INTERNATIONAL STANDARD

ISO 11199-1

> Second edition 2021-05

Assistive products for walking manipulated by both arms — Requirements and test methods —

Part 1: Walking frames

Produits d'assistance à la marche manipulés avec les deux bras — Exigences et méthodes d'essai — Cadre :: Cadre Cick to view

Partie 1: Cadres de marche



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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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

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

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

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

This second edition cancels and replaces the first edition (ISO 11199-1:1999), which has been technically revised.

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

- 3.1 was changed to be in accordance with ISO 9999;
- <u>Clause 6</u>, on general requirements for assistive products for walking, was added.

A list of all parts in the ISO 11199 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

A walking frame can be used when a person needs assistance when walking. The walking frame can provide stability when walking and standing and reduce the risk of falling. Walking frames are designed to support the user inside a frame to carry the user's full body weight.

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Assistive products for walking manipulated by both arms — Requirements and test methods —

Part 1:

Walking frames

1 Scope

This document specifies requirements and test methods for walking frames used as assistive products for walking, manipulated by both arms, without accessories, unless specified in the particular test procedure. This document also gives requirements relating to safety, ergonomics, performance and information supplied by the manufacturer, including marking and labelling.

The requirements and tests are based on everyday use of walking frames as assistive products for walking for a maximum user mass as specified by the manufacturer. This document includes walking frames specified for a user mass of no less than 35 kg.

2 Normative references

The following documents are referred to in the text on such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 8191-2, Furniture — Assessment of ignitability of upholstered furniture — Part 2: Ignition source: match-flame equivalent

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

ISO 13732-1, Ergonomics of the thermal environment — Methods for the assessment of human responses to contact with surfaces — Part 1: Hot surfaces

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

ISO 15223-1, Medical device – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements

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

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

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

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

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

ISO Online browsing platform: available at https://www.iso.org/obp

ISO 11199-1:2021(E)

IEC Electropedia: available at http://www.electropedia.org/

3.1

brake

device for slowing or stopping motion of a walking frame by contact friction

front handgrip reference point

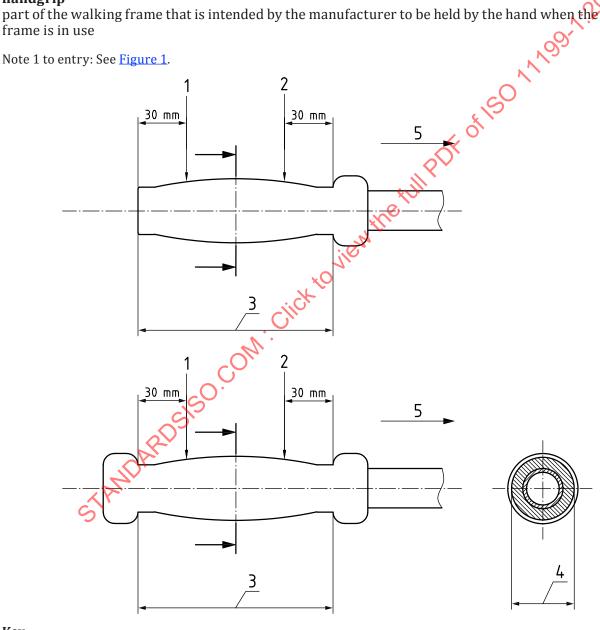
position on the upper surface of the handgrip located 30 mm from the front end of the handgrip length

Note 1 to entry: See Figure 1.

3.3

handgrip

part of the walking frame that is intended by the manufacturer to be held by the hand when the walking frame is in use



Key

- rear handgrip reference point 1
- 2 front handgrip reference point
- handgrip length 3

- handgrip width
- 5 front

Figure 1 — Details of a handgrip

3.4

handgrip length

dimension of the handgrip measured where the hand rests

Note 1 to entry: See Figure 1.

Note 2 to entry: Where the front end or the rear end of the handgrip is not clear, the full length of the handgrip that can comfortably support the mass of the user is defined as the handgrip length.

3.5

handgrip width

outside dimension of the handgrip measured at the thickest point where the hand rests

Note 1 to entry: See Figure 1.

3.6

handle

part of the walking frame to which the handgrip is attached

3.7

maximum user mass

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

Note 1 to entry: The maximum user mass is specified by the manufacturer of the walking frame.

3.8

maximum width

maximum outside dimension of a walking frame when the adjustments are at their maximum. measured horizontally at right angles to the direction of movement when the walking frame is in normal use

Note 1 to entry: See Figure 3.

3.9

parking brake

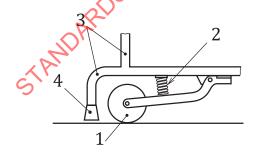
brake system that is intended for keeping the walking frame stationary on ground after being activated

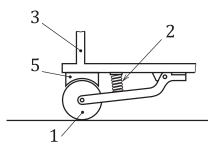
3.10

pressure brake

running brake that engages when a vertical load is applied on the handgrips or on supporting points of the walking frame

Note 1 to entry: See Figure 2





Kev

2

1 wheel 4 rubber tip (brake)

spring 5 brake pad

3 frame

Figure 2 — Two types of pressure brake with technical details

3.11

rear handgrip reference point

position on the upper surface of the handgrip located 30 mm from the rear end of the handgrip length

Note 1 to entry: See Figure 1.

