INTERNATIONAL STANDARD

ISO 11199-2

Second edition
2005-04-15

Walking aids manipulated by both arms — Requirements and test methods —

Part 2: Rollators

Aides à la marche manipulées avec les deux bras — Exigences et méthodes d'essai —

Partie 2: Déambulateurs

Reference number
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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 11199-2 was prepared by Technical Committee ISO/TC 173, *Assistive products for persons with disability*.

This second edition cancels and replaces the first edition (ISO 11199-2:1999), which has been technically revised.

ISO 11199 consists of the following parts, under the general title *Walking aids manipulated by both arms — Requirements and test methods*:

— *Part 1: Walking frames*

— *Part 2: Rollators*

— *Part 3: Walking tables*

Walking aids manipulated by both arms — Requirements and test methods —

Part 2: Rollators

1 Scope

This part of ISO 11199 specifies requirements and methods of testing the static stability braking capabilities, static strength and fatigue of rollators being used as walking aids with wheels, manipulated by the hands, without accessories, unless specified in the particular test procedure. This part of ISO 11199 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 usage of rollators as walking aids, for a maximum user mass as specified by the manufacturer. This part of ISO 11199 includes rollators specified for a user mass of no less than 35 kg.

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

NOTE Recommendations further to the requirements given in this part of ISO 11199 are given in an Annex A.

2 Normative references

The following referenced documents are indispensable for the application 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 9999:2002, *Technical aids for persons with disabilities — Classification and terminology*

EN 1041, *Information supplied by the manufacturer with medical devices*

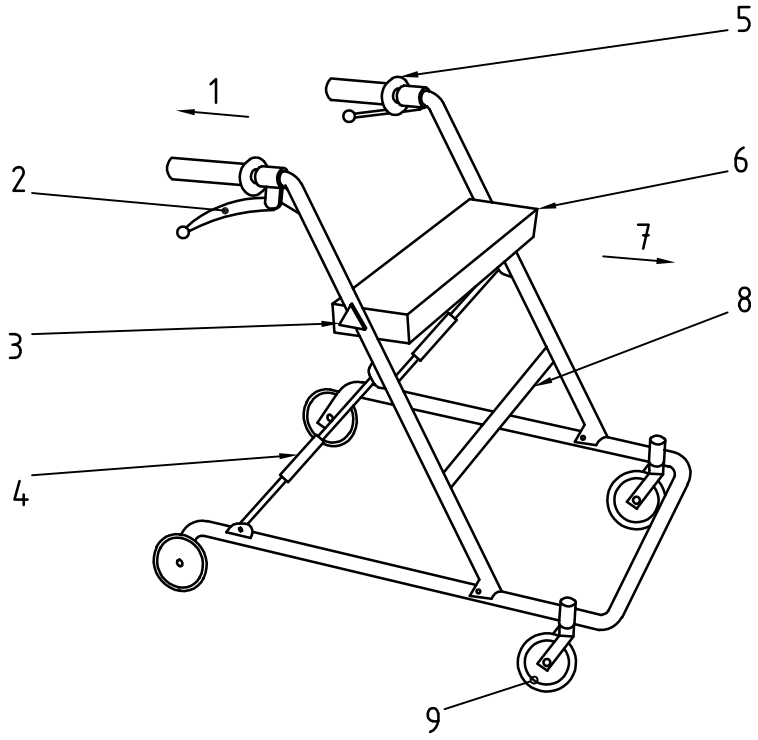
3 Terms and definitions

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

3.1
rollator
walking aids with built-in handgrips and three or more legs of which two or more are having wheels, which provide support whilst walking

See Figure 1.

NOTE Rollators include equipment with a seat for resting, as specified in ISO 9999:2002, Classification No. 12 06 06.



Key

1	rear	6	resting seat
2	brake handle	7	front
3	height adjustment mechanism	8	bracing member
4	folding mechanism	9	wheels
5	handle/handgrip		

Figure 1 — Example of components of a rollator

3.2
user mass
body mass of the person using the product as a walking aid

3.3
maximum length
maximum outside dimension of a rollator when the height adjustment is at its maximum, measured parallel to the direction of straight forward movement when the rollator is in normal use

See Figure 2.

3.4
maximum width
maximum outside dimension of a rollator when all adjustments are at their maximum, measured at right angles to the direction of straight forward movement when the rollator is in normal use

See Figure 2.

