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

Reference number
ISO 11199-2:2021(E)

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Published in Switzerland

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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).

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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.

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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.

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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

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— 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

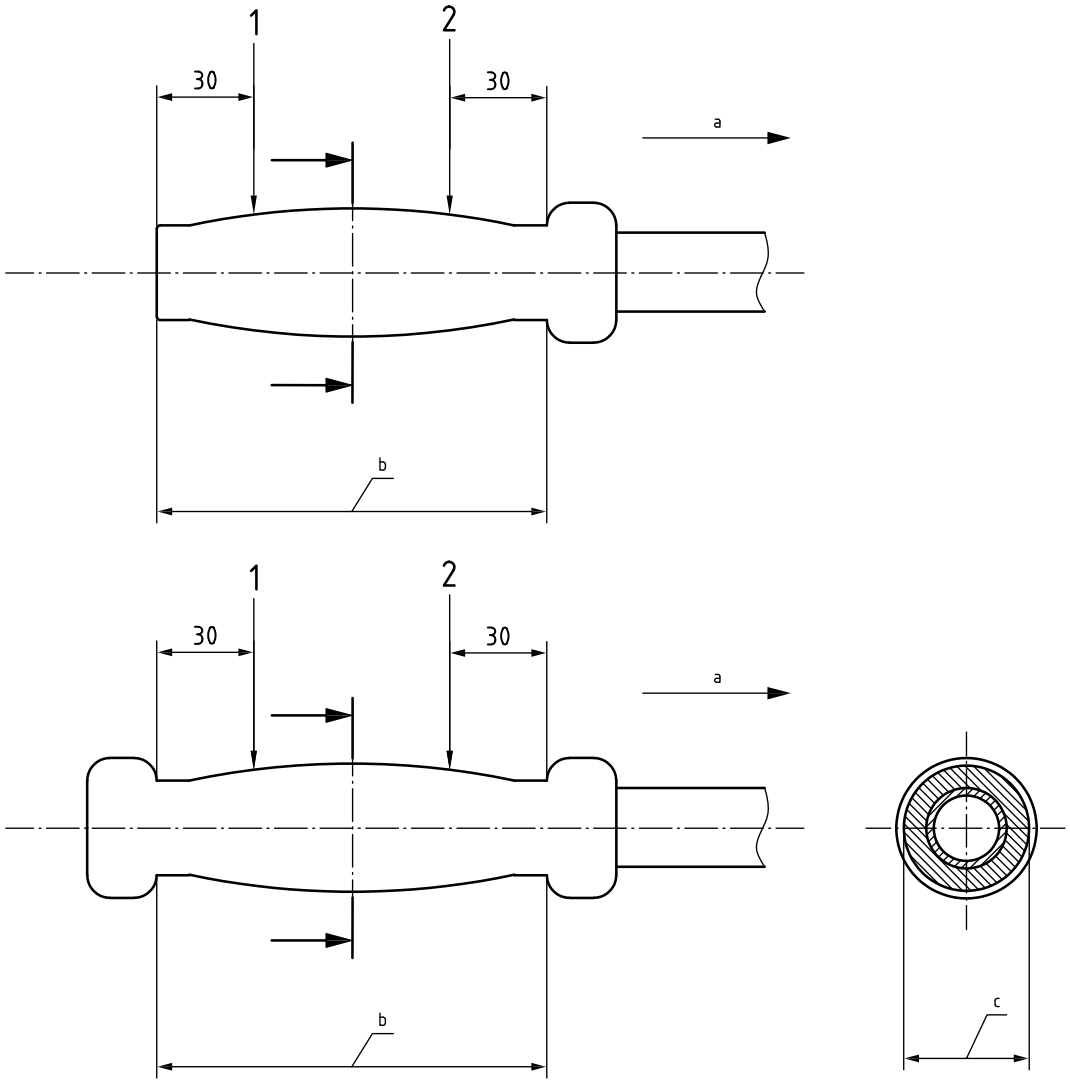
Note 1 to entry: See Figure 1.

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.

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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.