Note 2 to entry: If the grip protrudes further than the handle, the measurement is made from the end of the handle.

3.12

reciprocal walking frame

walking frame where each side of the frame moves alternately, allowing unilateral forward progression through the whole gait cycle

3.13

running brake

brake that is operated by the user during walking and where the braking effect depends proportionally on the activation force applied

3.14

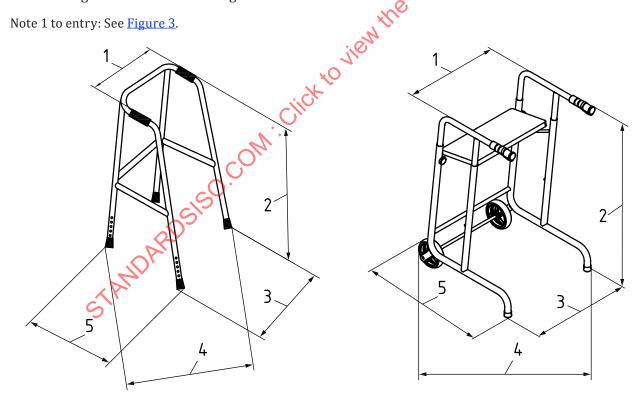
tip

part of a walking frame that is in contact with the ground

3.15

turning diameter

diameter of the largest circle described by a walking frame when the adjustments are at their maximum and walking frame is turned through 360° about its own central vertical axis



Key

- 1 width between handles
- 2 height
- 3 width

- 4 turning diameter
- 5 length

Figure 3 — Dimensions of a walking frame

3.16

walking frame

frame that a person lifts to move, which enables to support full body weight and to maintain stability and balance while walking or standing with hand grips, without forearm supports and with either four tips or two tips and two castors/wheels

Note 1 to entry: See Figure 4.

Note 2 to entry: ISO 9999, Classification No. 12 06 03.

Note 3 to entry: Double or more castors/wheels used for one pivot position shall be counted as one castor/wheel. The caster/wheel with a pressure brake shall be considered as the tip.

Note 4 to entry: Examples of walking frames include rigid or articulated walking frames assistive products for walking with two wheels combination with two rubber stick buffers/tips.

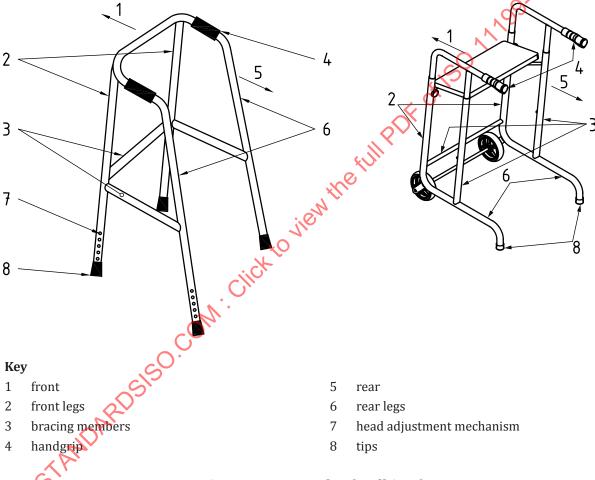
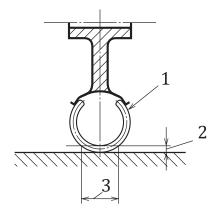


Figure 4 — Example of walking frame

3.17 wheel width

maximum dimension of the tyre of the wheel measured within 5 mm up from the walking surface when the walking frame is unloaded

Note 1 to entry: See Figure 5.



Key

- 1 tyre 3 wheel width
- 2 0 to 5 mm up from the walking surface

Figure 5 — Wheel width measurement

4 Apparatus

- **4.1** Means to apply a force with an accuracy of ± 5 % and with wate of application less than 1 N/s.
- **4.2 Means to measure force** with an accuracy of ±5 % in increments of 1 N.
- **4.3 Means to measure distance** in the range of 0 m to 3 m with an accuracy of ±5 mm or ±2 %, whichever is the greater
- **4.4** Means to measure angles to an accuracy of $\pm 0.5^{\circ}$.
- **4.5 Means to measure torque** with an accuracy of ±5 % in increments of 1 Nm in the range of 0,5 Nm to 10 Nm
- **4.6 A test plane** of sufficient size and stiffness to support the walking frame during testing, such that the whole surface is contained between two imaginary parallel planes 5 mm a part. The test plane can be adjustable, or fixed.
- NOTE 1 A wooden or steel frame with a plywood surface can be used.
- NOTE 2 A test surface of 1,5 m x 2 m is usually of sufficient size.
- **4.7 Stoppers** devices of sufficient height to prevent the walking frame from moving during testing, without interfering with the test or the walking frame.
- **4.8 Equipment for measuring pressure of air** with an accuracy of ±5 %

5 Test conditions

The following conditions shall be applied:

- a) The tests shall be performed at an ambient temperature of 21 °C \pm 5 °C.
- b) Adjustable parts of the walking frame shall be adjusted to the most adverse position according to manufacturer's instruction unless otherwise specified in the test procedure.