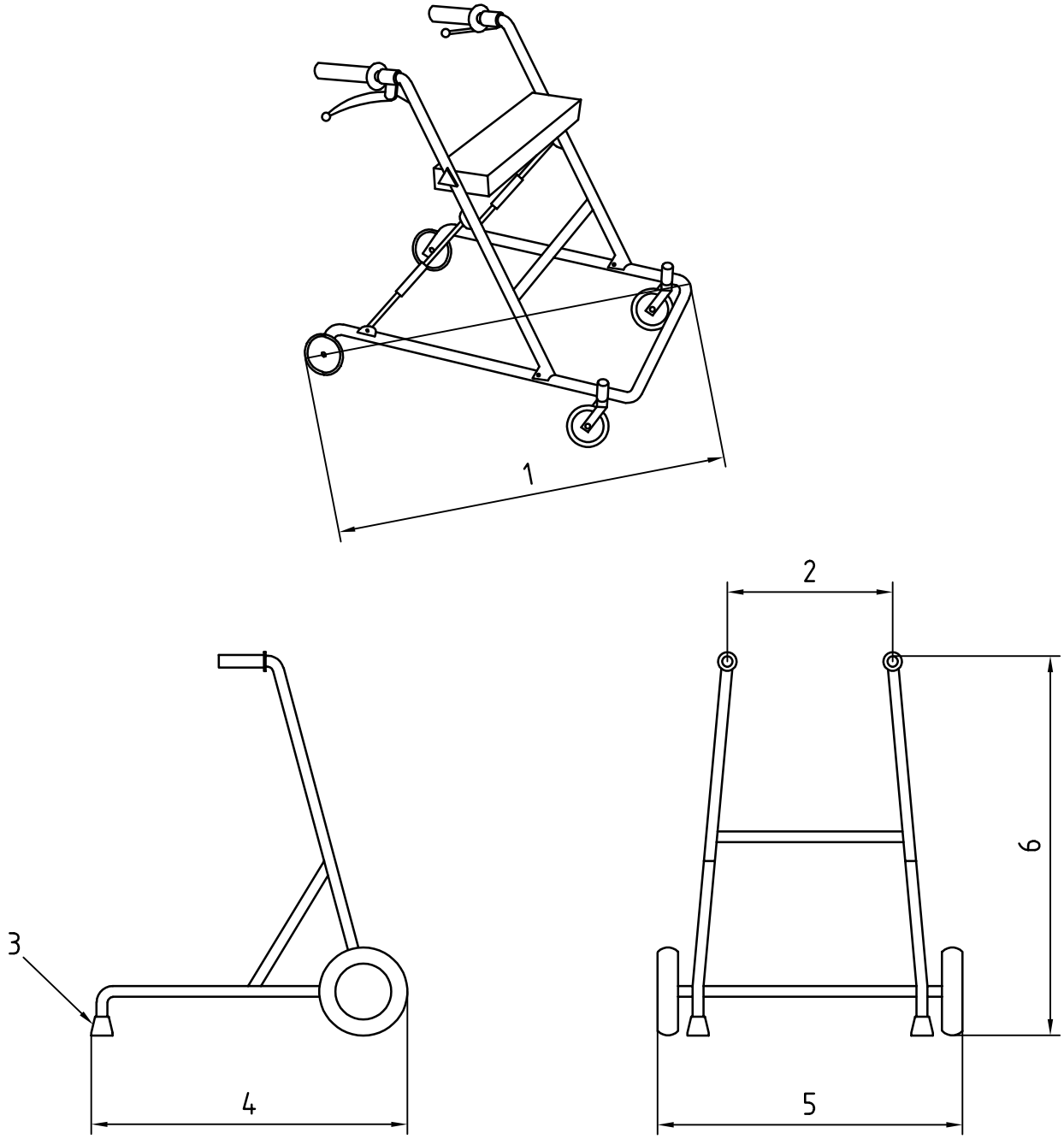
3.5
rollator height
vertical distance from the rear handgrip reference point to the ground

See Figure 2.

3.6
turning width
minimum distance between two parallel limiting walls in between which a rollator can be turned 180° around its own central vertical axis

See Figure 2.

NOTE The adjustments are to be at their maximum



Key

1 turning width
2 width between handles
3 tip
4 maximum length
5 maximum width
6 height

Figure 2 — Nomenclature of maximum dimensions for a rollator

3.7
folded dimensions
height, width and length of the rollator measured with the rollator folded together without the use of tools, all adjustments at their minimum

3.8
handgrip
that part of the rollator which is intended by the manufacturer to be held by the hand when the rollator is in use

See Figure 3.

3.9
handle
that part of the rollator to which the handgrip is attached

3.10
front handgrip reference point
that point on the upper surface of the handgrip located 30 mm inwards from the front end of the handgrip length

See Figure 3.

3.11
rear handgrip reference point
that point on the upper surface of the handgrip located 30 mm inwards from the rear end of the handgrip length

See Figure 3.

3.12
handgrip length
dimension of the handgrip measured longitudinally where the hand rests

See Figure 3.

NOTE Where the front end or the rear end of the handgrip is not clear, the full length of the handgrip that may comfortably support the mass of the user is defined as the handgrip length.

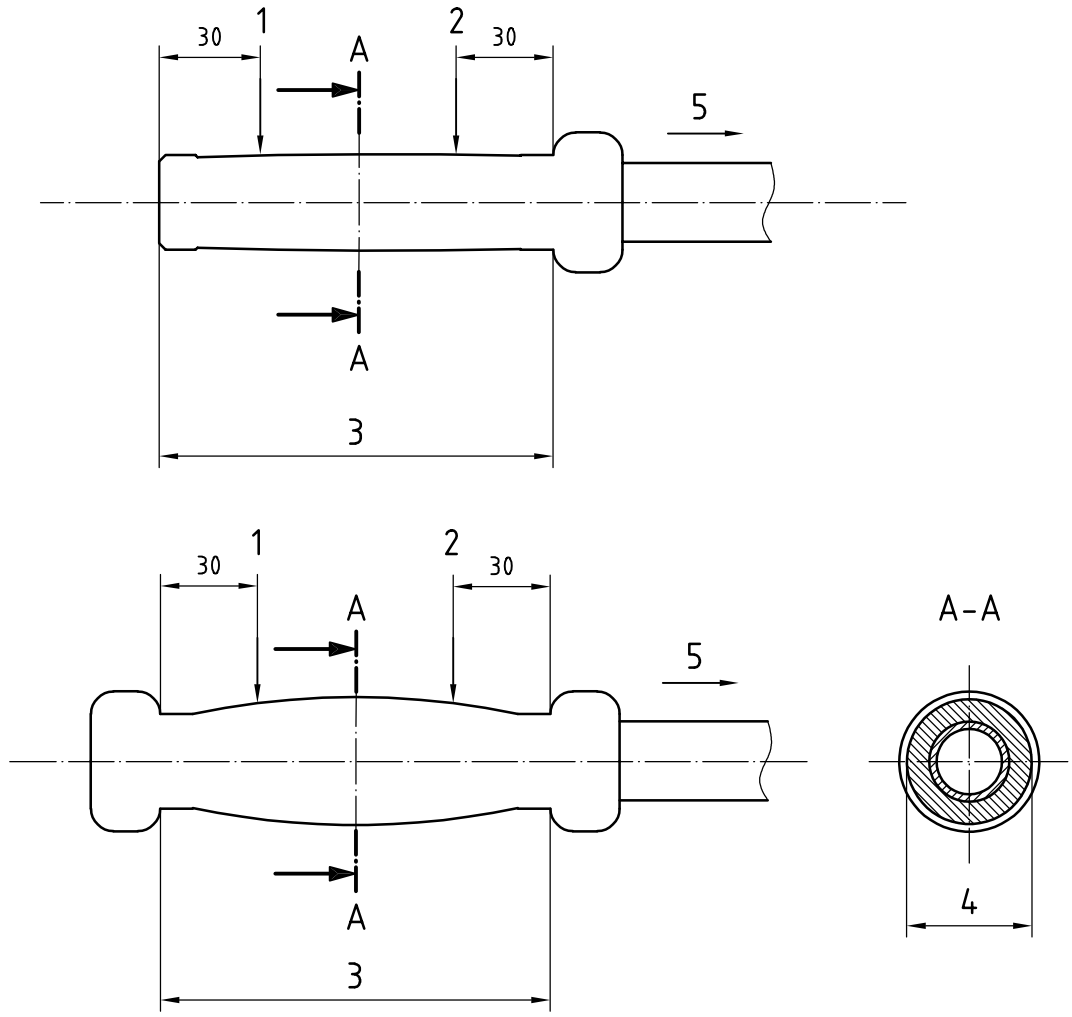
3.13
handgrip width
outside dimension of the handgrip measured horizontally at the thickest point where the hand rests

