INTERNATIONAL STANDARD

ISO 11199-2

Third edition
2021-07

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

Part 2: Rollators

Produits d'assistance à la marche manipulés avec les deux bras — Exigences et méthodes d'essai —

Partie 2: Déambulateurs

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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 third edition cancels and replaces the second edition (ISO 11199-2:2005), 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;

— subclause 16.3 on strength of backrest was added;

— Clause 6 on general requirements for assistive products 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 rollator can be used when a person needs assistance when walking. The rollator can provide stability when walking and standing and reduce the risk of falling. Rollators are designed to support the user inside a frame to carry the user's weight. Rollators can be equipped with a resting seat, backrest and/or shopping bag. Rollators are not intended to be moved with the user on the seat like a wheelchair. The seat is provided as a resting seat with brakes engaged.

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

Part 2: Rollators

1 Scope

This document specifies requirements and test methods of rollators being used as assistive products for walking with wheels, 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 every-day use of rollators as assistive products for walking for a maximum user mass as specified by the manufacturer. This document includes rollators specified for a user mass of no less than 35 kg.

This document is not applicable to rollators with horizontal forearm supports, classified as walking tables, for which ISO 11199-3 is applicable.

2 Normative references

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

ISO 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 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

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

3.1
brake
device for slowing or stopping motion of a rollator by contact friction

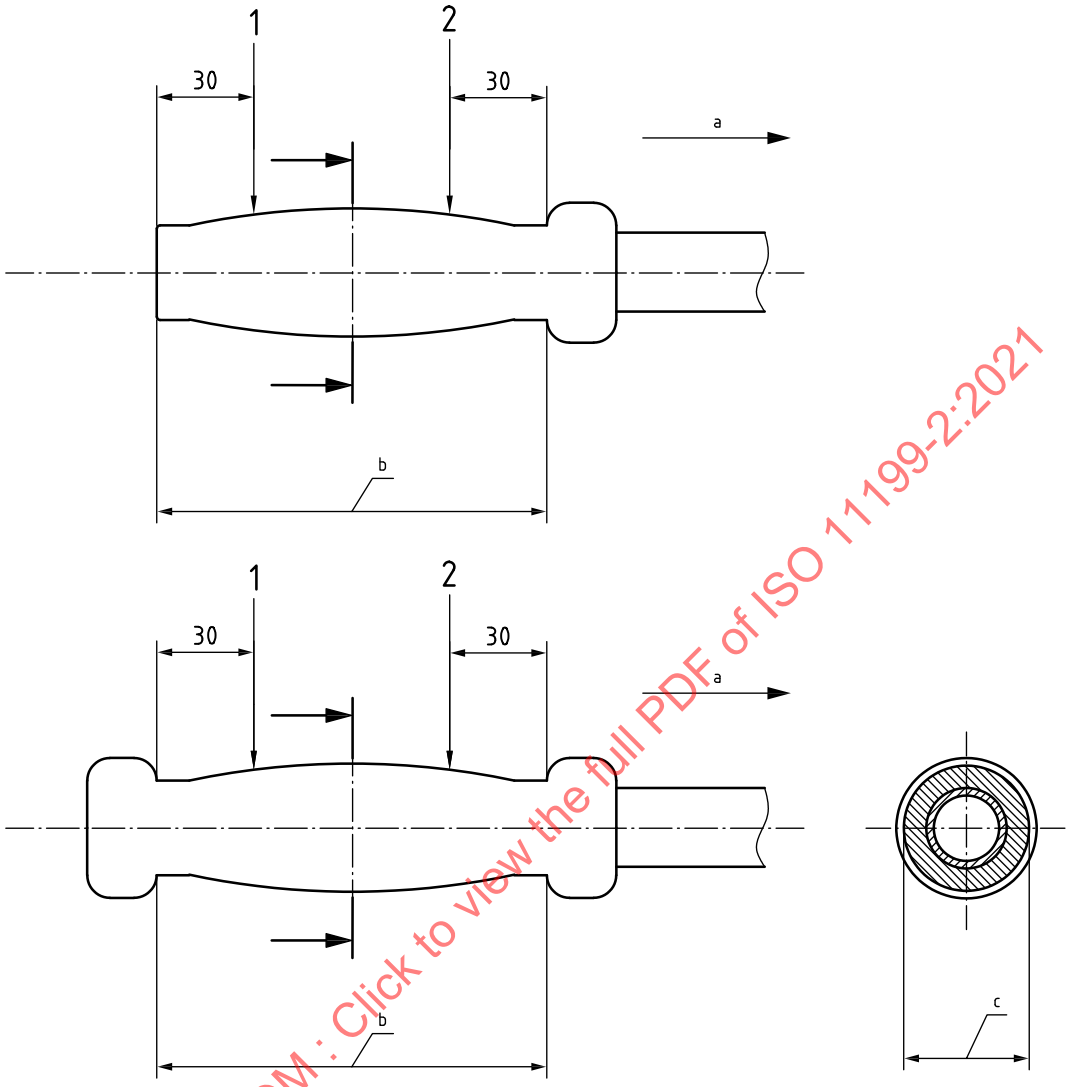
3.2
front handgrip reference point
position on the upper surface of the *handgrip* (3.3) located 30 mm from the front end of the handgrip length

Note 1 to entry: See Figure 1.

3.3
handgrip
part of the rollator that is intended by the manufacturer to be held by the hand when the rollator is in use

Note 1 to entry: See Figure 1.

Dimensions in millimetres



Key

1	rear handgrip reference point	b	Handgrip length.
2	front handgrip reference point	c	Handgrip width.
a	Front.		