- c) The swivelling wheels shall be positioned as if the walking frame is run forward as far as a condition is not specified in the test procedure.
- d) The handles shall be positioned at their maximum distance and maximum angles to provide the most adverse configuration as specified by the manufacturer as far as a condition is not specified in the test procedure. When the longitudinal centreline of the handle and the direction of forward motion are parallel, the angle is 0°. The angle shall always be recorded.
- e) The running brake and parking brake shall not be operated as far as the test procedure does not specify it.
- f) All abnormalities such as breakage on each test shall be recorded and be distinguished from the abnormalities on the subsequent tests.
- g) During the stability tests, the walking frame shall be prevented from sliding or rolling before tilting occurs. The results of the tests shall not be influenced by the means used. If the walking frame is less stable with the height adjustment at a lower height, the least stable position shall be tested.
- h) If the manufacturer offers alternative handle fittings as accessory equipment, all alternatives shall be supplied with the walking frame when tested so that the walking frame can be tested in the least favourable configuration (e.g. extended handles).
- i) Before testing, the walking frame shall be inspected to check conformity with this document. Any apparent defects shall be documented so that they shall not later be recorded as having been caused by the tests.
- j) A walking frame shall be tested in the following sequence:
 - measurements;
 - stability;
 - brakes;
 - handgrips;
 - rubber tips:
 - static strength of the walking frame;
 - static strength of the legs:
 - durability

6 General requirements and test methods

6.1 Risk analysis

The safety of a walking frame shall be assessed by the manufacturer by identifying hazards and estimating the risks associated with them using the procedures specified in ISO 14971. If relevant, ISO 12100 can be used additionally.

When a walking frame is intended by the manufacturer to be used in combination with other devices, the risks shall be assessed by the manufacturer.

NOTE 1 In the case of certain disabilities, there can be a need for higher levels of safety for equipment used to offset the effects of that disability.

NOTE 2 For precise information on the hazard causes a risk, refer to Annex A.

6.2 Walking frames that can be dismantled

If it is intended that a walking frame can be dismantled for storage or transportation, it shall not be possible to reassemble it in a manner that presents a hazard. Hazard condition should be checked by disassembling and re-assembling the walking frame according to the manufacturer instructions.

The fasteners that are loosened or removed to allow dismantling shall not be single use fasteners.

NOTE Single use fasteners include but are not limited to self-locking nuts/screws, wood screws and self-tapping screws. Bolts are examples of fasteners that can be used more than once.

6.3 Fasteners

All load-bearing fasteners shall be either self-locking or fitted with a locking device to prevent inadvertent detachment.

6.4 User mass/Load limits

The maximum user mass shall be declared by the manufacturer. For load carrying accessories, the load capacity of the accessories shall be declared by the manufacturer.

6.5 Structure requirements

A walking frame shall be designed to be manoeuvrable for indoor or outdoor use or a combination of the two:

For indoor use on a level surface

- the width of reciprocating walking frames, when reciprocated, shall be not less than 90 % of maximum width,
- the front wheel diameter shall be greater or equal to 75 mm, and
- the walking frame shall be equipped with parking brakes operating on two wheels. Rubber tips are deemed to be such parking brakes.

For outdoor use

- the front wheel diameter shall be greater or equal to 180 mm,
- the wheel width shall be greater or equal to 22 mm, and
- the walking frame shall be equipped with brakes operating on two wheels. The user shall be able to manipulate the brakes when walking. Rubber tips are deemed to be such brakes.

6.6 Brakes

6.6.1 Requirements

When tested in accordance with the test method in <u>6.6.2</u>, the walking frame shall not move more than 10 mm in 1 min.

If the effectiveness of the brake will be reduced by wear, it shall have means for the compensation of wear.

Brake performance shall not be adversely affected by folding, unfolding or adjusting actions. If readjustment of the brakes is necessary following an adjustment action of the walking frame, tools shall not be required (e.g. height adjustment).

6.6.2 Test method

All brakes shall be tested simultaneously. If either brake-operating device acts on both wheels (central brakes), each of the brake-operating device shall be tested separately.

The walking frame shall be placed with its tips and wheels on a test plane specified in 4.6. Position the walking frame so that a line through the axles of the wheel/tip is parallel $\pm 3^{\circ}$ to the axis of tip of the test plane. Apply the loading force vertically to the walking frame at the midpoint of the line joining the front handgrip reference points on the two handgrips.

For a user mass of 100 kg, the loading force shall be 500 N \pm 10 N. If the maximum user mass specified for the walking frame deviates from a user mass of 100 kg, the loading force shall be 5,0 N per kilogram of the maximum user mass \pm 2 %. The load shall be no less than 175 N \pm 3,5 N.