See Figure 3.

3.14
brake grip distance
distance measured, with the brake handle in the neutral position, at the midpoint of the handgrip length and normal to the centreline of the handle tubing, from the upper surface of the handgrip to the lower surface of the brake handle

See Figure 4.

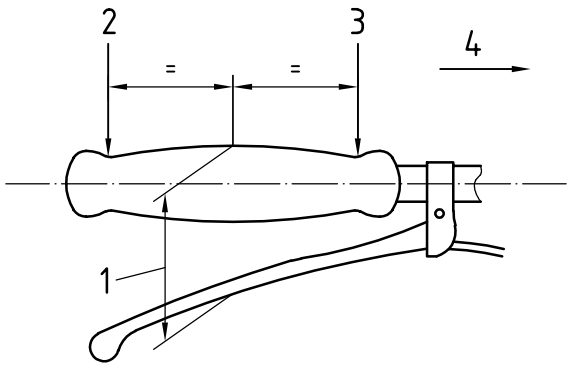
Dimensions in millimetres



Key

1 rear handgrip reference point
2 front handgrip reference point
3 handgrip length
4 handgrip width
5 front

Figure 3 — Detailed drawing of a handgrip



Key

1 brake grip distance
2 rear handgrip reference point
3 front handgrip reference point
4 front

Figure 4 — Brake grip distance

3.15
tips
load-bearing parts without wheels, which are in contact with the ground during use of a rollator

See Figure 2.

NOTE Tips are also used as pressure brakes on some four-wheeled rollators in addition to the wheels.

3.16
forearm support
that horizontal part on which the forearm rests, possibly combined with a handle with handgrip to keep the arm in position

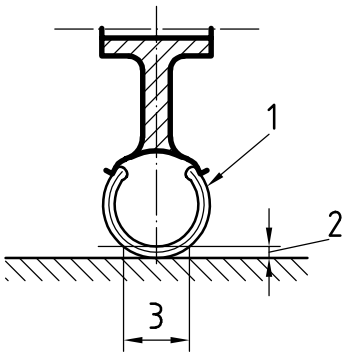
3.17
parking brake
brake that stays engaged after being activated

3.18
running brake
brake that is operated by the user during walking and where the braking effect depends proportionally on the activation force applied

3.19
pressure brake
a running brake that engages when a vertical load is applied on the handgrips or on supporting points of the rollator

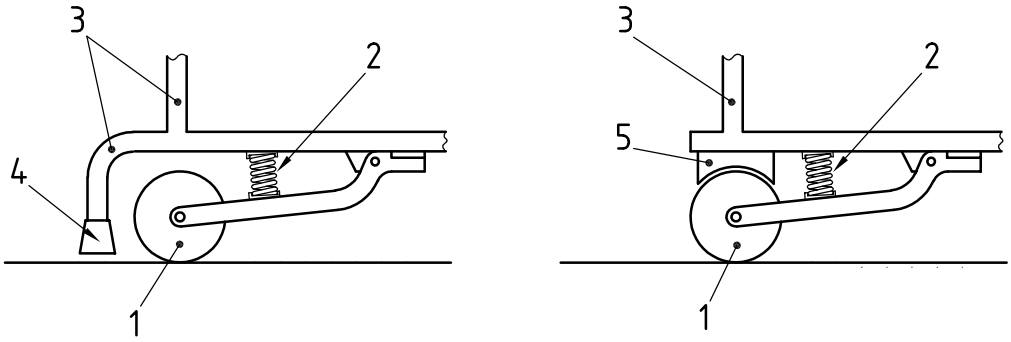
3.20
wheel width
maximum dimension of the tyre of the wheel measured within 5 mm up from the walking surface when the rollator is unloaded

See Figure 5.



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

Figure 5 — Wheel width measurement



Key

1 wheel
2 spring
3 frame
4 rubber tip (brake)
5 brake pad

Figure 6 — Two types of pressure brake with technical details

4 Requirements

4.1 Manoeuvrability

The front wheel diameter shall be no less than 75 mm.

The front wheel diameter of rollators manufactured for outdoor use shall be no less than 180 mm.

The wheel width of rollators manufactured for outdoor use shall be no less than 22 mm.

4.2 Stability

When tested according to the forward stability test (see 5.3), the angle of the plane at the point of rollator tilting shall be no less than 15,0° from the horizontal.

