INTERNATIONAL STANDARD

ISO 11334-1

Second edition
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Assistive products for walking manipulated by one arm — Requirements and test methods —

Part 1: Elbow crutches

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

Partie 1: Cannes à appui antibrachial

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 11334-1 was prepared by Technical Committee ISO/TC 173, *Assistive products for persons with disability*.

This second edition cancels and replaces the first edition (ISO 11334-1:1994), which has been technically revised.

ISO 11334 consists of the following parts, under the general title *Assistive products for walking manipulated by one arm — Requirements and test methods*:

— *Part 1: Elbow crutches*

— *Part 4: Walking sticks with three or more legs*

Assistive products for walking manipulated by one arm — Requirements and test methods —

Part 1: Elbow crutches

1 Scope

This part of ISO 11334 specifies requirements and test methods for elbow crutches fully equipped with handgrip and tip. The methods specify testing of separation, static load capacity, fatigue and resistance to low temperature embrittlement.

This part of ISO 11334 also gives the requirements relating to safety, ergonomics, performance, and information to be supplied by the manufacturer, including marking and labelling.

The requirements and tests are based on every-day usage of elbow crutches when performing the through-swing gait, for a maximum user mass as specified by the manufacturer. This part of ISO 11334 is applicable to elbow crutches specified for a user mass of not less than 35 kg.

Requirements and test methods for friction of rubber tips against the walking surface are dealt with separately.

NOTE The recommendations given in Annex A supplement the requirements given in this part of ISO 11334.

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, *Assistive products 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
elbow crutch
assistive product for walking with one leg, a handle and a non-horizontal forearm support

See Figure 1.

NOTE Classification no. 12 03 06, according to ISO 9999.

3.2
handle
part of the crutch to which the handgrip is attached

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

See Figure 1, item 5.

3.4
handgrip length
h
dimension of the handgrip measured longitudinally where the hand rests, starting at the lowest point as near as possible to the front stop of the handgrip, and ending at the point as near as possible to the rear stop and at the shortest possible distance from the tip

See Figures 1 and 2.

NOTE If there is no rear stop, the maximum handgrip length is 110 mm.

3.5
front handgrip reference point
lowest point next to the front stop where the handgrip length starts

See Figure 1, item 7 and Figure 2, item 6.

3.6
rear handgrip reference point
point next to the rear stop where the handgrip length stops

See Figure 1, item 8 and Figure 2, item 7.

3.7
handgrip support line
line drawn through the front and the rear handgrip reference points

See Figure 1, item 6 and Figure 2, item 4.

3.8
handgrip width
width of the handle measured horizontally at the thickest part of the handgrip where the hand rests

See Figure 2, item 5.

3.9
datum
point on the upper surface of the handgrip measuring one-third of the length from the rear handgrip reference point

See Figure 2, item 3.

3.10
arm section
part of the crutch which is above the rear handgrip reference point

3.11
leg section
part of the crutch which is below the rear handgrip reference point

3.12
cuff
forearm support as used on an elbow crutch to hold the forearm in the correct position and prevent sideways movement

See Figure 1, item 2.

3.13
cuff support line
line drawn from the rear handgrip reference point and touching the inside rear bottom face of the cuff at maximum extension of the arm section

See Figure 1, item 1 and Figure 2, item 1.

3.14
cuff internal width
y
maximum internal dimension of the cuff measured left to right

See Figure 3.

3.15
cuff internal depth
x
internal dimension of the cuff measured front to back

See Figure 3.

3.16
cuff internal height
z
inside measurement of the cuff which is approximately parallel to the cuff support line and which supports the forearm

See Figure 2.

3.17
tip
part of the crutch which is in contact with the ground

See Figure 1, item 3.

3.18
leg section axis
line drawn from the rear handgrip reference point and through the centre of the tip at maximum extension of the leg section