Activate the brakes by applying the force specified in <u>Table 3</u> to each of the brake-operating devices along the grip distance. Tilt the plane to an angle of 6° to test the forward direction braking performance (<u>Figure 7</u>). The friction between the braking wheels and the top surface of the plane shall be such that the wheels do not slide. Remove the stops. Leave the walking frame for 1 min. If the wheels turn, record the time for the walking frame to move 10 mm.

6.7 Handgrip

The handgrip width shall be no less than 20 mm and not more than 50 mm. This shall be checked by measurement.

NOTE This requirement is not applicable to anatomic handgrips.

The handgrip shall be securely fixed to the handle of the walking frame.

6.8 Leg section and tip

Where there is no wheel, the leg section shall end in a tip designed to prevent the leg section from piercing through it, when the walking frame is used as intended by the manufacturer.

Where there is no wheel, the tip shall be replaceable.

Where there is no wheel, the (i) shall not cause discolouring of the walking surface.

The part of the tip that contacts the walking surface shall have a minimum diameter of 35 mm.

The rubber tip shall be securely fixed to the leg of the walking frame.

The rubber tip shall fulfil the requirements of ISO 24415-1.

7 Materials

7.1 General

The materials used in a walking frame should not mark, or scratch.

The walking frame materials should not cause discoloration of skin or clothing when the walking frame is in normal use.

Manufacturers should, wherever possible, use materials that can be recycled for further use. It shall be stated in the instructions for use which parts can be recycled.

7.2 Flammability

Risk of flammability that can affect user safety shall be assessed by the manufacturer in the risk analysis. Parts identified by risk of flammability shall be tested according ISO 8191-2. Residual risks should be reported in the instruction.

7.3 Biocompatibility and toxicity

Materials that come into contact with the human body shall be assessed for biocompatibility in accordance with ISO 10993-1.

The assessment shall also take into account the intended use and contact by those involved in user care. The assistive products shall be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the assistive product. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction and other substances of very high concern (SVHCs).

The result of the assessment shall be incorporated in the risk analysis (see 6.1).

7.4 Infection and microbiological contamination

7.4.1 General

The walking frame and its auxiliary parts should be designed to be accessible for cleaning to prevent cross infection.

7.4.2 Cleaning and disinfection

The method and suitable cleaning and/or disinfection materials shall be described in the information supplied by the manufacturer.

NOTE For guidance see B.1.

If a walking frame is intended to be cleaned by automatic washing systems or hand-held jet stream/ steam washing, the details of the procedure, such as temperature, pressure, flow and pH value of the cleaning/rinsing solution shall be described in the instructions for use. Where practicable, the walking frame shall be labelled with appropriate symbols to represent the method of cleaning. See examples of labelling and an example of testing of machine washable walking frame in B.2.

7.5 Resistance to corrosion

The risk of corrosion affecting the safety of the user or an assistant shall be assessed in the risk analysis (see 6.1). Assistive products for walking that are identified to be at risk of corrosion shall be sufficiently protected against corrosion.

The salt spray test in accordance with ISO 9227 with a test duration of 72 hours can be used.

8 Ingress of liquids

If liquid can come unintentionally into any cavities or enclosure, it shall be able to drain through drain holes again.

The hazards that can be caused by the ingress of liquids shall be assessed in the risk analysis (see 6.1).

NOTE Hazards can be risk of corrosion or bacterial growth.

Test if there is a way for the liquid to get out of the enclosure or any cavities by using procedures as in normal use and handling of the product. If possible, tilt the product in different directions to verify this.

9 Temperatures of parts that come in contact with human skin

The risk analysis (see <u>6.1</u>) shall identify hazards and evaluate the risks associated with the surface temperature of parts that can come into contact with human skin during the intended conditions of use.

The risk analysis shall use the following:

- the range of ambient temperatures to be expected during the intended use and foreseeable misuse;
 NOTE These temperatures could include direct exposure to sunshine, extreme cold, saunas, etc.
- b) the ergonomic data on acceptable temperatures of touchable surfaces in accordance with ISO 13732-1;
- c) the use of the walking frame by people with insensitive skin (i.e. cannot feel heat) and/or damaged skin: in this case the maximum temperature shall not exceed 41° C when measured in accordance with the test methods given in ISO 13732-1; except that
 - 1) if a manufacturer cannot meet this requirement without impairing the intended performance of the walking frame, each product should be supplied with a warning identifying which surfaces may reach a higher temperature than that specified and description of the precautions necessary to offset the increased risk; and
 - 2) if a manufacturer cannot meet the surface temperature requirement, the reasons shall be set out in the technical documentation.

10 Safety of moving parts

10.1 Squeezing

If the intended purpose cannot be achieved without a hazard such as risk of squeezing (e.g. the elbow or knee flexion of limb prothesis)

- a) any moving parts that constitute a safety hazard shall be provided with guards that can only be removed by the use of a tool or.
- b) the gap between exposed parts of a walking frame that move relative to each other shall be maintained throughout the range of movement at less than the minimum value or more than the maximum value set out in Table 1.

These measurements shall be done before and after any relevant strength, durability and impact testing.

