# Walking aids — General requirements and test methods

The European Standard EN 1985:1998 has the status of a British Standard  $\,$ 

ICS 11.180



#### **National foreword**

This British Standard is the English language version of EN 1985:1998. It partially supersedes BS 4997:1991 Specification for wooden axilla crutches, BS 5181:1975 Specification for wooden walking sticks and BS 5205:1990 Specification for adjustable metal walking sticks.

The UK participation in its preparation was entrusted to Technical Committee CH/38, Walking aids, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this committee can be obtained on request to its secretary.

#### **Cross-references**

The British Standards which implement international or European publications referred to in this document may be found in the BSI Standards Catalogue under the section entitled "International Standards Correspondence Index", or by using the "Find" facility of the BSI Standards Electronic Catalogue.

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#### **Summary of pages**

This document comprises a front cover, an inside front cover, the EN title page, pages 2 to 7 and a back cover.

This British Standard, having been prepared under the direction of the Health and Environment Sector Committee, was published under the authority of the Standards Committee and comes into effect on 15 March 1999

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## EUROPEAN STANDARD NORME EUROPÉENNE EUROPÄISCHE NORM

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Descriptors: medical equipment, disabled persons aids, disabled persons, elbow crutches, walking rehabilitation carriages, design, equipment specifications, safety, accident prevention, hazards, protection against mechanical hazards, thermal protection, tests, information

English version

### Walking aids — General requirements and test methods

Aides à la marche — Prescriptions générales et méthodes d'essai

Gehhilfen — Allgemeine Anforderungen und Prüfmethoden

This European Standard was approved by CEN on 8 November 1998.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

#### CEN

European Committee for Standardization Comité Européen de Normalisation Europäisches Komitee für Normung

Central Secretariat: rue de Stassart 36, B-1050 Brussels

#### Page 2 EN 1985:1998

#### **Foreword**

This European Standard has been prepared by Technical Committee CEN/TC 293, Technical aids for disabled persons, the Secretariat of which is held by SIS.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 1999, and conflicting national standards shall be withdrawn at the latest by May 1999.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative annex Z, which is an integral part of this standard.

This standard provides a means to demonstrate that walking aids, which are also medical devices, conform to the essential requirements outlined in general terms in annex 1 of the EU Directive 93/42 EEC. It is not intended to provide a means to show conformity with the requirements of any other directive.

There are three levels of European Standards dealing with technical aids for disabled persons. These are as follows, with level 1 being the highest:

level 1: general requirements for technical aids; level 2: particular requirements for families of technical aids;

level 3: specific requirements for types of technical aids.

Where standards for particular aids or groups of aids exist (level 2 or 3), the requirements of lower level standards take presedence over higher level standards. Therefore, to address all requirements for a particular aid, it is necessary to start with standards of the lowest available standard.

This is a level 2 standard for walking aids, as specified in the scope. Lower level standards may specify the requirements of the higher level standards or may modify them. Where standards for particular types of walking aids exist (level 3 standards), this standard should not be used alone. The level 1 standard may be applicable.

All European Standards produced or currently being developed by CEN/TC 293 and which concern the family of walking aids are listed in annex A.

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#### 1 Scope

This standard specifies requirements and test methods for walking aids manipulated by one arm (walking aids used singly or in pairs, each manipulated by one of the arms, possibly in combination with the upper body) and walking aids manipulated by both arms (walking aids used singly, manipulated by both arms, possibly in combination with the upper body), as covered by the subclasses 1203 and 1206 in EN ISO 9999:1998.

This standard does not apply to walking aids specially designed or with adaptations for specific disabled persons.

NOTE Appropriate parts of this standard may be applied to the above products and other walking aids outside this scope.

#### 2 Normative references

This European Standard incorporates by dated or undated references, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN 1441, Medical devices — Risk analysis. EN ISO 9999:1998, Technical aids for disabled persons — Classification.

prEN 12182:1997, Technical aids for disabled persons — General requirements and test methods.

#### 3 Definitions

For the purpose of this standard the following definitions apply.

#### 3.1

#### walking aid

device which, together with one or both legs, is designed to give support to the user for walking

#### 3.2

#### user weight

body mass of the person the walking aid is designed to accommodate

#### 4 Risk analysis

EN 1441 applies.

## 5 Requirements regarding design and construction

**5.1** A walking aid shall conform to prEN 12182:1997, clauses **11** and **12** in respect of safety of moving parts and prevention of traps for the human body.

- **5.2** Materials used in the manufacture of a walking aid shall conform to prEN 12182:1997, **5.2**.
- **5.3** The materials used in a walking aid shall not mark, scratch or discolour the surroundings or the walking surface.
- **5.4** All parts of a walking aid and its auxiliary parts shall be designed so as to be accessible for cleaning. Any cavities in which liquid could accumulate shall be self-draining. Compliance shall be verified by inspection.
- **5.5** For ergonomical principles, prEN 12182:1997, clause **22** shall apply.