When tested according to the backward stability test (see 5.4), the angle of the plane at the point of rollator tilting shall be no less than 7,0° from the horizontal.

When tested according to the sideways stability test (see 5.5), the angle of the plane at the point of rollator tilting shall be no less than 3,5° from the horizontal.

4.3 Brakes

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

All rollators with more than two wheels and which have a resting seat, or are designed for outdoor use, shall have parking brakes, which may be integrated with the running brakes.

Maximum grip distance for operating running brakes shall be no greater than 75 mm as measured in accordance with 5.7.1.1 (see Figure 4).

When tested according to the running brake test (see 5.7.1), the rollator shall not move more than 10 mm in 1 min.

Maximum force to apply and release parking brakes shall not exceed

a) 60 N pushing force, and

b) 40 N pulling force.

When tested for the parking brake test (see 5.7.2), the rollator 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 re-adjustment of the brakes is necessary following an adjusting action of the rollator, tools shall not be required (e.g. height adjustment).

4.4 Handgrip

The handgrip width shall be no less than 20 mm and not more than 50 mm.

This requirement is not applicable to anatomic handgrips.

The handgrip shall be securely fixed to the handle of the rollator as judged by the inspector.

The handgrip shall be replaceable or easy to clean.

4.5 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 rollator is used as intended by the manufacturer (see 4.7).

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

Where there is no wheel, the tip shall not cause discolouring of the walking surface, as verified by visual inspection.

That part of the tip that contacts the walking surface shall have a minimum diameter of 35 mm. Compliance shall be verified by measurement.

When inspected in accordance with 5.9, the rubber tip shall be securely fixed to the leg of the rollator as judged by the inspector.

4.6 Resting seat

When tested in accordance with 5.10, no part of the rollator shall crack or break.

4.7 Mechanical durability

When tested in accordance with the static loading test (see 5.11), no part of the rollator shall crack or break and the permanent set of the rollator height shall not exceed 1 %.

When tested in accordance with the fatigue test (see 5.12), no part of the rollator shall crack or break.

4.8 Adjusting devices

Each of the height adjustment devices shall be clearly marked with its maximum allowable elongation.

When the walking aid is inspected in accordance with 5.13, the adjustment mechanisms shall operate as intended by the manufacturer.

4.9 Folding mechanism

When the walking aid is in the working position and inspected in accordance with 5.13, the folding mechanism shall stay securely locked, as judged by the inspector.

4.10 Adjustment of handles

The handles may be adjustable but shall be securely fixed when in use and verified by inspection.

On rollators having handles that may be angled or positioned so that they come outside the rollator and jeopardizes the stability of the rollator, either a physical stop shall prevent the unsafe position or a warning showing the safe limits of adjustment shall be fixed on the rollator. The instructions for use shall explain the consequences such an adjustment may have on the stability.

4.11 Materials and finish

The rollator materials shall not cause discolouring of skin or clothing when the rollator is in normal use.

All parts of the rollator shall be free from burrs, sharp edges or projections that could cause damage to clothing or discomfort to the user.

5 Test methods

5.1 General

All tests, if not otherwise specified, shall be performed at an ambient temperature of 21 °C ± 5 °C.

If not otherwise specified, all tests shall be performed with the height adjustments at their maximum. Swivelling wheels shall be positioned as if the rollator is run forward, if not otherwise stated. The handles shall be positioned at their maximum distance and maximum angles in the horizontal plane relative to the direction of motion as specified by the manufacturer. 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.

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.

Parking or running brakes shall not be activated unless specified in the test procedure.

If the manufacturer offers alternative handle fittings as accessory equipment, all alternatives shall be supplied with the rollator when tested so that the rollator may be tested in the least favourable configuration (e.g. extended handles).

5.2 Sampling and inspection

One rollator shall be tested. The sequence of tests shall be as follows:

— measurements;

— stability;

— brakes;

— handgrips;

— rubber tips;

— static loading of resting seat;

— static loading of handles;

— fatigue.

Immediately before being tested, the rollator shall be inspected to check compliance with this part of ISO 11199. Any apparent defects shall be noted so that they shall not later be recorded as having been caused by the tests.

5.3 Forward-direction stability test

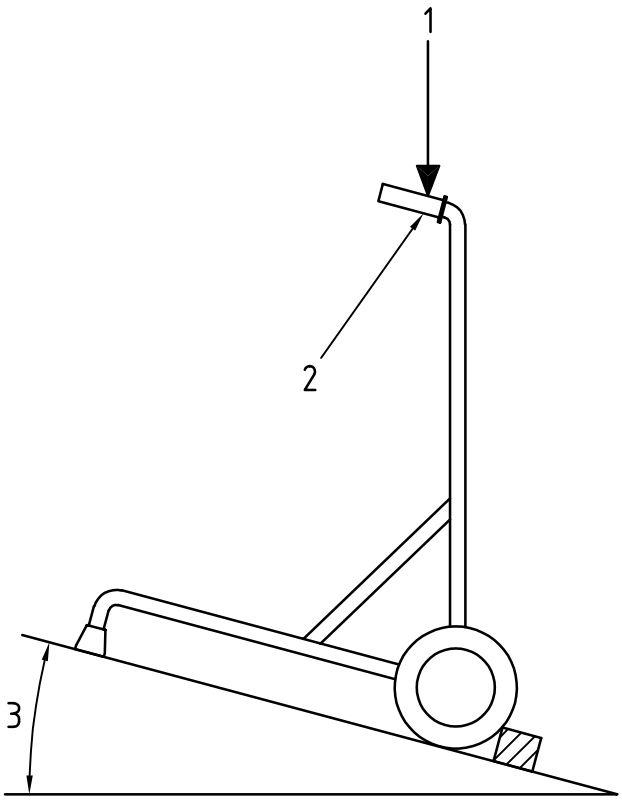
5.3.1 Loading geometry

Height adjustment and handles shall be positioned as specified in 5.1. Swivelling wheels shall be in the least stable position.