To avoid Safe distances for adults Safe distances for childrena Finger traps Less than 8 mm or Less than 4 mm or more than 25 mm more than 25 mm Less than 35 mm or Less than 25 mm or Foot traps more than 120 mm more than 120 mm Less than 120 mm or Head traps Less than 60 mm or more than 300 mm more than 300 mm Genitalia traps Less than 8 mm or Less than 8 mm or more than 75 mm more than 75 mm Also includes adults with a height of less than 146 cm, or a mass of less than 40 kg, or a BMI of less than 17.

Table 1 — Safe distances between moving parts

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

10.2 Mechanical wear

Parts subject to mechanical wear likely to result in a safety hazard shall be accessible for inspection, unless it is intended to be replaced by a service interval specified by the manufacturer.

11 Prevention of traps for parts of the human body

11.1 Holes and clearances

Holes in and clearances between stationary parts that are accessible to the user and/or assistant during the intended use of a walking frame shall be as specified in <u>Table 2</u>.

These measurements shall be done before and after any relevant strength, durability and impact testing.

To avoid	Safe distances for adults	Safe distances for children ^a
Finger traps	Less than 8 mm or more than 25 mm	Less than 5 mm or more than 12 mm
Foot traps	Less than 35 mm or more than 100 mm	Less than 25 mm or more than 45 mm
Head traps	Less than 120 mm or more than 250 mm	Less than 60 mm or more than 250 mm
Genitalia traps	Less than 8 mm or more than 75 mm	Less than 8 mm or more than 75 mm
^a Also includes adults with a height of less than 146 cm, or a mass of less than 40 kg, or a BMI of le		

Table 2 — Safe distances between stationary parts

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

For stationary parts that can cause a trap, manufacturers shall take into consideration those parts of the body that are at risk. A warning and instructions on how to operate the assistive product for walking safely shall be provided in the instructions for use.

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

NOTE A force might cause a hole/clearance to widen. This can then cause a failure, as specified in <u>Table 2</u>

11.2 V-shape openings

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

12 Folding, adjusting and locking mechanisms

12.1 General

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

If a walking frame incorporates folding and/or adjusting mechanisms it shall conform to <u>Clause 10</u> and <u>Clause 11</u>.

If the walking frame is height adjustable, the increments shall not exceed 25 mm.

Adjustments shall be securely fixed when in use.

The maximum allowable elongation shall be clearly marked.

After the durability test (see $\frac{17.3}{}$), the adjustment/folding mechanisms shall operate as intended by the manufacturer.

Folding walking frames shall lock into working position when unfolded.

12.2 Folding mechanisms

To avoid a hazard where parts of the body can be trapped when the walking frame is folded, the following shall be assessed:

- the walking frame shall incorporate means to protect the user from trapping and/or squeezing hazards; or
- the gap between exposed parts of a walking frame that move relative to each other shall be maintained throughout the range of movement at less than the maximum value or more than the maximum value set out in Table 1; or
- if the intended purpose of a walking frame cannot be met without a hazard such as squeezing, a warning and instructions on how to operate the walking frame safely shall be provided in the instructions for use.

If guards are applied, the design of a guard shall take into consideration the forces that can be applied in normal use.

12.3 Locking mechanisms

The locking mechanisms shall be capable of being securely locked when the walking frame is in any fixed working configuration. It shall also be capable of being securely locked when folded if it constitutes a risk for the user or assistant. It shall be protected against unintended release.

13 Lifting and carrying handles

13.1 General

Manufacturers should note that national or other requirements can demand test loads different to the following.

If a walking frame or a part of a walking frame has a mass of 10 kg or more and the intended purpose is for it to be portable or to be handled according to manufacturer's instructions, it shall either

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

13.2 Requirement

If a walking frame incorporates carrying handles or grips, they shall not become detached from the walking frame and there shall not be any permanent distortion, cracking or other evidence of failure when tested as specified in 13.3.

After the completion of the test, the walking frame shall operate as intended by the manufacturer.

13.3 Test method

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

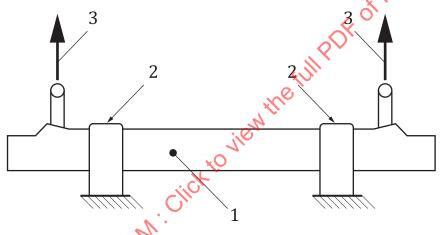
If a walking frame has more than one handle or grip, determine the force on each handle or grip when the walking frame is carried or lifted in the intended manner.

On each handle or grip, determine the force necessary to carry the walking frame in the intended manner with a tolerance of ±3% If there is more than one intended manner determine the highest force.

Restrain the walking frame from being lifted or moved during the following test. Apply a force to each handle or grip, equal to twice that determined above with a tolerance of $\pm 3\%$ uniformly distributed over a 70 mm ± 5 mm length in the centre of the handle or grip, avoiding shock (see Figure 6).

Maintain the force for at least 60 s.

Remove the force and the restraints and inspect the walking frame for damage and satisfactory operation.