Figure 1 — Detailed drawing of a handgrip

3.4
handgrip length
dimension of the *handgrip* (3.3) 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* (3.3) measured at the thickest point where the hand rests

Note 1 to entry: See Figure 1.

3.6
handle
part of the rollator to which the *handgrip* (3.3) 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 rollator.

3.8
maximum width
maximum outside dimension of a rollator when the width is adjusted at its maximum, measured horizontally at right angles to the direction of movement

Note 1 to entry: See Figure 4.

3.9
parking brake
braking system that is intended for keeping the rollator stationary on ground after being activated

3.10
rear handgrip reference point
position on the upper surface of the *handgrip* (3.3) located 30 mm from the rear end of the handgrip length

Note 1 to entry: See Figure 1.

3.11
resting seat
seat for the user to take a rest

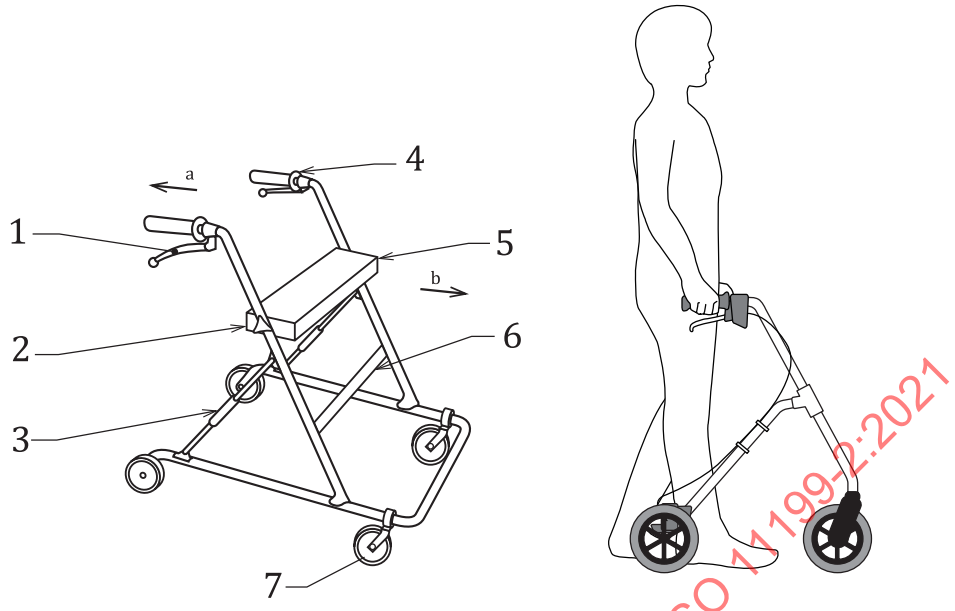
3.12
rollator
walking device, which can be moved by pushing or pulling, that enables a person to maintain stability and balance while walking, that has *handgrips* (3.3) or a transverse bar and three or more castors/wheels without forearm supports

Note 1 to entry: See Figure 2.

Note 2 to entry: Double or more castors/wheels used for one pivot position shall be counted as one castor/wheel.

Note 3 to entry: Included are, for example, rollators with a seat for resting, knee walkers, reverse rollators that are pulled with the opening in the front.

Note 4 to entry: ISO 9999, Classification No. 12 06 06.



Key

1	brake handle	6	bracing member
2	height adjustment mechanism	7	wheels
3	folding mechanism	a	Rear.
4	handle/handgrip	b	Front.
5	resting seat		

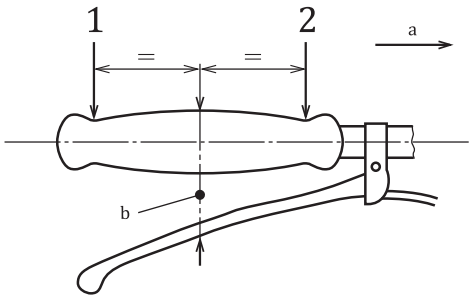
Figure 2 — Example of a rollator

3.13
rollator height
vertical distance from the highest point of the *handle* (3.6) to the ground surface

Note 1 to entry: See Figure 4.

3.14
running brake
braking system that is operated by the user during walking to reduce the speed of the rollator or stop it completely

Note 1 to entry: See Figure 3.



Key

1	rear handgrip reference point	a	Front.
2	front handgrip reference point	b	Brake grip distance.

