair with folding or rigid frame, three or four wheels, push-handles, seat and backrest with preset tilt, head support and footrests Accepts range of PSDs Wheels and castors can be in various sizes suitable to the terrain: • smaller diameter and narrower width for indoor or urban outdoor terrain • larger diameter and wider width for outdoor peri-urban or rural terrain
Requirements for standard Configuration	Frame: • frame with mechanism(s) to fold or dismantle • integrated or removable seat and backrest • accepts range of PSDs; seat with preset tilt; variable (dynamic) recline or tilt is optional  • head support integrated in or separate from backrest • single or dual footrests with adjustable height Single or double wheels with puncture-proof tyres

	PSDs: • required accessories – pelvic belt and head support • optional accessories – shoulder harness, foot straps, hip guides, trunk side supports, tray Size range: • seat width range – minimum four sizes • seat depth can be extended by at least 50 mm without additional parts

2. Wheelchairs, manual for active use

2.1 Active urban wheelchair



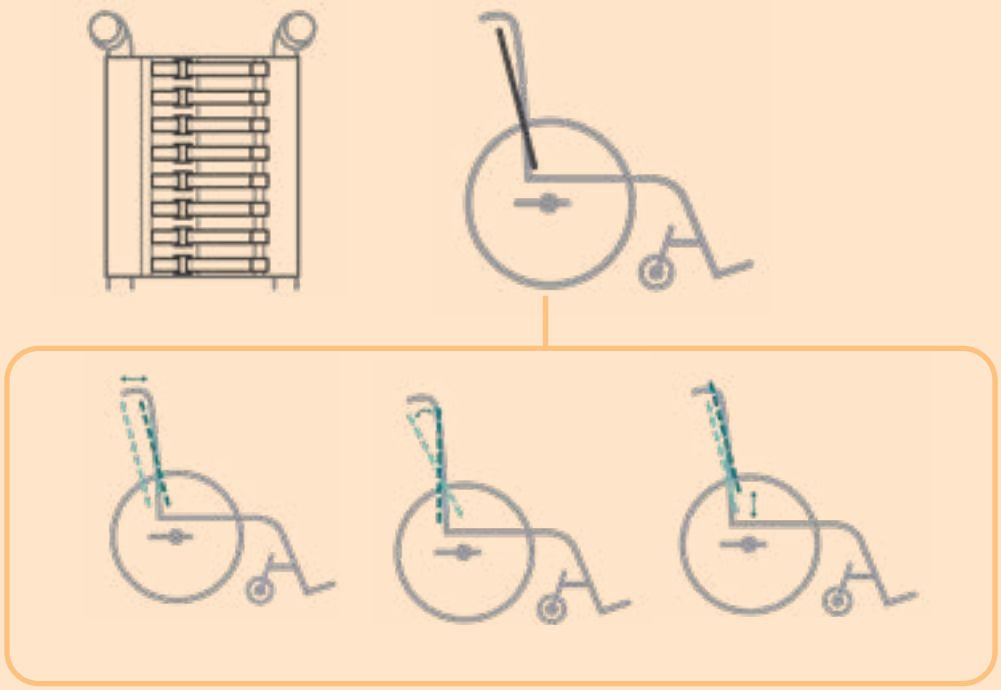
Typical user	Child or adult with basic, intermediate or advanced[15] posture support needs Primarily for people who self-propel, but also for people who need assistance For use in urban, indoor and outdoor environments People with advanced mobility skills may also use this wheelchair for short distances on uneven terrain
Specific characteristics	Wheelchair with folding or rigid frame, three or four wheels with large rear wheels, seat and backrest, armrests and footrests Overall length and wheelbase are similar to or shorter than transport wheelchair with large rear wheels Rear wheels and front castors appropriate for urban indoor and outdoor use

15 For intermediate and advanced posture support needs, posture support needs should be met with the available seat unit configuration adjustments or addition of PSDs. Should not be used for people who needs daily adjustable (dynamic) tilt.