Key

- 1 walking frame
- 2 restraints
- 3 test force

Figure 6 — Carrying handle test (example)

14 Surfaces, corners and edges

If not required for the intended function for a walking frame, all accessible edges, corners and surfaces shall be smooth and be free from burrs and sharp edges.

If not required for the intended function, the walking frame shall not have protruding parts. Where possible, necessary protruding parts shall have protection to prevent injury and/or damage.

15 Static stability

15.1 Requirements for static stability

When tested in accordance with the forward-direction stability test (15.2.2), the angle of the test plane at the point of walking frame tilting shall be not less than 10.0° from the horizontal.

When tested in accordance with the rearward-direction stability test (15.2.3), the angle of the test plane at the point of walking frame tilting shall be not less than 7,0° from the horizontal.

When tested in accordance with the sideway-direction stability test (15.2.4), the angle of the test plane at the point of walking frame tilting shall be not less than 3,5° from the horizontal.

It is acknowledged that a reciprocal walking frame cannot meet this sideways stability requirement. Therefore, an analysis of the risks related to the instability shall be assessed by the manufacturer, and appropriate guidance and warnings on limitations for use shall be given. As a minimum the reciprocal walking frame shall meet the stability requirements in its fixed neutral position.

15.2 Test method for static stability

15.2.1 General requirement

The walking frame shall be tested in the least stable configuration as described in Clause 5.

15.2.2 Forward-direction static stability test

The forward-direction static stability test shall be performed as follows:

The walking frame shall be placed with its tips and/or wheels on a test plane that can be tilted from the horizontal with the centreline of the hinges parallel to the line joining the tips and/or wheels of the front legs, and at right angles to the normal direction of movement when the walking frame is in use (Figure 7). The loading force shall be applied vertically to the walking frame. The loading line shall remain vertical and pass through the midpoint of the line joining the front handgrip reference points on the two handgrips.

A static force of 250 N ± 5 N shall be applied. The test plane is tilted and the maximum angle of the test plane at the point of the walking frame tilting is recorded. Accuracy of measurement shall be less than or equal to ±0,5°.

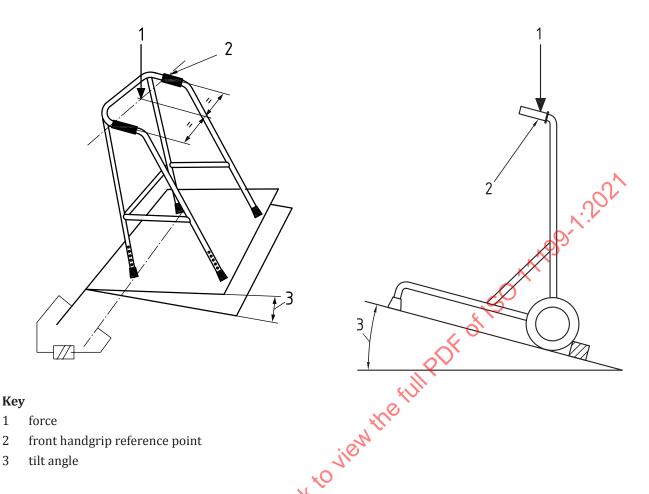


Figure 7 — Loading geometry for forward-direction static stability test

15.2.3 Rearward-direction static stability test

The rearward-direction static stability test shall be performed as follows.

The walking frame shall be placed with its tips and/or wheels on a test plane that can be tilted from the horizontal with the centreline of the hinges parallel to the line joining the tips and/or wheels of the rear legs, and at right angles to the normal direction of movement when the walking frame is in use (Figure 8). The loading force shall be applied vertically to the walking frame. The loading line shall remain vertical and pass through the midpoint of the line joining the rear handgrip reference points on the two handgrips.

A static force of 250 N \pm 5 N shall be applied. The test plane is tilted and the maximum angle of the test plane at the point of the walking frame tilting is recorded. Accuracy of measurement shall be less than or equal to $\pm 0.5^{\circ}$.

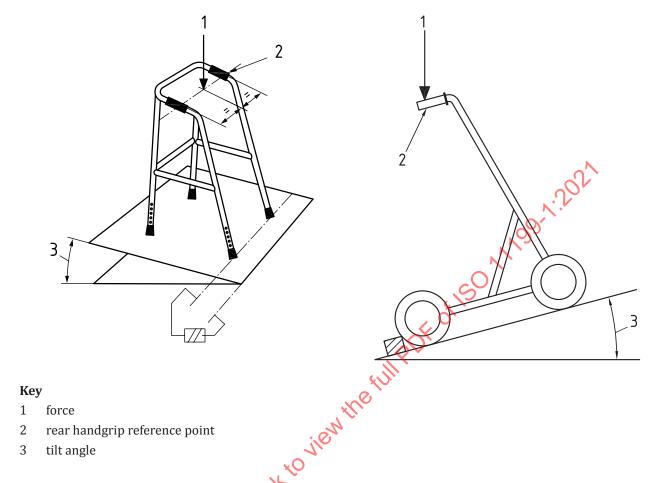


Figure 8 — Loading geometry for rearward-direction static stability test

15.2.4 Sideway-direction static stability test

The sideway-direction static stability test shall be performed as follows.