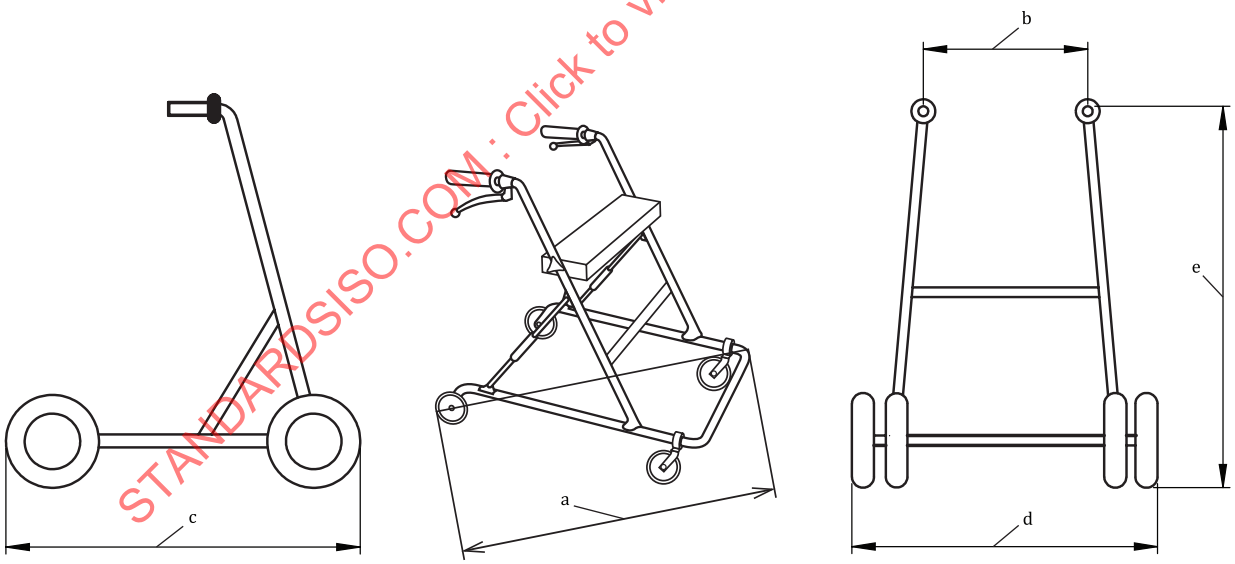
Figure 3 — Brake grip distance

3.15
shopping bag
bag attached on the rollator to carry goods

3.16
turning width
minimum distance between two parallel limiting walls in between which a rollator can be turned 180°

Note 1 to entry: See Figure 4.

Note 2 to entry: The adjustments are to be at their maximum.



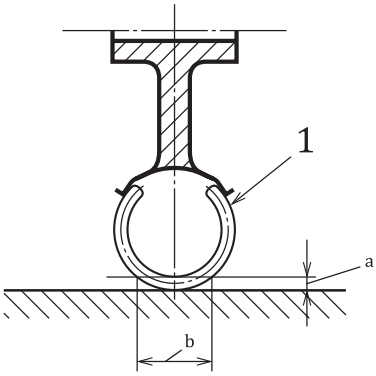
Key

a	Turning width.	d	Width.
b	Width between handles.	e	Height.
c	Length.		

Figure 4 — Dimensions of a rollator

3.17
wheel width
maximum dimension of the tyre of the wheel measured within 5 mm up from the walking surface when the rollator is unloaded

Note 1 to entry: See Figure 5.



Key

1 tyre
a 0 mm to 5 mm up from the walking surface.
b Wheel width.

Figure 5 — Wheel width measurement

4 Apparatus

4.1 Means to apply a force with an accuracy of ±5 % and with a rate 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 ±0,5°.

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 rollator 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 rollator from moving during testing, without interfering with the test or the rollator.

4.8 Equipment for measuring pressure of air with an accuracy of ±5 %.

4.9 Seat loading pad shall be of a rectangular construction 340 mm ± 3 mm width, minimum 200 mm long and the height to be sufficient for the loading pad to be stiff enough to take the test load without

deforming significantly. The base of the seat loading pad that contacts the seat shall be covered with cellular foam of density 75 kg/m^3 ± 15 kg/m^3. The lining shall be 15 mm ± 3 mm thick and be chamfered at approximately 45° at a depth of approximately 10 mm to 15 mm along the side edges.

5 Test conditions

The following conditions shall be applied:

a) The tests shall be performed at an ambient temperature of 21 °C ± 5 °C.

b) Adjustable parts of the rollator shall be adjusted to the most adverse position according to manufacturer's instructions unless otherwise specified in the test procedure.

c) The Swivelling wheels shall be positioned as if the rollator 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 rollator 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 rollator 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 rollator when tested so that the rollator can be tested in the least favourable configuration (e.g. extended handles).

i) Before testing, the rollator 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) One rollator shall be tested in the following sequence:

   — measurements;
   — stability;
   — brakes;
   — handgrips;
   — strength of resting seat;
   — strength of the backrest;
   — static strength of the rollator;
   — durability.

6 General requirements and test methods

6.1 Risk analysis

The safety of a rollator 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 rollator 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 Rollators that can be dismantled

If it is intended that a rollator 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 reassembling the rollator according to the manufacturer's 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 limit

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

6.5 Structure requirements

A rollator 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 front wheel diameter shall be greater or equal to 75 mm;

— the rollator shall be equipped with parking brakes operating on two wheels.

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;

— the rollator shall be equipped with brakes operating on two wheels. The user shall be able to manipulate the brakes when walking;

— a rollator shall be equipped with parking brakes operating on two wheels.

6.6 Brakes

6.6.1 General requirements

All rollators shall have running brakes that are easy to operate by the user when the rollator is in motion.

All rollators that have a resting seat shall have parking brakes that can be integrated with the running brakes.

All rollators that are designed for outdoor use shall have parking brakes that can be integrated with the running brakes.

Maximum grip distance for operating running brakes shall be not greater than 75 mm, measured (see Figure 3, Key 1).

NOTE For rollators with pressure brakes, there is no grip distance.

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 rollator, tools shall not be required (e.g. height adjustment).

6.6.2 Brake effectiveness

6.6.2.1 Requirements

This requirement applies to both, parking brakes and running brakes.

The rollator shall not move more than 10 mm in 1 min if the running brake or the parking brake is activated.

The maximum force to apply and release the brakes shall not exceed

— 60 N for pushing forces, and

— 40 N for pulling forces.

Operating device acts on both wheels (central brakes), each of the brake-operating devices shall be tested separately.

6.6.2.2 Test method

Place the rollator with its wheels on the test plane specified in 4.6. Position the rollator so that a line through the axles of the wheels is parallel ±3° to the axis of tip of the test plane. Apply the loading force vertically to the rollator 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 ± 10 N. If the maximum user mass specified for the rollator deviates from a user mass of 100 kg, the loading force shall be 5,0 N per kilogram of the maximum user mass ±2 %. The load shall be no less than 175 N ± 3,5 N.