Requirements for standard configuration

Frame:

- frame with mechanism(s) to fold or dismantle
- push-handles can be integrated into frame, supplied as add-on components, or omitted if not required
- backrest or back posts with adjustable height or supplied with range of back posts with fixed height
- backrest contouring options, such as tension-adjustable backrest or rigid backrest that can be adjusted independently from back posts or with forward and backward and angle adjustment, including separate padded cover; can be mounted at different heights on back posts; quick-release mechanism to allow folding



- footrests with adjustable height – available in at least two adjustment ranges on all sizes of wheelchair to accommodate people with shorter and longer legs
- two flip-up, swing-away or removable footrests on folding frame
- optional – armrests and clothing guards with minimal profile

Rear wheels:

- quick-release or removable without tools
- optional camber with maximum 3 ° (off from vertical)
- diameter 508-660 mm
- width 25–35 mm

Requirements for standard configuration

Front castors:

- diameter 127-203 mm
- width 13-50 mm

Range of size and width options available

Puncture-proof or pneumatic rear tyres and front castors

Frame and wheel adjustments:

- rear wheel or seat unit relative to wheelbase can be horizontally adjusted using tools

- front and rear seat-to-floor heights can be adjusted through wheel or frame adjustments or through range of different fixed-frame seat heights to optimize fit for foot propelling on folding-frame wheelchairs

Optional for basic-level services but required for postural support for intermediate- and advanced-level services:

- wheel or frame adjustments using tools to change seat angle; minimum adjustment range 10–15 °; if seat angle is independently adjustable, seat-to-backrest angle must also be adjustable

Requirements for standard configuration	• backrest to seat angle (recline) adjustments with or without use of tools; minimum adjustment range 10–15 °  • mechanism or adjustment options are available to maintain backwards stability with maximum combined seat and backrest configuration adjustments Additional requirements on adjustability for postural support for intermediate- and advanced-level services: • removable backrest upholstery with back-post capabilities to accept third-party backrests[16] • armrests with adjustable height, and short and full-length armpads; design and function of armrests should not restrict fitting of third-party backrests Frame size range: • seat width appropriate for profile of users; includes child, adult and bariatric sizes with 25–50 mm increments • seat depth adjustable or with option for seat extension or supplied with range of seat frame depth options

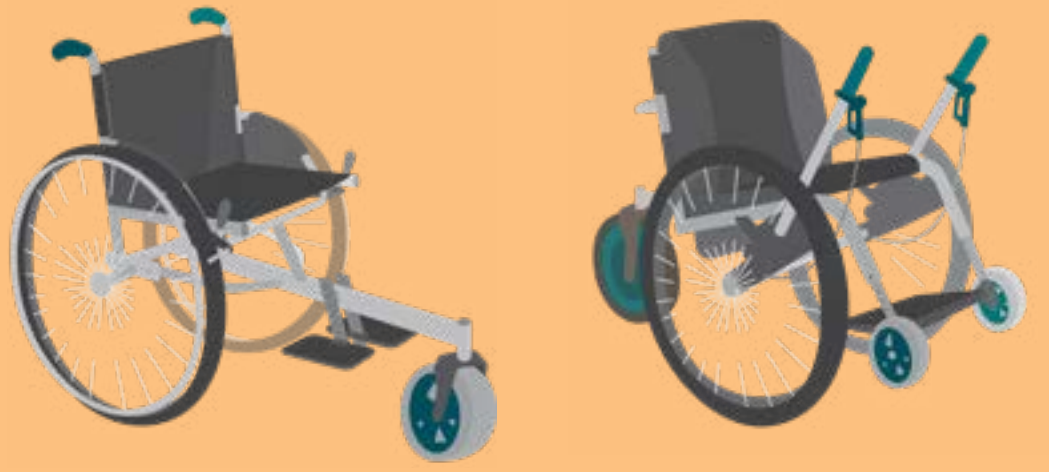
16 The term "third party" applies to a backrest designed and manufactured to fit on a variety of wheelchairs and not a particular model or range only.