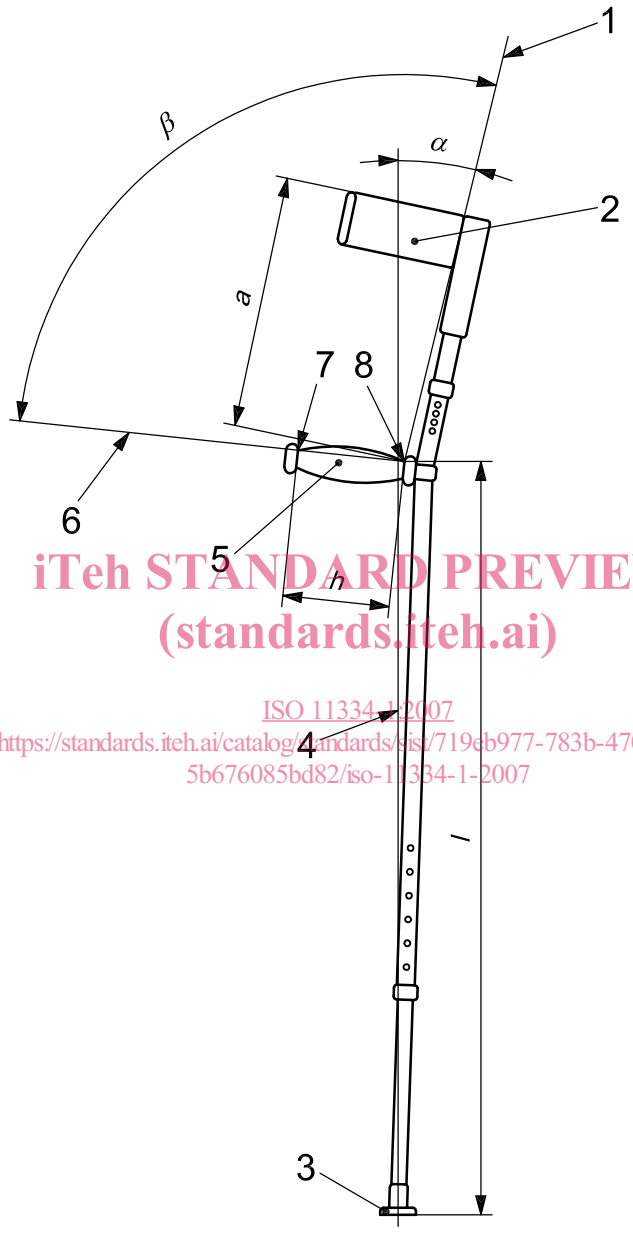
See Figure 1, item 4.

3.19
arm section length
a
distance measured between the rear handgrip reference point and the highest point where the cuff support line touches the inside rear face of the cuff

See Figure 1.

3.20
leg section length
l
distance measured between the rear handgrip reference point and the centre of the bottom of the tip

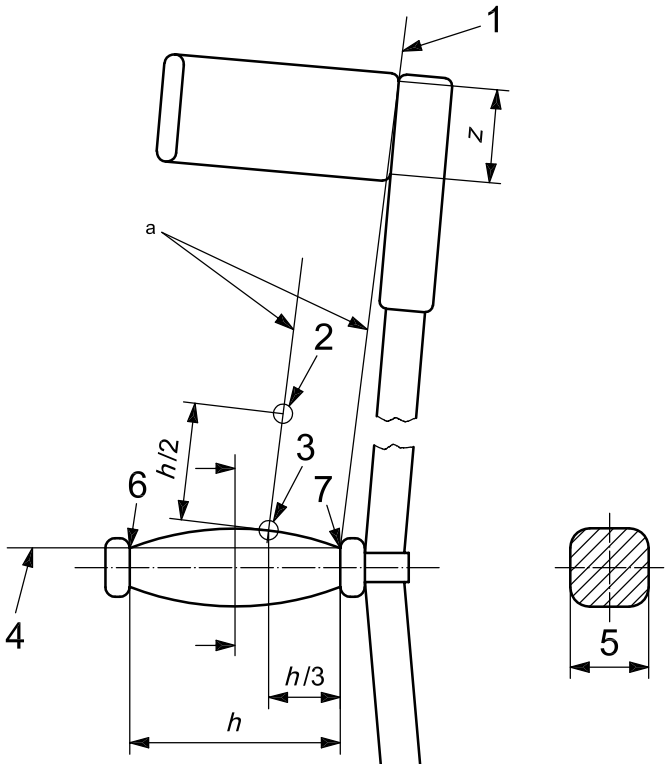
See Figure 1.