Activate the brakes by applying the force specified in Table 3 to each of the brake-operating devices along the grip distance. Tilt the test plane to an angle of 6° +0,5/-0,0. Remove the stoppers. The friction between the braking wheels and the top surface of the plane shall be such that the wheels do not slide. Leave the rollator for 1 min. If the wheels turn, the rollator shall not move more than 10 mm in 1 min.

Repeat the procedure with the rollator facing uphill as in Figure 8.

Measure the forces necessary to set and to release the brakes, to an accuracy of ±2 %, by applying the force along the grip distance line of each brake-operating devices.

If the brake-operating device is a lever that is not operated by squeezing a bar against the handgrip with fingers, the force shall be applied at a point 20 mm inwards from the end of the lever and in a direction perpendicular to the line connecting the point of force application with the pivot of the lever.

6.6.3 Durability of brakes

6.6.3.1 Requirements

The following requirement applies to both parking brakes and running brakes:

No part of the brakes shall crack or break and the effectiveness of the brake shall meet the requirements in 6.6.2.1 after the durability test.

6.6.3.2 Test methods

If the rollator has two identical running or parking brakes, only one of the running and parking brakes shall be tested.

The maximum force to apply and release the brakes for the test shall not exceed

— 60 N for pushing forces, and

— 40 N for pulling forces.

Place the rollator with its wheels on the test plane specified in 4.6. Move the lever of the brake from non-braking position to the braking position for 100 000 cycles at a frequency not greater than 0,5 Hz. The maintenance can be carried out during the testing only in accordance with the manufacture's instructions. The durability test of the parking brake and running brake can be performed sequentially or simultaneously.

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 rollator.

7 Materials

7.1 General

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

The rollator materials should not cause discoloration of skin or clothing when the rollator 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

7.2.1 General

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.

7.2.2 Upholstered parts

If the manufacturer claims that the upholstered parts are resistant to ignition by cigarette, progressive smouldering ignition and flaming ignition shall not occur when the materials used for the upholstered parts of an assistive product are tested in accordance with ISO 8191-2.

7.3 Biocompatibility and toxicity

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

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 that 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 rollator 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.1.1.

If a rollator is intended to be cleaned by automatic washing systems or hand-held jet stream/steam washing, the details of the procedure, such as temperature, pressure, flow and pH value of cleaning/rinsing solution shall be described in the instructions for use. Where practicable, the rollator shall be labelled with appropriate symbols to represent the method of cleaning. See examples of labelling and an example of testing of machine washable rollator in B.1.1.

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 according to 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 6.1) shall identify hazards and evaluate the risks associated with the surface temperature of parts that can come into contact with human skin during the intended conditions of use.

The risk analysis shall use:

a) the range of ambient temperatures to be expected during the intended use and foreseeable misuse;

NOTE These temperatures could include direct exposure to sunshine, extreme cold, saunas, etc.

b) the ergonomic data on acceptable temperatures of touchable surfaces according to ISO 13732-1;

c) use of the rollator by people with insensitive skin (i.e. cannot feel heat) and/or damaged skin: the maximum temperature shall not exceed 41 °C when measured according to 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 rollator, each product should be supplied with a warning identifying which surfaces can reach a higher temperature than that specified and with a 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 rollator 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.

Table 1 — Safe distances between moving parts

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

[a] 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.

For moving parts that can cause squeezing, manufacturers shall take into consideration what part/parts of the body are at risk. The user/user group has to 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 rollator shall be as specified in Table 2.

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

Table 2 — Safe distances between stationary parts

To avoid	Safe distances for adults	Safe distances for children[a]
Finger traps	Less than 8 mm or more than 25 mm	Less than 5 mm or more than 12 mm
Foot traps	Less than 35 mm or more than 100 mm	Less than 25 mm or more than 45 mm
Head traps	Less than 120 mm or more than 250 mm	Less than 60 mm or more than 250 mm
Genitalia traps	Less than 8 mm or more than 75 mm	Less than 8 mm or more than 75 mm

[a] 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.

If the intended purpose of a rollator 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 rollator safely shall be provided in the instructions for use.

For stationary parts that can cause a trap, manufacturers shall take into consideration what parts of the body 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 Table 2.

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 rollator 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 rollator incorporates folding and/or adjusting mechanisms, it shall conform to Clauses 10 and 11.

If the rollator 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 17.2), the adjustment/folding mechanisms shall operate as intended by the manufacturer.

12.2 Folding mechanisms

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

— the rollator shall incorporate means to protect the user from trapping and/or squeezing hazards; or

— the gap between exposed parts of a rollator 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; or

— if the intended purpose of a rollator cannot be met without a hazard such as squeezing, a warning and instructions on how to operate the rollator 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

Locking mechanisms shall be required to maintain the rollator in the folder or in the working configuration if the absence of the locking device presents a hazard to the user. Locking mechanisms shall lock securely and shall be protected from unintended release.

13 Carrying handles

13.1 General

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

If a rollator or a part of a rollator 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 rollator 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 rollator or its part can be lifted safely and describe how they should be handled during lifting, assembly and/or carrying. If practical, the rollator 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 Requirements

If a rollator incorporates carrying handles or grips, they shall not become detached from the rollator 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 rollator shall operate as intended by the manufacturer.

13.3 Test method

If a rollator has one handle or grip, or if a rollator 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.