2.2 Active dual-terrain wheelchair

Typical user	Child or adult with basic, intermediate or advanced posture support needs Primarily for users who self-propel, but also for users who need assistance For use in indoor and outdoor uneven urban, peri-urban and rural environments Offers better outdoor mobility for users who do not have advanced wheelchair mobility skills
Specific characteristics	Wheelchair with folding or rigid frame, three or four wheels with large rear wheels, seat and backrest, armrests and footrests Footrests positioned in line or behind front castors Longer wheelbase and shorter or similar overall length than transport wheelchair with large rear wheels Rear wheels and front castors appropriate for indoor and outdoor mixed terrain
Requirements for standard configuration	Frame: • frame with mechanism(s) to fold or dismantle • push-handles can be integrated into frame, supplied as add-on component, or omitted if not required • backrest or back-posts with adjustable height or supplied with range of back-posts with fixed height • backrest contouring options, such as tension-adjustable backrest or rigid backrest that can be adjusted independently from back-posts or with forward and backward and angle adjustment, including separate padded cover (see illustrations in 2.1); can be mounted at different heights on back posts; quick-release mechanism to allow folding • footrests with adjustable height; available in at least two adjustment ranges on all sizes of wheelchair to accommodate people with shorter and longer legs • two flip-up, swing-away or removable footrests on folding frames • optional: armrests and clothing guards with minimal profile

Requirements for standard configuration	Rear wheels: • quick-release or removable without tools for rigid frames • quick-release or removable without tools for folding frames is optional • camber ranges from 0 ° (rear wheel perpendicular to ground) to 1–3 ° (off from vertical) • diameter 508–660 mm • width 35–44 mm Front castors: • diameter and width variable: 203 x 50 mm, 102 x 76 mm Range of size and width options available Puncture-proof or pneumatic rear tyres and front castors Frame and wheel adjustments: • rear wheel or seat unit relative to wheelbase can be adjusted horizontally using tools (see illustrations in 2.1) • front and rear seat-to-floor heights can be adjusted through wheel or frame adjustments or supplied through range of different fixed-frame seat heights (see illustrations in 2.1) Optional for basic-level services but required for postural support for intermediate- and advanced-level services: • wheel or frame adjustments using tools to change seat angle (see illustrations in 2.1); minimum adjustment range 10–15 °; if seat angle independently adjustable, seat-to-backrest angle must also be adjustable • backrest to seat angle (recline) adjustments with or without tools (see illustrations in 2.1); minimum adjustment range 10–15 ° • mechanism or adjustment options available to maintain backwards stability with maximum combined seat and backrest configuration adjustments Additional requirements on adjustability for postural support for intermediate- and advanced-level services: • removable backrest upholstery with back-post capabilities to accept third-party backrests • armrests with adjustable height, and short and full-length armpads; design and function of armrests should not restrict fitting of third-party backrests Frame size range: • seat width appropriate for profile of users; includes child, adult and bariatric sizes with 25–50 mm increments • seat depth adjustable or with option for seat extension or supplied with range of seat depth options

2.3 Active rough terrain wheelchair



Typical user	Child or adult with basic, intermediate and advanced posture support needs to self-propel in rough outdoor terrain Also users who need assistance (excluding lever-propelled wheelchairs)
Specific characteristics	Wheelchair with folding or rigid frame; three, four or more wheels, with two larger drive wheels; seat and backrest; and footrests behind front castors May be lever-propelled Similar or longer wheelbase than dual-terrain wheelchair; larger overall length than transport wheelchair with large rear wheels Low centre of gravity to ensure stability Rear wheels and castors appropriate for outdoor rough terrain
Requirements for standard configuration	Frame: • frame with mechanism(s) to fold or dismantle • push-handles can be integrated into frame, supplied as an add-on component or omitted • integrated stability options for feet • backrest or back-posts with adjustable height or supplied with range of back-posts with fixed height • backrest contouring options, such as tension-adjustable backrest or rigid backrest that can be adjusted independently from back-posts or with forward and backward and angle adjustment, including separate padded cover (see illustrations in 2.1); can be mounted at different heights on back-posts; quick-release mechanism to be removed to allow folding • footrests with adjustable height; available in at least two adjustment ranges on all sizes of wheelchair to accommodate people with shorter and longer legs • two flip-up, swing-away or removable footrests on folding frames • optional: armrests and clothing guards with minimal profile