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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

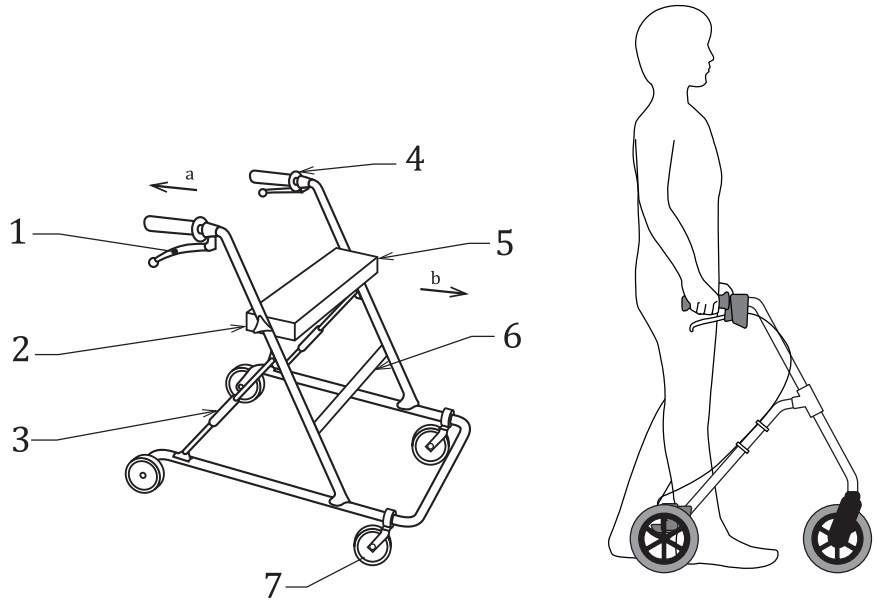
Note 1 to entry: See Figure 2.

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.

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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

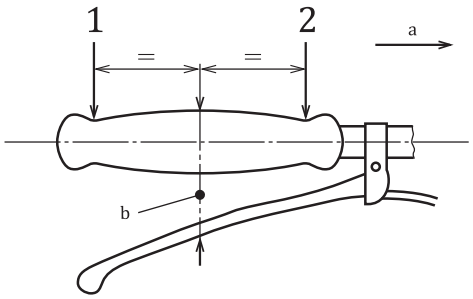
3.13
rollator height
vertical distance from the highest point of the *handle* (3.6) to the ground surface

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.

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Key

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

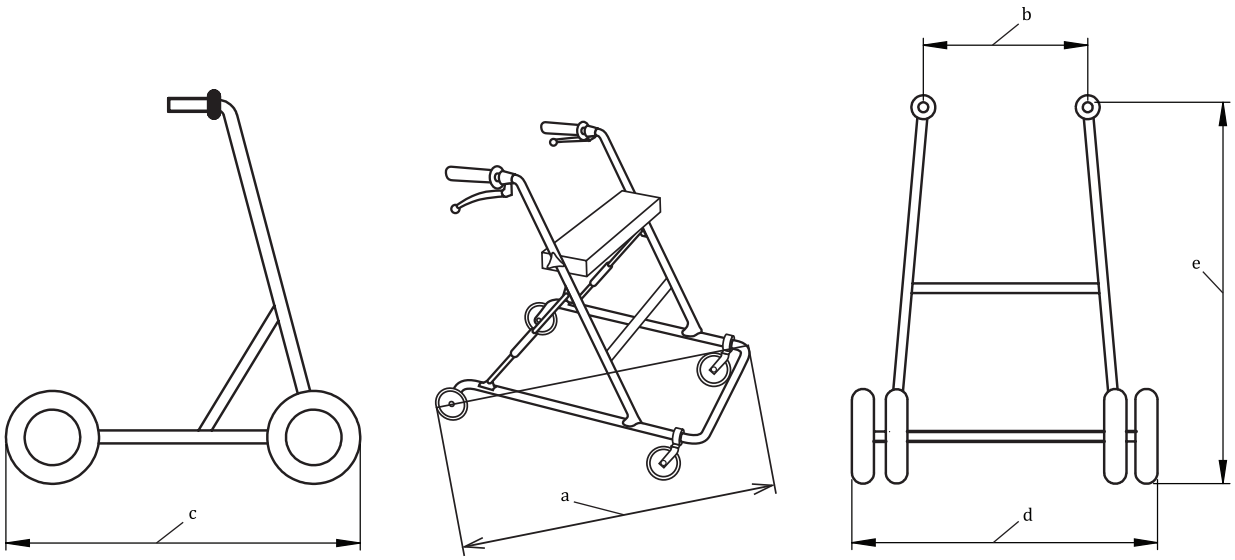
Figure 3 — Brake grip distance

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

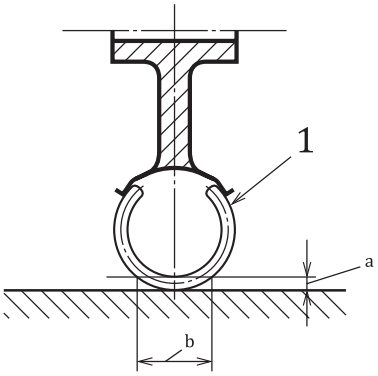
a	Turning width.	d	Width.
b	Width between handles.	e	Height.
c	Length.		

Figure 4 — Dimensions of a rollator

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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

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