The walking frame shall be placed with its tips and/or wheels on a test plane that can be tilted from the horizontal with the centreline of the hinges parallel to the line joining the tips and/or wheels of the front and rear legs on the same side of the walking frame as is the loading handgrip (Figure 9). The loading force shall be applied vertically to the walking frame through a point halfway between the front and the rear reference points of that handgrip nearest to the hinges of the tilting test plane.

A static force of 250 N \pm 5 N shall be applied. The plane is tilted and the maximum angle of the plane at the point of walking frame tilting is recorded. Accuracy of measurement shall be less than or equal to $\pm 0.5^{\circ}$. If it is not symmetric, sideway stability shall be tested on both handgrips in this manner and the lower value found shall be recorded as the sideway stability of the walking frame.

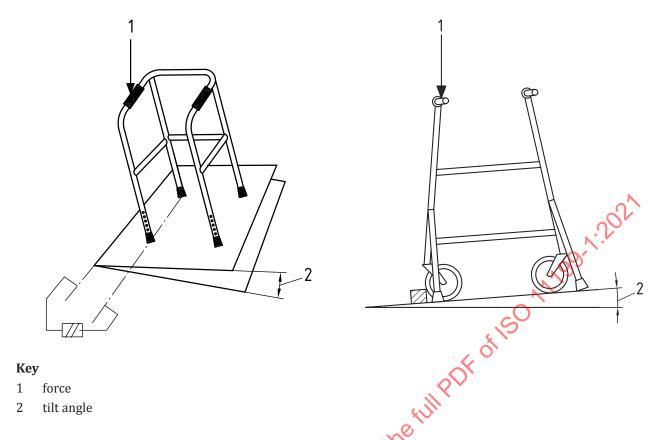


Figure 9 — Loading geometry for sideway-direction static stability test

16 Static strength

16.1 Static strength of walking frame

16.1.1 General requirement

The walking frame shall be tested in the most adverse condition as described in <u>Clause 5</u>.

16.1.2 Requirements for static strength of walking frame

No part of the walking frame shall crack or break after the test (16.1.3).

16.1.3 Test method for static strength of walking frame

The static strength test for walking frame shall be performed as follows.

The walking frame shall be placed stationary with its tips and/or wheels on the test plane. A vertical loading force shall be applied to the walking frame as shown in Figure 10.

The loading force shall be 1 500 N \pm 30 N. If the maximum user weight specified for the walking frame deviates from the standard maximum user weight of 100 kg, a force of 15,0 N per kilogram of maximum user weight, \pm 2%, shall be applied. The load shall be not less than 525 N \pm 10,5 N.

The loading force shall be gradually applied over a minimum period of 2 s up to maximum force. This maximum force shall be maintained for a minimum of 5 s.

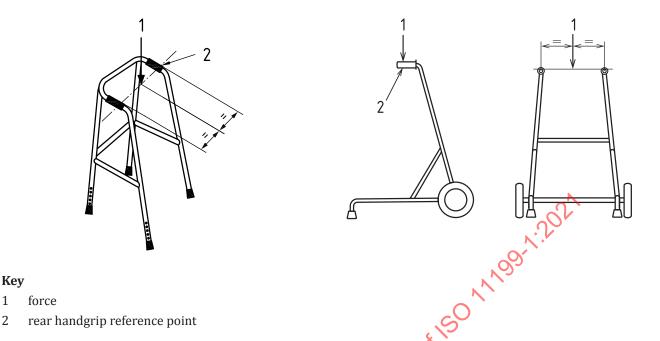


Figure 10 — Loading geometry for walking frame static strength and durability test

16.2 Static strength for the legs with tip

16.2.1 General requirement

1

2

The walking frame shall be tested in the most adverse condition as described in <u>Clause 5</u>.

16.2.2 Requirements for static strength of the legs with tip

No leg of the walking frame shall crack, break or show any permanent set of more than 15 mm measured at the end of the leg, after the test (16.2.3).

16.2.3 Test method for static strength of the legs with tip

Static strength test for legs with tip shall be performed as follows.

A loading force shall be applied in turn to each of the legs of the walking frame. The loading force shall be applied at right angles to the leg at a point 10 mm further out than the lower end of the leg, and directed towards the centre of the frame. This is achieved by removing the rubber tip and inserting a tightly fitting plug up to a maximum of 100 mm into the tubing comprising the lower part of the leg. This plug shall protrude more than 10 mm outside the leg, in order to receive the loading force.

The leg being tested shall be supported as near the lower brace as possible on the handgrip side of the brace, and at a point near the top of the walking frame (see Figure 11).

The loading force shall be 300 N \pm 6 N. The loading force shall be gradually applied over a minimum period of 2 s up to maximum force. This maximum force shall be maintained for a minimum of 5 s.