The rollator shall be placed with its wheels and/or tips on a 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.

5.3.2 Procedure

A static force of 250 N ± 2 % shall be applied. The plane shall be tilted and the maximum angle of the plane at the point of rollator tilting recorded. Accuracy of measurement shall be less than or equal to ± 0,5°.



Key

1 load
2 front handgrip reference point
3 tilt angle

Figure 7 — Loading geometry for forward-direction stability test

5.4 Backward-direction stability test

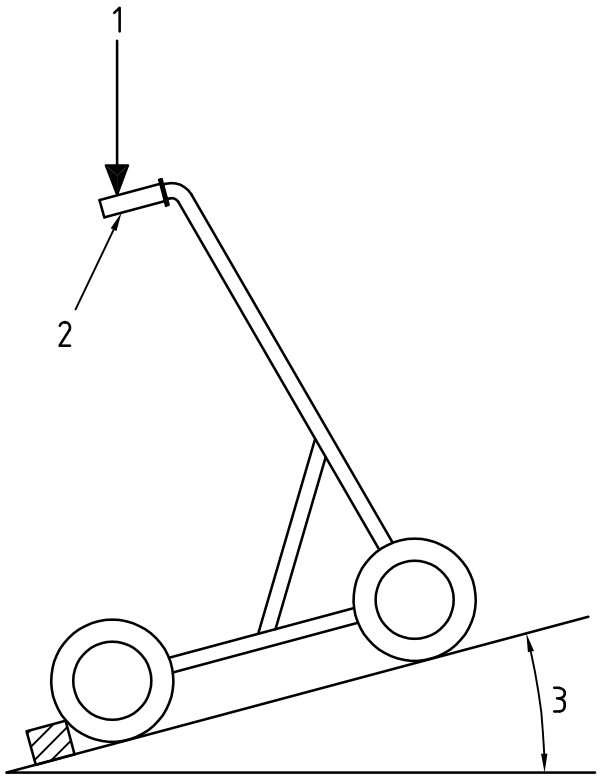
5.4.1 Loading geometry

Height adjustment and handles of the rollator shall be positioned as specified in 5.1. Swivelling wheels shall be in the least stable position.

The rollator shall be placed with its wheels and/or tips on a plane which can be tilted from the horizontal with the centreline of the hinges parallel to the line through the axis of the rear wheels or tips of the rear legs, 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.

5.4.2 Procedure

A static force of 250 N ± 2 % shall be applied. The plane shall be tilted and the maximum angle of the plane at the point of rollator tilting recorded. Accuracy of measurement shall be less than or equal to ± 0,5°.



Key

1 load
2 rear handgrip reference point
3 tilt angle

Figure 8 — Loading geometry for backward-direction stability test

5.5 Sideway-direction stability test

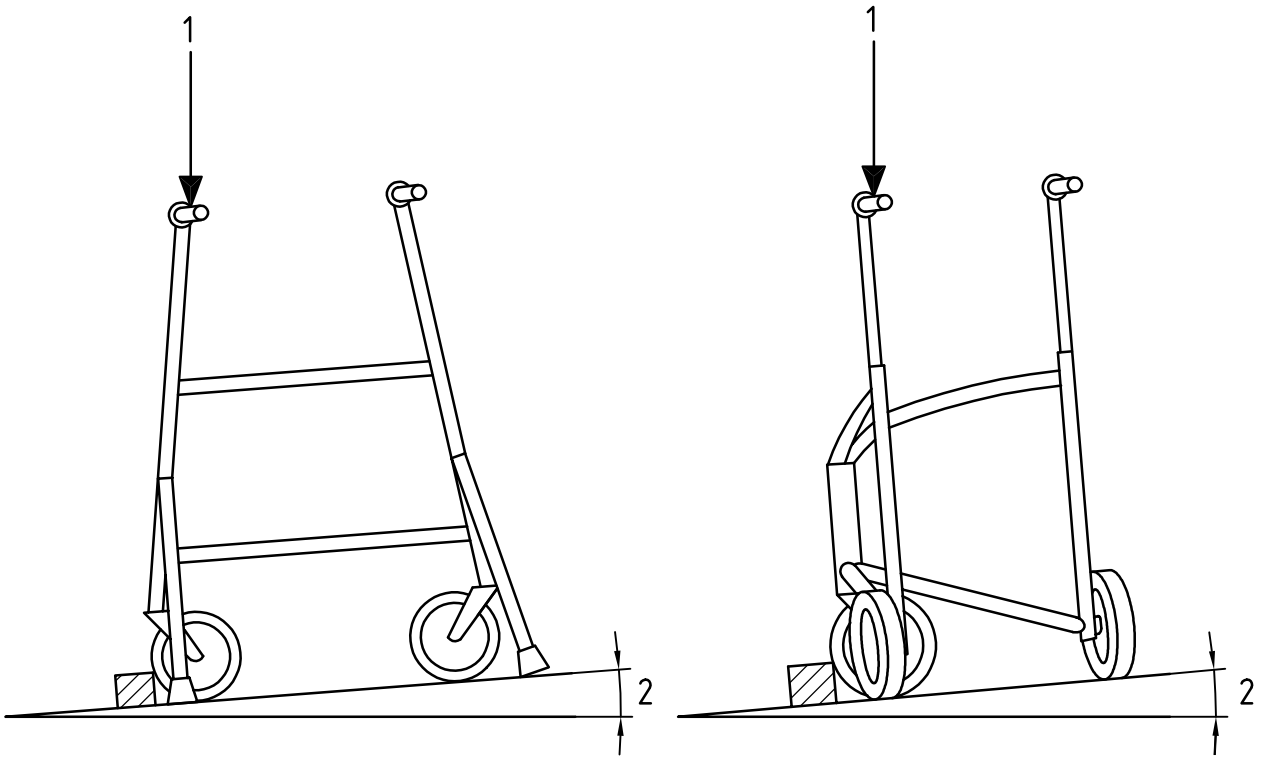
5.5.1 Loading geometry

Height adjustment and handles shall be positioned as specified in 5.1. Swivelling wheels shall be in the least stable position.