Requirements for standard configuration	
	Rear wheels (manual propelling): • with push-rims or lever-propelled • quick-release or removable without tools for rigid frames for transport; optional for wheelchairs with folding frame • camber minimum 3 ° (off from vertical) for stability • diameter 610–711 mm • width 35–44 mm • wider or larger-tread tyres Front castors (manual propelling): • diameter over 203 mm • width over 50 mm Range of size and width options available Puncture-proof or pneumatic rear tyres and front castors Rear and front wheels (lever propelling): • size and width of front and rear wheels appropriate for rough terrain and wheelchair design • three or multiple wheels • puncture-proof or pneumatic wheels Frame and wheel adjustments: • rear wheel axle or seat unit relative to wheelbase can be horizontally adjusted using tools (see illustrations in 2.1) • front and rear seat-to-floor heights can be adjusted through wheel or frame adjustments or supplied through range of different fixed-frame seat heights (see illustrations in 2.1) Optional for basic-level services but required for postural support for intermediate- and advanced-level services: • wheel or frame adjustments using tools to change seat angle (see illustrations in 2.1); minimum adjustment range 10–15 °; if seat angle independently adjustable, seat-to-backrest angle must also be adjustable • backrest to seat angle (recline) adjustments with or without use of tools (see illustrations in 2.1); minimum adjustment range 10–15 ° • mechanism or adjustment options available to maintain backwards stability with maximum combined seat and backrest configuration adjustments Additional features and adjustability required for postural support for intermediate- and advanced-level services (optional for basic-level services): • removable backrest upholstery with back-post capabilities to accept third-party backrests • armrests with adjustable height, and short and full-length armpads; design and function of optional armrests should not restrict fitting of third-party backrests

Requirements for standard configuration	Frame size range: • seat width appropriate for profile of users; includes child, adult and bariatric sizes with 25–50 mm increments • seat depth adjustable or with option for seat extension or supplied with range of frame seat depth options

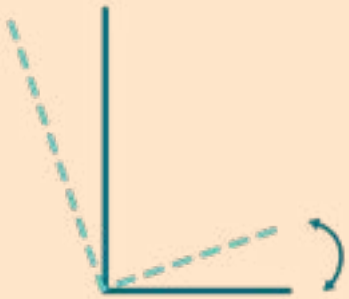
3. Wheelchairs, manual with postural support

3.1 Wheelchair, manual with postural support (variable-position wheelchair)

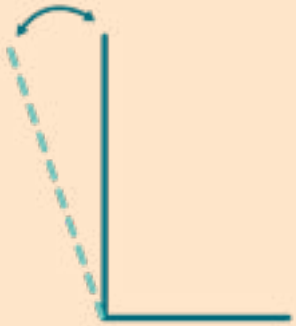
Typical user	Child or adult with intermediate or advanced posture support needs who requires variable tilt or recline, or larger range of static tilt or recline than available on manual wheelchairs For users who self-propel or need to be assisted For use in both indoor and uneven urban, peri-urban and rural outdoor environments
Specific characteristics	Wheelchair with folding or rigid frame, three or four wheels, push-handles, rigid seat and backrest, armrests or tray table, and footrests Range of integrated or included PSDs and posture support cushion Large-range adjustable recline and large-range adjustable and variable (dynamic) tilt Rear wheels and front castors appropriate for indoor and outdoor mixed terrain
Requirements for standard configuration	For intermediate and advanced service levels only: Frame: • frame with mechanism(s) to fold or dismantle • rigid backrest and seat; removable without tools on folding frame

Requirements for standard configuration

- adjustable tilt[17] with minimum 20 ° without tools



- adjustable recline[18] with minimum 20 ° with tools; optional variable (adjustable without tools) recline minimum 20 °



- integrated mechanism or adjustment options to prevent tip-over when chair used with tilt or recline
- footrests with adjustable height; available in at least two adjustment ranges on all sizes of wheelchair to accommodate people with shorter and longer legs; two flip-up, swing-away or removable footrests for wheelchairs with folding frames
- mechanism or adjustment options available to maintain backwards stability with maximum combined seat and backrest configuration adjustments
- for self-propelled wheelchairs: adjustment options to improve reach to rear

Rear wheels:

- diameter – 559–660 mm for self-propelled wheelchairs or from 305 mm for assistant-propelled wheelchairs
- quick-release or removable without tools on rigid frames for self-propelled wheelchairs

Castors:

- diameter 76–203 mm
- width 13–50 mm
- may be larger and wider if only one castor (depending on terrain)