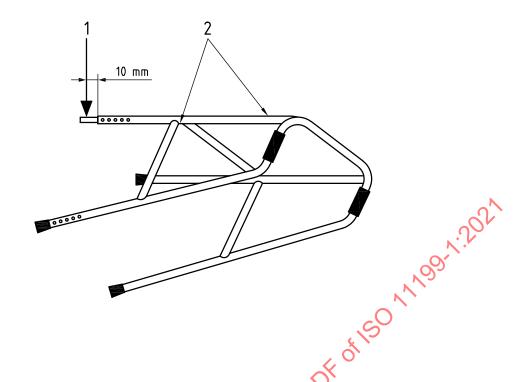


Figure 11 — Loading geometry for walking frame legs static strength test

17 Durability test

Key

2

force

supports

17.1 General requirement

The walking frame shall be tested in the most adverse condition as described in the <u>Clause 5</u>.

17.2 Requirement for durability

No part of the walking frame shall crack or break, and the lock for fixing shall not be loosened, after the test (see 17.3).

17.3 Test method for durability

Durability test for walking frame shall be performed as follows.

The walking frame shall be placed with its tips and/or wheels on a test plane. The loading force shall be applied vertically to the walking frame as shown in <u>Figure 10</u>. The loading line shall pass through the midpoint of the line joining the rear handgrip reference points of the two handgrips.

A cyclic force of 800 N \pm 16 N shall be applied. If the maximum user weight specified for the frame deviates from the standard maximum user weight of 100 kg, a force of 8,0 N per kilogram of maximum user weight, \pm 2%, shall be applied. The load shall be not less than 280 N \pm 5,6 N.

The time of loading applied shall not be shorter than 1 s.

The number of cycles shall be 200 000.

As the wheels are not loaded when they rotate, the rotation of the wheels during the durability test is not needed.

18 Ergonomic principles

An assistive product for walking shall be designed to the ergonomic principles set out in EN 614-1+A1, taking into account the special needs of the person with a disability for whom the assistive product is intended.

An assistive product for walking can be used not only by whom it is primarily intended for, but also by an assisting person. The ergonomic principles set out in EN 614-1+A1 shall apply to all involved persons.

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

- a) the distance between any handle (part intended to be grabbed) requiring an operating force of more than 10 N and any construction part of the assistive product shall not be less than 35 mm;
- b) the distance between any upper surface of a pedal (in its operating position) and any other part of the assistive product shall have a vertical toe clearance of not less than 75 mm;
- c) the diameter of any operating handles and/or knobs requiring an operating force of more than 10 N shall be between 19 mm and 43 mm;
- d) for assistive products operated from a standing position, pedals (tipping aid) shall be placed not more than 300 mm above the surface of the floor;
- e) for assistive products operated from a standing position hand operated controls shall be placed at a height of 800 mm to 1 200 mm above the surface of the floor;
- f) handles for pushing and/or pulling shall be placed at a minimum height of 900 mm;
- g) for a walking frame operated from a sitting position, controls intended to be operated by the occupant while seated shall be within the occupant's reach space;
- h) the operating forces or torques required for those parts of the walking frame that are designed to be operated by fingers, hands/arms or feet shall not exceed the values in <u>Table 3</u>.

Table 3 — Operating forces

Operation	Force/torque
operation by using a finger	5 N
operation by using a hand/arm (pushing)	60 N
operation by using a hand/arm (pulling)	40 N
operation by using a foot	300 N
operation by turning	1,9 Nm
rotation of seat surface	60 N

19 Packaging

The hazards that can be caused by inadequate protective packaging shall be assessed in the risk analysis (see 6.1).

NOTE For guidance, see Annex B.

20 Information supplied by the manufacturer

20.1 General

The information supplied by the manufacturer comprises the data in the instructions for use and/or on the label.

ISO 11199-1:2021(E)

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

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

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

In addition, the manufacturer, should provide the information in the instructions for use in two separate sections: user and service information as specified in 20.2. and 20.3. These may be provided as separate printed documents or in other forms of media to meet the needs of individual users or their assistants.

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

20.2 Information marked on the product

Each walking frame shall be clearly and indelibly marked with following:

- a) manufacturer's model identification name and/or number;
- b) maximum user mass:
- c) name or trade name and address of the manufacturer or authorized representative according to local requirements;
- d) year and month of manufacture;
- e) maximum safe working load (to be marked on the accessories);
- f) maximum allowed angle between the longitudinal centre line of the handle and the direction of motion, if the handles are sideways adjustable;
- g) (if there is no mechanical stop) the maximum extension position of height adjustment;
- h) all information shall as far as possible be available in pictogram in accordance with ISO 7000 and ISO 15223-1.

20.3 Instruction manual

Instruction manual shall contain the followings for the walking frame:

- a) information on how to obtain the user information in a format appropriate for use by people with visual, reading or cognitive disabilities;
- b) a description of the intended use and the intended environment;
- c) the intended user;
- d) maximum user mass;
- e) maximum safe working load for load carrying accessories;
- f) minimum and maximum height of the walking frame;
- g) maintenance instructions, if applicable;
- h) if the walking frame is intended to be cleaned, a description of the method and suitable cleaning materials, including precautions needed to avoid corrosion, if applicable;
- i) if the walking frame is intended to be disinfected, a description of the method and suitable materials, including any precautions needed to avoid corrosion, if applicable;