The rollator shall be placed with its wheels and/or tips on a plane which 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 plane.

5.5.2 Procedure

A static force of 250 ± 2 % shall be applied. The 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

1 load
2 tilt angle

Figure 9 — Loading geometry for sideways stability test

5.6 Accessory equipment

Rollators being supplied with accessories such as a drip holder, basket, tray, shopping bag and/or oxygen cylinder holder shall be tested for stability in accordance with 5.3, 5.4 and 5.5 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 4.2.

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. In the event that no specification has been given for the basket, tray or shopping bag, a bag of sand exerting a force of 50 N ± 2 % shall be placed, with the sand evenly distributed, in the bottom of the basket, tray and shopping bag.

5.7 Brake tests

The height adjustment and handles shall be positioned as given in 5.1.

Pressure brakes shall be tested as running brakes only.

5.7.1 Running brakes

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

5.7.1.1 Grip distance measurement

Measure the maximum grip distance and note the dimension to the nearest millimetre (see Figure 4).

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

5.7.1.2 Loading geometry

The rollator shall be placed with its wheels on a 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 travel (see Figure 7, without stops on the front wheels). The loading force shall be applied 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 $\pm$ 2 %. 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 $\pm$ 2 %. The load shall be no less than 175 N $\pm$ 2 %.

5.7.1.3 Procedure

Place the rollator on the plane against the stops (see Figure 7). Apply the load to the handgrips front reference points. Activate the brakes by applying to each of the running brake-operating devices a pulling force of 40 N $\pm$ 2 % or a pushing force of 60 N $\pm$ 2 % along the grip distance, whichever is the motion to activate the brakes. Tilt the plane to an angle of 6°. 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 rollator for 1 min. If the wheels turn, note the time for the rollator to move 10 mm.

5.7.2 Parking brakes

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

5.7.2.1 Set and release force

Measure the forces necessary to set and to release the parking brakes, to an accuracy of $\pm$ 2 %, by applying the force along the grip distance line of each brake-operating device and note the values to the nearest newton.

If the brake-operating device is a lever that is not operated by squeezing a bar against the handgrip with the 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.

5.7.2.2 Loading geometry

The rollator shall be placed with its wheels on a 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 travel (see Figure 7). The loading force shall be applied 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 ± 2 %. 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 ± 2 %.

5.7.2.3 Procedure

Place the rollator on the plane against the stops (see Figure 7). Apply the load to the handgrip front reference points. Set the parking brakes to the lock position. Tilt the plane to an angle of 6°. 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 rollator for 1 min. If the wheels turn, note the time for the rollator to move 10 mm.

5.8 Handgrip test

The handgrip shall be inspected for secure fit.

5.9 Rubber tip test

The rubber tips shall be inspected for secure fit.

5.10 Resting seat test

5.10.1 Test dummy

The test dummy shall be of a rectangular construction 340 mm ± 3 mm wide, minimum 200 mm deep and the height to be sufficient for the dummy to be stiff enough to take the test load without deforming significantly. The base of the test dummy shall be lined 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.

5.10.2 Loading geometry and force

Place the dummy on the seat so that the midpoint of the base of the dummy is vertically aligned with the centre of the resting seat.

Gradually apply a vertical loading force of 1 200 N ± 2 %, including the force exerted by the mass of the test dummy, 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 ± 2 %.

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

5.11 Static loading test

5.11.1 Loading geometry

The height adjustment and the handles shall be positioned as given in 5.1. Swivelling wheels shall be turned inwards towards the centre of gravity.

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.

5.11.2 Testing surface

The rollator shall be placed with its wheels and tips on a horizontal stationary surface.

5.11.3 Loading force

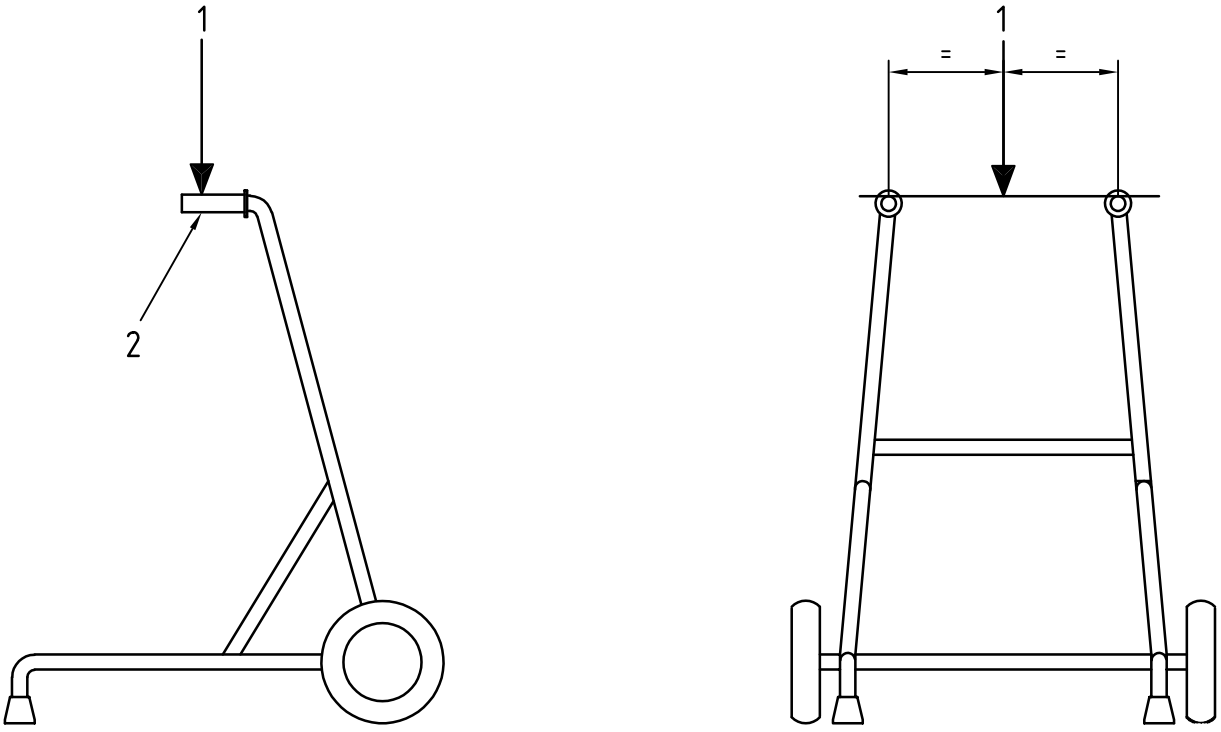
A loading force of 1 200 N ± 2 % shall be applied for a user mass of 100 kg. If the maximum user mass specified for the rollator deviates from a user mass of 100 kg, a force of 12,0 N per kilogram of user mass ± 2 % shall be applied. The load shall be no less than 420 N ± 2 %.