Range of size and width options available

17 Seat, backrest and footrests move together without change in configuration.

18 Increased seat-to-backrest angle.

Requirements for standard configuration	Puncture-proof or pneumatic rear tyres and front castors Integrated PSDs: • rigid backrest: – separate padded cover designed to allow for modifications to optimize pelvis and trunk support – rigid pelvis and trunk side (lateral) supports are width (horizontal) and height (vertical) adjustable – height adjustable or available in different lengths to optimize trunk support (at least at shoulder height or higher) – not integrated into back-posts; separate component removable from back-posts if required, or part of integrated, removable seat–backrest unit – optional: rigid backrest independently adjustable from back-posts, with forward and backward and angle adjustments (see illustration in 2.1); can be mounted at different heights on back posts • headrest attached to back of backrest and with adjustable forward and backward, sideways, height and angle; must be able to support head behind, in line or in front of back support as required • pelvis strap (positioning belt) with adjustable length • adjustable and removable knee separator pad (medial knee support); may be integrated in cushion; standard on child size and optional on adult size • calf or foot straps with adjustable length • tray table or flip-up or removable armrests with adjustable height • posture support cushion: – removable – matches wheelchair seat size configurations – removable cover – can be modified to optimize pelvis, hip and thigh support – can be separately replaced Optional PSDs: outside (lateral) thigh or knee pads (supports) for seat, shoulder harness and chest strap Size range: seat width appropriate for profile of users; includes child, adult and bariatric sizes with 25–50 mm increments seat depth adjustable or supplied with range of seat depth options of minimum 102 mm

3.2 Wheelchair, manual base frame only to be fitted with PSDs (variable-position wheelchair, base frame only)

Typical user	Child or adult with intermediate or advanced posture support needs who requires variable tilt or recline, or larger range of static tilt or recline than available on manual wheelchairs For users who self-propel or need to be assisted For use in both indoor and uneven urban, peri-urban and rural outdoor environments
Specific characteristics	Wheelchair with folding or rigid frame, three or four wheels, push-handles, rigid seat, armrests or tray table, footrests, and seat and back posts that can fit range of PSDs Large-range adjustable recline and large-range adjustable and variable (dynamic) tilt Rear wheels and front castors appropriate for indoor and outdoor mixed terrain
Requirements for standard configuration	For intermediate and advanced service levels only: • frame with mechanism(s) to fold or dismantle • rigid seat; removable without tools on folding frame • adjustable tilt with minimum 20 ° without tools (see illustrations in 3.1) • adjustable recline with minimum 20 ° with tools (see illustrations in 3.1); optional variable (adjustable without tools) recline (seat-to-backrest angle adjustment) minimum 20 ° • integrated mechanism or adjustment options to prevent tip-over when chair used with tilt or recline • back-posts with adjustable height or supplied with range of fixed-height options where back support is at least at shoulder height or higher; accepts range of third-party backrests

Requirements for standard configuration	• headrest to attach to third-party backrest; must be ordered separately with backrest • footrests with adjustable height; available in at least two adjustment ranges on all sizes of wheelchair to accommodate people with shorter and longer legs; two flip-up, swing-away or removable footrests for wheelchairs with folding frames • mechanism or adjustment options to maintain backwards stability with maximum combined seat and backrest (back support) configuration adjustments • for self-propelled wheelchairs – adjustment options to improve reach to rear wheels Rear wheels and castors: • self-propelled rear wheels can be quick-release or removable without tools on rigid frames; optional for folding frames • diameter 559–711 mm for self-propelled wheelchairs; from 203 mm for assistant-propelled wheelchairs Front castors: • diameter 76–203 mm • width 13–50 mm • may be larger and wider if only one castor (depending on terrain Range of size and width options available Puncture-proof or pneumatic rear tyres and front castors Integrated PSDs: • pelvis strap (positioning belt) with adjustable length • calf or foot straps with adjustable length • tray table or flip-up or removable armrests with adjustable height; design should not restrict fitting of third-party backrests Optional PSDs: • outside (lateral) thigh or knee pads (supports) for seat, shoulder harness and chest strap • knee separator pad (medial knee support), adjustable and removable Size range: • seat width appropriate for profile of users; includes child, adult and bariatric sizes with 25–50 mm increments • seat depth adjustable or supplied with range of seat depth options of minimum 102 mm

General design requirements

The wheelchair must meet the user's needs (enable effective mobility, transfers, transport) and environmental conditions (indoor and outdoor mobility over local terrain), provide postural support (appropriate size, adjustments and posture-support options), and be safe and durable.