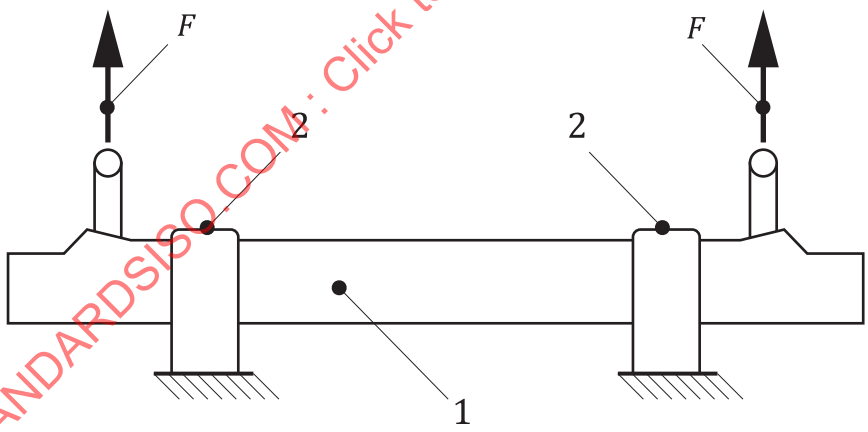
If a rollator has more than one handle or grip, determine the force on each handle or grip when the rollator is carried or lifted in the intended manner.

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

Restrain the rollator 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 ±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 rollator for damage and satisfactory operation.



Key

1 rollator
2 restraints
F test force

Figure 6 — Carrying handle test (example)

14 Surfaces, corners and edges

If not required for the intended function for a rollator, all accessible edges, corners and surfaces shall be smooth and be free from burrs and protruding parts and sharp edges shall be rounded or chamfered.

If not required for the intended function, the rollator 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

The rollator shall not tilt when tested according to 15.2.

In forward direction, the angle of the plane at the point of rollator tilting shall be no less than 15,0° from the horizontal.

In backward direction, the angle of the plane at the point of rollator tilting shall be no less than 7° from the horizontal.

To the sideways direction the angle of the plane at the point of rollator tilting shall be no less than 3,5° from the horizontal.

15.2 Test method for static stability

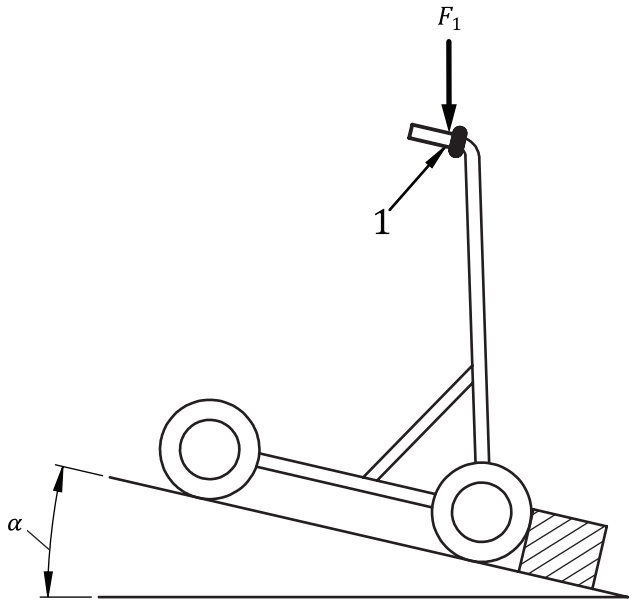
The rollator shall be tested in the least stable configuration as described in Clause 5.

15.2.1 Forward-direction static stability test

Forward-direction static stability test shall be performed as follows.

The rollator shall be placed with its wheels on a test plane that can be tilted from the horizontal with the centreline of the hinges parallel to the line through the axis of the front wheels, and at right angles to the normal direction of movement when the rollator is in use (see Figure 7). The loading force shall be applied vertically to the rollator. 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 shall be tilted and the maximum angle of the test plane at the point of rollator tilting recorded. Accuracy of measurement shall be less than or equal to ±0,5°.



Key

1 front handgrip reference point

F_1 loading force

α tilt angle

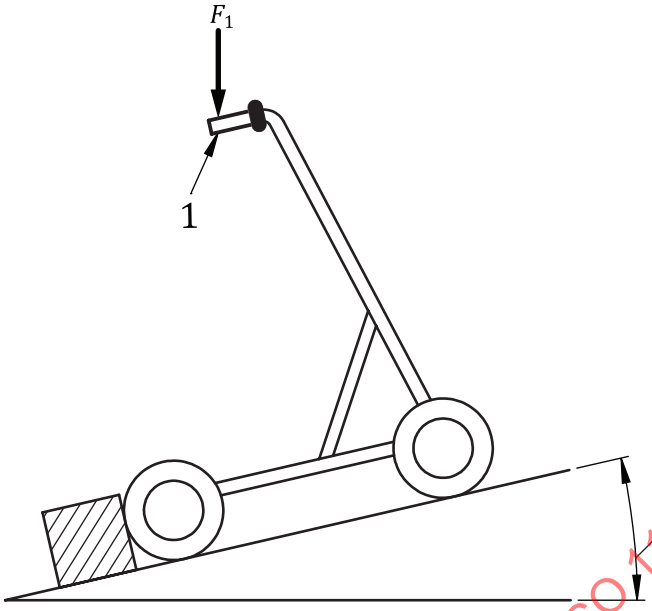
Figure 7 — Loading geometry for forward-direction static stability test

15.2.2 Rearward-direction static stability test

Rearward-direction static stability test shall be performed as follows.