Key

1 cuff support line
2 cuff
3 tip
4 leg section axis
5 handgrip
6 handgrip support line
7 front handgrip reference point
8 rear handgrip reference point
a arm section length
h handgrip length
l leg section length
α support angle
β grip angle

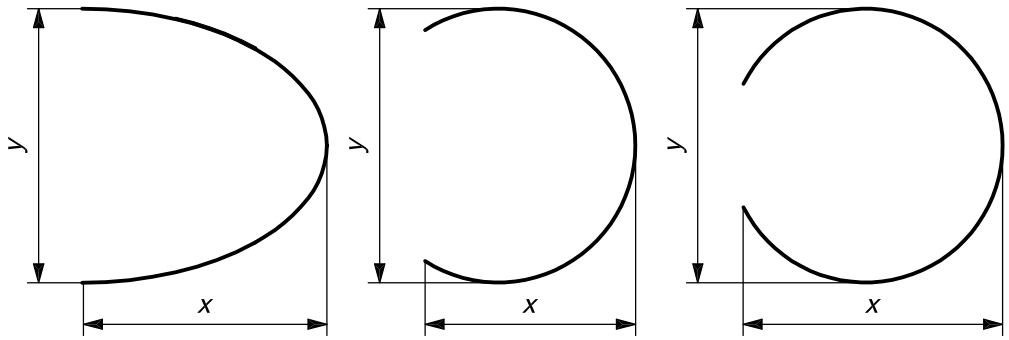
Figure 1 — Example of an elbow crutch



Key

1 cuff support line
2 wrist hinge point
3 datum
4 handgrip support line
5 handgrip width
6 front handgrip reference point
7 rear handgrip reference point
h handgrip length
z cuff internal height
a Parallel.

Figure 2 — Details of an elbow crutch



Key

x cuff internal depth
y cuff internal width

Figure 3 — Cuff dimensions

3.21
support angle
α
angle formed by the leg section axis and the cuff support line

See Figure 1.

3.22
grip angle
β
angle formed by the cuff support line and the handgrip support line

See Figure 1.

4 Requirements

4.1 Cuff

The cuff internal depth against the forearm shall be larger than half of the internal width. This is verified by measurement, as indicated in 5.3.2 and Figure 3.

For the arm not to be trapped in accidentally, the cuff shall have an opening in the front side. When tested in accordance with 5.4, it shall be possible to increase this opening to 75 mm by applying a pulling force of maximum 120 N. The permanent deformation of the cuff opening shall not be more than 5 mm.

The cuff shall be securely fixed when tested in accordance with 5.5.

4.2 Handgrip

The handgrip may be adjustable, but shall be securely fixed when tested in accordance with 5.5.

The handgrip width shall be not less than 25 mm and not more than 50 mm. This requirement does not apply to anatomic handgrips. This is verified by measurement, as indicated in 5.3.2 and Figure 2, item 5.

4.3 Leg section and tip

The leg section shall end in a tip of a design that will prevent the leg section from piercing through the tip when tested in accordance with 5.6 and 5.7. This is verified by inspection.

The tip shall be replaceable, but shall be secure when fitted. This is verified by inspection.

The part of the tip that is in contact with the walking surface shall have a minimum diameter of 35 mm. This is verified by measurement, as indicated in 5.3.2.

4.4 Adjusting devices

The means of height adjustment shall not become loose. This is verified by inspection after the crutch has been subjected to the tests described in 5.6 and 5.7.

Each of the height adjustments shall be clearly marked with its maximum allowable elongation. This is verified by measurement, as indicated in 5.3.2.

4.5 Materials

If structural load carrying components moulded from recycled plastic materials are included, the components shall be of a strength equivalent to virgin materials throughout the life of the crutch.

4.6 Mechanical durability

When tested in accordance with the separation tests (see 5.5), none of the joints where parts of the crutch are joined together shall come apart.

When tested in accordance with the static loading test (see 5.6), the crutch shall stand the load and no part of the crutch shall crack or break.

When tested in accordance with the fatigue test (see 5.7), no part of the crutch shall crack or break.

When tested in accordance with the low temperature falling test (see 5.8), no part of the crutch shall crack or break.

5 Test methods

5.1 General

All tests, if not otherwise specified, shall be performed with the crutch adjustments at their maximum extension length setting.

5.2 Testing environment

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

5.3 Sampling

5.3.1 Test object

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

— measurements;

— separation;

— static loading;

— fatigue;

— low temperature falling.

5.3.2 Measurements

Measure the crutch and, at the same time, inspect the crutch for compliance with the manufacturer's specification. Make note of all the measurements taken and of any apparent defects, so that they shall not later be recorded as having been caused by the tests.

5.4 Forearm withdrawal test

5.4.1 General

This test applies only to elbow crutches with a cuff opening smaller than 75 mm.