Standards

EN 12183:2014 Manual Wheelchairs – Requirements and Test Methods (or a more recent version or equivalent)

ISO 7176–1 Wheelchairs – Part 1: Determination of Static Stability

ISO 7176–3 Wheelchairs – Part 3: Determination of Effectiveness of Brakes

ISO 7176–5 Wheelchairs – Part 5: Determination of Dimensions, Mass and Manoeuvring Space

ISO 7176–7 Wheelchairs – Measurement of Seating and Wheel Dimensions

ISO 7176–8 Wheelchairs – Part 8: Requirements and Test Methods for Static, Impact and Fatigue Strengths

ISO 7176–15 Wheelchairs – Requirements for Information Disclosure, Documentation and Labelling

ISO 7176–16 Wheelchairs – Part 16: Resistance to Ignition of PSDs

Specific product standard for manual wheelchairs to be used as seating in a motor vehicle:

ISO 7176–19:2008 Wheeled Mobility Devices for Use as Seats in Motor Vehicles or Equivalent (test should be executed with head support attached to wheelchair)

Current product standards for posture-support devices:

ISO 16840–3 Wheelchair Seating: Part 3: Determination of Static, Impact and Repetitive Load Strengths for PSDs

Size and weight

Information about overall width, height and length of manual wheelchair, seat depth and width, and backrest (back support), armrest (arm support) and footrest (foot supports) height must be provided

If applicable, adjustment ranges and dimensions in operating and folded modes must be provided

Overall weight of wheelchair and its configuration when weighed must be provided

Rear wheel and front castor diameter and width must be provided

The user's maximum weight capacity should be indicated for each type and size of wheelchair

Accessories and spare parts[19]

The following optional wheelchair mobility accessories, add-ons and spare parts may be procured for active wheelchairs. To ensure mobility accessories are compatible with a particular wheelchair, they must be added to the "requirements for standard configuration" section for the relevant wheelchair:

- Removable large-diameter castor: for users of active manual four-wheel wheelchairs to improve outdoor access over long distances or uneven terrain. Raises front castors and turns wheelchair into three-wheel device. Swivel castor is detachable and has a large diameter; it can be quick-release or removable without tools. Castor attaches to footrests or frame. Storage bracket is attached to frame. Additional adaptor bar to be included for folding frame. Complete with all attachments for storage and use.

- One-arm drive unit: for users of manual wheelchairs who have limited or no arm and hand function on one side of their body. Designed to be self-propelled with one hand or arm only. Unit consists of two push-rims on one side. Each push-rim can be used independently to change direction or be used together to go in a straight line. To clamp on to the wheelchair frame: if it is a folding frame, the unit should fold with it when attached. Width is adjustable or supplied with a range of options.

19 Given the importance of these accessories, add-ons and spare parts for achieving the full function of the product, they are provided with detailed technical specifications.

- Clamp-on propelling lever: for users of wheelchairs who are travelling long distances over uneven terrain. Designed to require less force to move the wheelchair. Left and right levers attached to rear wheels with a mechanism designed to allow wheel propulsion via levers replacing push-rim propulsion. Gearing system can be used to allow easier propulsion up steep slopes or faster propulsion on flat ground. Left and right arm levers and attaching mechanisms allow forward movement of the manual wheelchair.

- Removable trike attachment: for users of active manual wheelchairs to improve efficiency over long distances. Designed to be self-propelled by users. The attachment is removable to allow wheelchair access to small spaces such as buildings and homes. The attachment/detachment mechanism should be quick-release or removable without tools. When connected, the trike attachment lifts front castor wheels off ground when locked in place. Hand-powered drive train to front drive wheel.