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

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



Key

1 rear handgrip reference point

F_1 loading force

α tilt angle

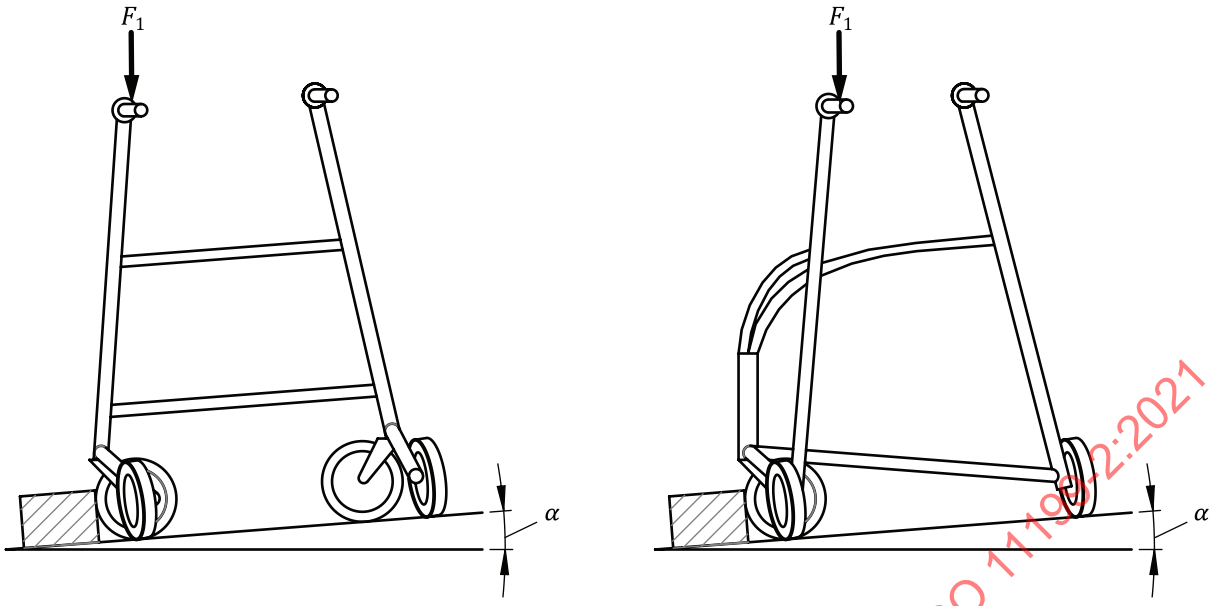
Figure 8 — Loading geometry for rearward-direction static stability test

15.2.3 Sideway-direction static stability test

Sideway-direction static stability test shall be performed as follows.

The rollator shall be placed with its wheels on a test plane that can be tilted from the horizontal with the centreline of the hinges parallel to the line through the centres of the areas of contact between the surface of the plane and the wheels or tips on the same side of the rollator as is the loaded handgrip (see Figure 9). The loading force shall be applied vertically to the rollator through a point halfway between the front and the rear reference points of that handgrip nearest to the hinges of the tilting test plane. The loading line shall always be vertical.

A static force of 250 N ± 5 N shall be applied. The test plane shall be tilted and the maximum angle of the plane at the point of rollator tilting recorded. Sideways stability shall be tested on both handgrips in this manner and the lower value found shall be recorded as the sideways stability of the rollator. Accuracy of measurement shall be less than or equal to ±0,5°.



Key

F_1 loading force

α tilt angle

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

15.2.4 Accessory equipment static stability test

Rollators being supplied with accessories such as a drip holder, basket, tray, shopping bag and/or oxygen cylinder holder shall be tested for static stability in accordance with 15.2.1, 15.2.2 and 15.2.3, depending on where on the rollator the accessories are fixed. Tests shall be performed with each of the accessories and in combination, affixed to the rollator as recommended by the manufacturer under the worst-case conditions for each test. The results of the tests shall be within the limits given in 15.1.

During the tests, the drip holder shall be loaded to maximum capacity, the basket, tray or shopping bag shall be loaded to the capacity specified by the manufacturer and the oxygen cylinder shall be full. If no specification has been given for the basket, tray or shopping bag, a bag of sand exerting a force of 50 N ± 1 N shall be placed, with the sand evenly distributed, in the bottom of the basket, tray and shopping bag.

16 Static strength

16.1 Static strength of resting seat

16.1.1 General

The rollator shall be tested in the most adverse condition as described in Clause 5.

16.1.2 Requirements for static strength of resting seat

No part of the rollator shall crack or break.

16.1.3 Test method for static strength of resting seat

Set the rollator stationary on a flat horizontal test floor. When equipped with a parking brake, apply the brake and hold it.

Place the seat loading pad (see 4.9) on the seat so that the midpoint of the base of the loading pad is vertically aligned with the centre of the resting seat. Gradually apply a vertical loading force of 1200 N ± 24 N, including the force exerted by the mass of the loading pad to the centre of the resting seat. If the maximum user mass specified for the rollator deviates from a user mass of 100 kg, a force of 12,0 N per kilogram of maximum user mass ±2 % shall be applied. The load shall be no less than 420 N ± 8,4 N.

Leave the resting seat loaded for a minimum period of 1 min.

16.2 Static strength of the rollator

16.2.1 General

The rollator shall be tested in the most adverse condition as described in Clause 5.

16.2.2 Requirements for static strength of the rollator

No part of the rollator shall crack or break and the permanent set of the rollator height shall not exceed 1 %.