5.11.4 Loading time

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

5.11.5 Permanent set

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



Key

1 load
2 rear handgrip reference point

Figure 10 — Loading geometry for fatigue and static loading tests

5.12 Fatigue test

5.12.1 Loading geometry

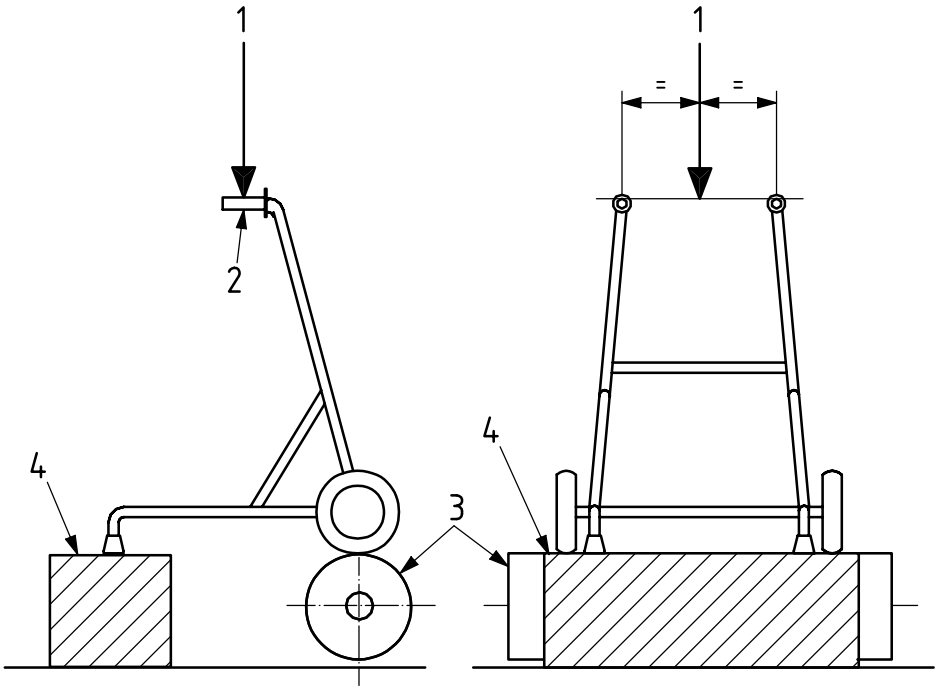
A vertical loading force shall be applied to the rollator as specified in 5.11.1 and in accordance with Figure 10.

5.12.2 Testing surface

The rollator shall be placed with its wheels on a surface travelling at a speed not less than 0,4 m/loading cycle, and if relevant, with its tips on a horizontal stationary surface at the same level as the travelling surface. Pressure brakes are to be treated like tips.

NOTE An example of set-up of the fatigue test for a rollator with two wheels and two rubber tips is shown in Figure 11.

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 load applied through datum point
2 rear handgrip reference point
3 travelling surface
4 stationary surface

Figure 11 — Example of the fatigue test for a rollator with two wheels and two tips

5.12.3 Loading force

A cyclic force of 800 N ± 2 % 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 ± 2 %. The waveform of the cyclic loading force shall be of a sinusoidal or smooth kind without exaggerating pulses.

5.12.4 Loading frequency

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

5.12.5 Loading cycles

The number of cycles shall be 200 000.

Inspect the rollator for cracks or fractures and report their presence, location and potential hazard. If failure occurs, record this and the number of cycles to failure.

5.13 Final inspection

When all tests have been completed, inspect the rollator and all its mechanisms and functions for satisfactory operation as specified by the manufacturer.

6 Information supplied by the manufacturer

6.1 General

The information applied to, and supplied with, rollators shall conform to the relevant parts of EN 1041 together with, but not limited to, the following requirements.

NOTE In connection with marking and labelling, attention is drawn to ISO/IEC Guide 71 and the sensory abilities of older persons, in particular persons with visual impairment.

The information shall include advice on which other devices and/or types of devices that can be used in combination with the rollator in question, and any precautions or limitations needed to ensure user safety.