Add-on PSDs include (but are not limited to):

- tension-adjustable backrests with range of back height options;
- rigid backrests with no or low-profile side (lateral) supports with option to fit with additional trunk side (lateral trunk) supports, or both trunk and pelvis side (lateral) supports (range of back height options/adjustability);
- rigid backrests with medium (extending to mid-axilla line) or deep profile (extending to front of body) to provide appropriate level of trunk or pelvis support (range of back height options/adjustability);
- headrests;
- tray tables;
- range of arm supports;
- range of thigh supports;

- range of footrests with seat-to-lower leg support angle and lower leg support-to-foot support angle options/adjustability;
- range of straps or harnesses for trunk, pelvis, thighs, lower legs and feet;
- outside (lateral) thigh or knee pads (supports) for seat;
- adjustable and removable knee separator pad (medial knee support).

Each item should have an appropriate range of adult and child sizes and match the wheelchair configuration. Mounting systems should be included where appropriate.

White canes

Name of product

White canes

ISO 9999 code

12 39 03 Tactile sticks or white canes

Description and intended use

White canes are long rod-like devices intended for use by children and adults with blindness or low vision. They give the user information about the environment they are moving through, such as obstacles in their path, stairs they are coming to, curb edges they are approaching, and many other aspects of their environment that must be dealt with.

General features

A white cane has a handle on one end and a tip or roller on the other. The handle may have a wrist loop to hang the cane up when not in use. The body of the white cane is covered with reflective tape to make the user visible.

Some white canes have a section of red or yellow paint or reflective tape at the tip to indicate the user is blind. Some canes have alternating colours of white and red indicating both vision and hearing loss.

Inclusion

Straight, angular or folding white canes

Exclusion

White canes with electronic or ultrasonic features

Keywords

Independent mobility, mobility aids, safe mobility

Functional requirements

1. Straight white cane

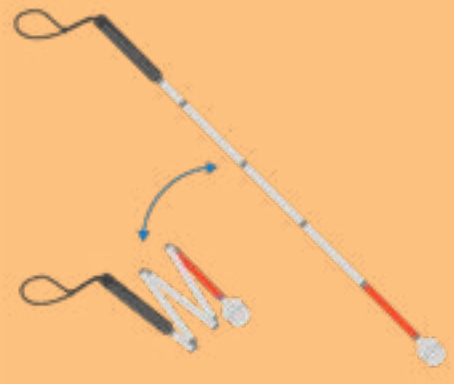
Typical user	Child or adult with blindness or low vision who can walk independently with ease
Specific characteristics	Cane with straight tubing
Requirements for standard configuration	Aluminium, fibreglass or carbon fibre straight tubing with outer diameter 1.2 cm or smaller 360 ° turn roller or marshmallow-style nylon tip 2–3 cm thick Length range: • tall adults: 145 cm ± 5 cm • adults: 120–140 cm ± 5 cm • children: 70 cm ± 5 cm Plastic or rubber handgrip of length 20 cm and diameter 2.5 cm and wrist loop

2. Angular white cane

Typical user	Child or adult with blindness or low vision who can walk independently with ease
Specific characteristics	Cane with straight tubing with bent handgrip

Requirements for standard configuration	Aluminium, fibreglass or carbon fibre straight tubing with outer diameter 1.2 cm or smaller 360 ° turn roller or marshmallow-style nylon tip 2–3 cm thick Length range: • tall adults: 145 cm ± 5 cm • adults: 120–140 cm ± 5 cm • children: 70 cm ± 5 cm Plastic or rubber handgrip of length 20 cm and diameter 2.5 cm and bent at 150 ° from the main body of the cane, and wrist loop

3. Folding white cane



Typical user	Adult with blindness or low vision who can walk independently with ease
Specific characteristics	Cane with foldable tubing
Requirements for standard configuration	Foldable aluminium, fibreglass or carbon fibre tubing with outer diameter 1.2 cm or smaller; with four or five folds; and with elastic cord running through the middle of the tubing 360 ° turn roller or marshmallow-style nylon tip 2–3 cm thick Length of cane after connecting joints should be 140 cm for adults Plastic or rubber handgrip of length 20 cm and diameter 2.5 cm and wrist loop

General design requirements

The white cane should be strong, durable and lightweight to withstand wear and tear during travel. Its parts should be replaceable. The elastic cord used in a folding cane should be durable. The tip should be made of durable material and be a good insulator of electricity.