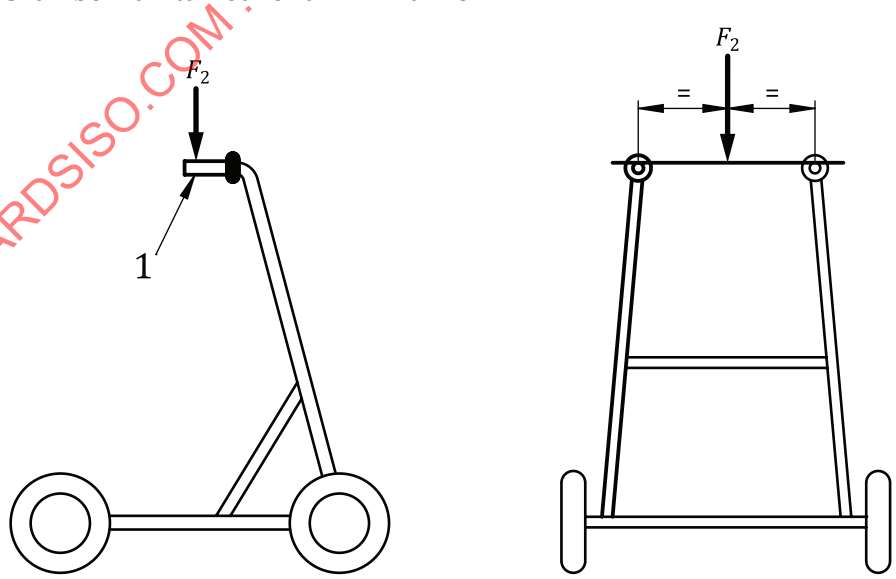
16.2.3 Test method for static strength of the rollator

Measure the rollator height within an accuracy of measurement of ±2 mm before and after performing the loading test. The rollator height reduction shall be recorded.

The loading force shall be applied vertically to the rollator as shown in Figure 10. The loading line shall pass through the midpoint of the line joining the rear handgrip reference points of the two handgrips.

A loading force of 1 200 N ± 24 N shall be applied for a user mass of 100 kg. If the maximum user mass specified for the rollator deviates from a user mass of 100 kg, a force of 12,0 N per kilogram of user mass ±2 % shall be applied. The load shall be no less than 420 N ± 8,4 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 1 min.



Key

1 rear handgrip reference points

F_2 loading force

Figure 10 — Loading geometry for static strength test

16.3 Strength of backrest

16.3.1 General

The rollator shall be tested in the most adverse condition as described in Clause 5.

16.3.2 Requirement for strength of backrest

No part of the rollator shall crack or break.

16.3.3 Test method for strength of backrest

Set the rollator stationary on a flat horizontal test plane.

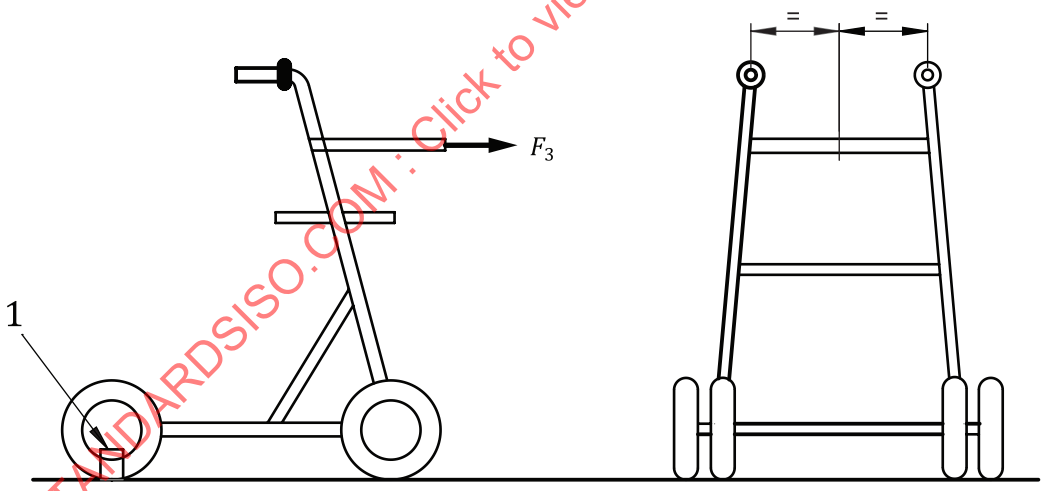
The rear wheels of the rollator shall be secured in such a way that the rollator does not move when the backrest is statically loaded. The static force shall be applied 90° to the backrest surface horizontally. The static force shall gradually be applied to the centre of the backrest, in the worst-case position during normal use (see Figure 11).

The force is applied in a 50 mm wide region in the middle of the backrest. For example, a 50 mm wide lashing strap as described in EN 12195-2.

The force shall be 4,5 N/kg of the maximum user weight ±2 %. The loading force shall not be less than 450 N ± 9 N.

The test force is gradually increased over a minimum period of 2 s until reaching the maximum value. This maximum force shall be maintained for at least 60 seconds.

This test shall be repeated 10 times.



Key

1 fixation point

F_3 static force

Figure 11 — Loading geometry for backrest strength test

17 Durability test

The rollator shall be tested in the least stable position as described in Clause 5.

17.1 Requirement for durability

No part of the rollator shall crack or break and all adjustments and locking devices shall work as intended.

17.2 Test method for durability

The fixation of the rollator shall be arranged in a way to not hinder the free deformation of the frame under the load.