6.2 Information marked on the product and/or accessories

Each rollator shall be clearly and indelibly marked with the following:

a) maximum user mass;

b) maximum safe working load (SWL) to be marked on accessories;

c) maximum allowed angle between the longitudinal centreline of the handle and the direction of motion, if the handles are sideways adjustable;

d) manufacturer's name or trade name and address;

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

f) month and year of manufacture;

g) maximum extension of the height adjustment, marked on the adjusting members;

h) maximum width of the rollator;

i) whether or not the walking aid is designed for indoor or outdoor use, in accordance with 4.1.

6.3 Documentation

The following information shall be contained in the instructions for use and/or assembly, or clearly and indelibly marked on the product:

a) maximum rollator height;

b) minimum rollator height;

c) maintenance and cleaning instructions, including a description of the method and suitable cleaning agents and any precautions needed to avoid corrosion and/or ageing of the materials used in construction of the rollator;

d) instructions for assembly, adjustment of all kinds, folding and unfolding;

e) warnings and advice about precautions relating to safe distances between moving and stationary parts (see EN 12182:1999, Clauses 12 and 13, for guidance);

f) maximum safe working load (SWL) for load carrying accessories such as basket, tray, shopping bag, etc.

NOTE 1 Most countries require that information be in one or more of their official languages.

NOTE 2 The guidance document ISO/IEC Guide 37, *Instructions for use of products of consumer interest*, can be of help when preparing this information.

Manufacturers are recommended to present their information in separate parts that cover use, prescription, technical and/or paramedical aspects and medical aspects.

7 Test report

The test report shall contain but not be limited to the following information:

a) name and address of the manufacturer;

b) name and address of the supplier of the product for test;

c) name and address of the testing institution;

d) classification code and name in accordance with ISO 9999;

e) maximum permissible user mass;

f) handgrip position by stating the angle between the longitudinal centreline of the handgrip and the direction of motion used during testing;

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

h) supplier's type and model identification name and/or number;

i) photograph of the rollator;

j) month and year when the test was performed;

k) inspection report, as specified in 5.2;

l) diameter of that part of the tip that is in contact with the walking surface, if applicable;

m) whether or not the product complies with the requirements of this part of ISO 11199 (ISO 11199-2:2005);

n) information of how to get access to the supplementary test report of A.4, if available.

Annex A
(informative)

Recommendations

A.1 General

This annex gives supplementary information and guidance on details which also should be taken into account in the design, manufacture and testing of rollators.

A.2 Recommendations

A.2.1 Mechanical durability

When tested according to the tests specified in 5.10, 5.11 or 5.12, the rollator should not show any deformation resulting in a permanent set such as to impair the use of the rollator or adjusting mechanism(s).

A.2.2 Stability

When tested according to the sideways stability test (see 5.5), the angle of the plane at the point of rollator tilting should be no less than 6,0° from the horizontal.

A.2.3 Handle and handgrip and resting seat

The shape and/or the material of the handgrip should prevent the hand from sliding when gripped.

The material of the handgrip should be non-absorbent. The material of the resting seat for outdoor use should be non-absorbent

A.2.4 Leg section and tip

The tip should be pliable, hard wearing and have a high coefficient of friction against the walking surface.

The tip tread against the walking surface should be such that any “suction cup” effect is avoided.

The tip should be secure when fitted.

A.2.5 Adjusting devices and folding mechanisms

It should be possible to operate adjustment devices and folding mechanisms without the use of tools.

When folded into its position for transport or storage, the rollator should stay folded when lifted.

Verify by inspection.

A.2.6 Material and finish

The rollator should not rattle when in use.

For cleaning purposes, the materials and surface treatments used should withstand ordinary alkaline domestic cleaning detergents or spirits, and be easy to dry. After such cleaning agents have been used, corrosion or ageing of the rollator materials should not accelerate.

Taking into account the intended use and contact by those involved in user care or transportation and storage of the product, rollator materials which come into contact with the human body should be assessed for biocompatibility using the guidance given in ISO 10993-1.

A.2.7 Light-reflecting material

Light-reflecting material should be mounted as close as possible to the vertical, as close as possible to right angles to the line of travel, as low as possible on the rollator and not higher than 800 mm above the walking surface.

A.2.8 Angle adjustments of handles

Rollators having handgrips that may be angled sideways in the horizontal plane, the angle should be adjusted to 20° outwards at the rear or inwards at the front (depending on the construction) relative to the direction of walking, and sideway-direction stability tests performed in accordance with 5.5. The results of the tests should be within the limits given in 4.2.

A.3 Marking and labelling

Each rollator should, in addition to the requirements given in Clause 6, be marked with the following:

a) the supplier's name;

b) the supplier's model identification name and/or number.

A.4 Supplementary test report

The test report may, in addition to the requirements given in Clause 7, contain part of or all the following information:

a) results of test described in 5.3;

b) results of test described in 5.4;

c) results of test described in 5.5;

d) results of test described in 5.6;

e) results of test described in 5.7;

f) results of test described in 5.8;

g) results of test described in 5.9;

h) results of test described in 5.10;

i) results of test described in 5.11;

j) results of test described in 5.12;

k) any findings of interest during inspection described in 5.13;

l) maximum rollator height;

m) minimum rollator height;

n) maximum rollator width;

o) maximum rollator length;

p) maximum rollator turning diameter;

q) width between the centrelines of the handgrips;

r) handgrip width;

s) folded rollator dimensions;

t) mass of rollator without accessories;

u) whether or not tools are necessary to operate the adjustment and folding devices;

v) any other relevant information.

Bibliography

[1] ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing*

[2] ISO 11199-3, *Walking aids manipulated by both arms — Requirements and test methods — Part 3: Walking tables*

[3] ISO/IEC Guide 37, *Instructions for use of products of consumer interest*

[4] ISO/IEC Guide 71, *Guidelines for standards developers to address the needs of older persons and persons with disabilities* [1)]

[5] EN 12182:1999, *Technical aids for disabled persons — General requirements and test methods*

1) Equivalent to CEN/CENELEC Guide 6.

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