Standards

None

Size and weight

Information about length of white cane should be required; if applicable, include dimensions in operating and folded modes

For straight canes, minimum and maximum lengths with types of handles should be provided

For folding canes, minimum and maximum number of folds and lengths should be provided[20]

Environment of use

White canes should withstand various terrain.

Accessories and spare parts

The following spare parts should be required:

- white cane tips;
- elastic cords (for foldable white canes only).

20 The length of the cane needed is determined by the height of the user. Generally it should reach the breastbone when held vertically.

References

1. A manual for public procurement of assistive products, accessories, spare parts and related services. Geneva: United Nations Children's Fund and World Health Organization; 2020.
2. Seventy-first World Health Assembly adopts resolution on assistive technology. WHA71.8. (https://www.who.int/phi/implementation/assistive_technology/71stWHA-adopts-resolution-on-assistive-technology/en/).
3. WHO priority assistive products list. Geneva: World Health Organization; 2016 (https://apps.who.int/iris/bitstream/handle/10665/207694/WHO_EMP_PHI_2016.01_eng.pdf?sequence=1).
4. ISO 9999:2016: assistive products for persons with disability – classification and terminology. Geneva: International Organization for Standardization; 2016 (https://www.iso.org/standard/60547.html).
5. Fader M, Cottenden A, Chatterton C, et al. An International Continence Society (ICS) report on the terminology for single-use body worn absorbent incontinence products. Neurourol Urodynam 2020;1–9.
6. Guidelines for hearing aids and services for developing countries. Geneva: World Health Organization; 2004 (https://apps.who.int/iris/bitstream/handle/10665/43066/9241592435_eng.pdf;jsessionid=82CD4C17D81B8458562DB27E4E84FFA0?sequence=1).
7. Preferred profile for hearing-aid technology suitable for low- and middle-income countries. Geneva: World Health Organization; 2017 (https://apps.who.int/iris/bitstream/handle/10665/258721/9789241512961-eng.pdf;jsessionid=BA94F850272B7A7655622FDB96EE4385?sequence=1).
8. Specification 800: Braille books and pamphlets. Washington DC: Library of Congress National Library Service for the Blind and Physically Handicapped; 2008 (http://www.loc.gov/nlsold/specs/800_march5_2008.pdf).

Further reading

Training in assistive products (TAP) (e-learning modules). Geneva: World Health Organization (https://www.who.int/news-room/feature-stories/detail/personnel-training-in-priority-assistive-products-(tap)).

Vision

International standards for vision rehabilitation: report of the International Consensus Conference on vision rehabilitation. Rome, 9–12 December 2015 (https://www.iapb.org/learn/resources/international-standards-for-vision-rehabilitation-international-consensus-conference-report/).

Van Rens GHMB, Vreeken HL, van Nispen RMA, editors. Visual disorders, rehabilitation and referral.

Hearing

Preferred profile for hearing-aid technology suitable for low- and middle-income countries. Geneva: World Health Organization; 2017 (https://apps.who.int/iris/bitstream/handle/10665/258721/9789241512961-eng.pdf;jsessionid=BA94F850272B7A7655622FDB96EE4385?sequence=1).

Primary ear and hearing care: training resource. Geneva: World Health Organization; 2006 (https://www.who.int/deafness/activities/hearing_care/en/).

Guidelines for hearing aids and services for developing countries. Geneva: World Health Organization; 2004 (https://apps.who.int/iris/bitstream/handle/10665/43066/9241592435_eng.pdf?sequence=1).

Mobility

Guidelines on the provision of manual wheelchairs in less resourced settings. Geneva: World Health Organization; 2008 (https://www.who.int/publications-detail/guidelines-on-the-provision-of-manual-wheelchairs-in-less-resourced-settings).

Wheelchair service training packages. Geneva: World Health Organization; 2017 (htttps://www.who.int/phi/implementation/assistive_technology/wheelchair-pub-training/en/).

Standards for prosthetics and orthotics. Geneva: World Health Organization; 2017 (https://www.who.int/phi/implementation/assistive_technology/prosthetics_orthotics/en/).

Self-care

Further information on continence product advice for users, carers and healthcare professionals: www.continenceproductadvisor.org.

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