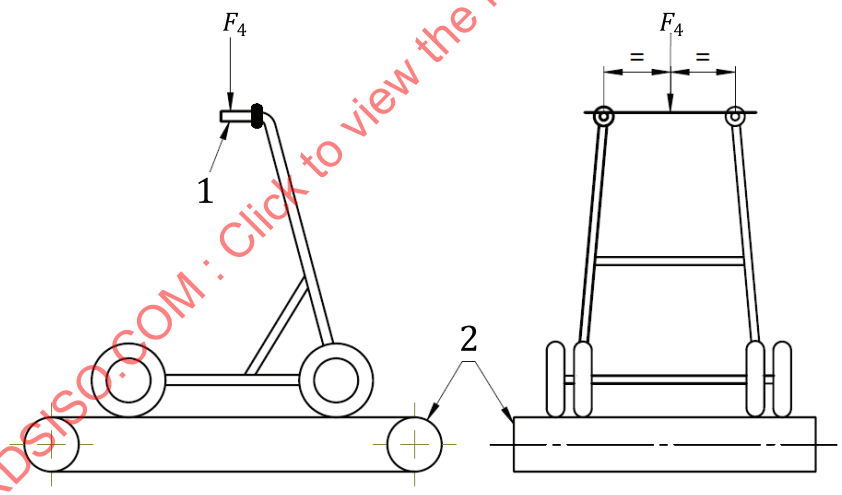
The loading force shall be applied vertically to the rollator as shown in Figure 12. The loading line shall pass through the midpoint of the line joining the rear handgrip reference points of the two handgrips.

The rollator shall be placed with its wheels on a surface travelling at a speed not less than 0,4 m/ loading cycle. If the rollator is equipped with pressure brakes, the test shall be performed on a rigid floor instead of on the travelling surface.

For the durability test either the double-drum test equipment or the running belt test equipment can be used.

NOTE An example of set-up of the fatigue test for a rollator with four wheels is shown in Figure 12.

If the travelling surface is a cylinder, the diameter shall be equal to or greater than 250 mm ± 25 mm and the positioning of any of the rollator wheels shall at all times during the test be such that the vertical line through the wheel centre does not deviate from the vertical plane through the centre of the cylinder by more than ±5 mm.



Key

1 rear handgrip reference points
2 test surface
F_4 force

Figure 12 — Durability test for a rollator with four wheels

A cyclic force of 800 N ± 16 N shall be applied for a user mass of 100 kg. If the maximum user mass specified for the rollator deviates from a user mass of 100 kg, apply a force of 8,0 N per kilogram of maximum user mass ±2 %. The loading force shall be no less than 280 N ± 5,6 N. The waveform of the cyclic loading force shall be of a sinusoidal or smooth kind without exaggerating pulses.

The frequency of the cyclic loading shall not exceed 1 Hz.

The number of cycles shall be 200 000.

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 1200 mm above the surface of the floor;

f) for a rollator operated from a sitting position, controls intended to be operated by the occupant while seated shall be within the occupant's reach space;

g) the operating forces or torques required for those parts of the rollator that are designed to be operated by fingers, hands/arms or feet shall not exceed the values in Table 3.

If the intended purpose of a rollator can only be performed without meeting this requirement, a warning and instructions on how to operate the rollator safely shall be provided in the instructions for use based upon the risk analysis

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.

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 rollator.

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, respectively. These may be provided as separate printed documents or in other forms of media to meet the needs of individual users or their assistants.

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

20.2 Information marked on the product

Each rollator shall be clearly and indelibly marked with following:

a) manufacturer's model identification name and/or number;

b) whether or not the rollator is designed for indoor or outdoor use;

c) maximum user mass;

d) name or trade name and address of the manufacturer or authorized representative according to local requirements;

e) year and month of manufacture;

f) maximum safe working load (to be marked on the accessories);

g) maximum width of the rollator;

h) maximum allowed angle between the longitudinal centre line of the handle and the direction of motion, if the handles are sideways adjustable;

i) 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 rollator:

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 including intended user and the intended environment;

c) maximum user mass;

d) maximum safe working load for load carrying accessories such as basket, tray, shopping bag, etc.;

e) minimum and maximum height of the rollator;

f) maintenance instructions, if applicable;

g) if the rollator is intended to be cleaned, a description of the method and suitable cleaning materials, including precautions needed to avoid corrosion, if applicable;

h) if the rollator is intended to be disinfected, a description of the method and suitable materials, including any precautions needed to avoid corrosion, if applicable;

i) the overall dimensions (width, length and height) of the rollator, expressed in millimetres, and its mass, expressed in kilograms, when it is ready for use and, if applicable, when it is folded or dismantled;

j) the mass expressed in kilograms, if the rollator can be dismantled or has any removable parts that has a mass that is heavier than 10 kilograms;

k) if the rollator is supposed to be used in combination with other products, the manufacturer shall state which products, and how this can be done in a safe way;

l) a list of accessories, detachable parts and materials that the manufacturer has determined as being intended for use with the rollator;

m) whether and how the rollator can be folded or dismantled to assist in storage or transport;

n) the location and the type of identification number/word on the rollator shall be given for the unique identification number of the assistive product;

o) any adjustment or settings required before the rollator can be used and information on how adjustments or settings affect the rollator;

p) information on adjustment possibilities and the competence required to carry out these adjustments;

q) instructions on operation of all controls;

r) instructions on dismantling and re-assembly of the rollator or any removable parts;

s) the positions of points where the component parts can be gripped for safe moving and handling and/or a method for handling during dismantling, assembly or carrying;

t) a warning if surface temperatures can increase / decrease when exposed to external sources of heat (e.g. sunlight, outdoor environment);

u) if the intended purpose of the rollator cannot be met without a hazard (e.g. holes, V-shaped opening), a warning and instructions on how to operate the assistive product safely;

v) if the intended purpose of the rollator cannot be met without a hazard due to moving parts such as squeezing, a warning and instructions on how to operate the rollator safely;

w) how to obtain information about the warranty;

x) warning of the risk of falling from the rollator such as “Incorrect use can lead to hazardous situation – Do not use the products to transport a person”.

20.4 Test report

The test report shall at least contain the following information:

a) unique report number;

b) name and address of the test institution, if needed the accreditation number;

c) the date of issue of the test report;