## 6 Requirements regarding construction and environmental properties

- **6.1** Ancillaries supplied by the manufacturer or supplier for use in combination with a walking aid and the possible mechanisms for fixing them to a walking aid, shall be according to the same safety requirements and quality as for the walking aid.
- **6.2** Unless a specific part of the function of a walking aid, all accessible edges, corners and surfaces shall conform to prEN 12182:1997, clause **17**.
- **6.3** A walking aid shall be designed so as to be manoeuvrable for indoor or outdoor use or a combination of the two. Where applicable, the following requirements apply:

#### Indoor use on a level surface

- the front wheel diameter shall be greater or equal to 75 mm (to aid manoeuvrability on carpets);
- a walking aid shall be equipped with parking brakes operating on two wheels (rubber tips are deemed to be such parking brakes);
- the maximum width of a walking aid shall be smaller or equal to 650 mm for use in private homes;

#### Outdoor use

- the front wheel diameter shall be greater or equal to 180 mm;
- the wheel width shall be greater or equal to 28 mm;
- a walking aid shall be equipped with brakes operating on two wheels. The user shall be able to manipulate the brakes when walking. Rubber tips are deemed to be such brakes;
- a walking aid shall be equipped with parking brakes operating on two wheels. Rubber tips are deemed to be such parking brakes.

## 7 Protection against mechanical and thermal risks

**7.1** A walking aid shall function as intended by the manufacturer and there shall be no material failure of any part of the walking aid subjected to the static loading, fatigue, stability and temperature tests either as specified in the relevant level 3 standard, or to comparable performance criteria for those walking aids where no level 3 standard has been specified. The manufacturer shall provide evidence validating such performance criteria.

NOTE Recommendations are given in **B.5.1**.

Values for some of the loadings specified in the specific level 3 standards are related to a user weight of 100 kg, and will be adjusted according to the user weight specified by the manufacturer for each individual walking aid.

**7.2** A walking aid shall be clearly and indelibly marked with the maximum limits of its adjustment ranges.

Compliance shall be verified by inspection.

**7.3** Folding and adjusting mechanisms shall be securely locked when a walking aid is in the working position.

Compliance shall be verified by inspection.

## 8 Information supplied by the manufacturer

- **8.1** The requirements given in prEN 12182:1997, clause **23** apply together with **8.2** to **8.5** below.
- **8.2** Information on whether or not the walking aid is designed for indoor or outdoor use, according to **6.3**.
- **8.3** Information regarding assembly, adjustment of all kinds, folding and unfolding of a walking aid shall accompany each product or be clearly marked on it.
- **8.4** A walking aid shall be clearly and indelibly marked with the maximum permissible user weight.
- **8.5** A walking aid shall be clearly and indelibly marked with the maximum limits of its adjustment ranges (see **7.2**).

#### Annex A (informative)

## European Standards concerning walking aids, produced or currently being developed by CEN/TC 293

Level 1: prEN 12182, Technical aids for disabled persons — General requirements and test methods.

Level 2: EN 1985, Walking aids — General requirements and test methods (this document).

Level 3: EN ISO 11334-1:1997, Elbow crutches — Requirements and test methods.

prEN ISO 11199-1, Walking frames — Requirements and test methods.

prEN ISO 11199-2, Rollators — Requirements and test methods.

prEN ISO 11334-4, Walking sticks with three or more legs — Requirements and test methods.

NOTE The above listed level 3 documents are International Standards as well. The use or the status as International Standards is not affected by the European 3 level system.

## Annex B (informative) Walking aids — Recommendations

#### B.1 Scope

This annex gives supplementary information and guidance on details which also should be taken into account when a walking aid is designed, manufactured and tested.

#### **B.2** General

- **B.2.1** A walking aid should be of an aesthetic design.
- **B.2.2** 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 and as low as possible on a walking aid, not higher than 800 mm above the walking surface.

- **B.2.3** The operating force for operating devices to activate, hold, move and release by arm (and hand) should not exceed 60 N.
- **B.2.4** The operating force for operating devices to activate, hold, move and release by hand or fingers should not exceed 13,5 N.

#### **B.3 Design and construction**

- **B.3.1** 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 materials should not accelerate.
- **B.3.2** Precautions should be taken to prevent adverse effects to the materials and construction of a walking aid when exposed to extreme circumstances of very low or very high temperatures.

#### **B.4** Construction and environmental properties

- **B.4.1** A walking aid should not endanger the user in any way.
- **B.4.2** A walking aid should, if applicable, be designed in such a way as to allow accessibility of an attendant.
- **B.4.3** A walking aid should be so designed that slipping on wet surfaces is reduced to a minimum, e.g. draining patterns in wheels and tips.

## B.5 Protection against mechanical and thermal risks

**B.5.1** Referring to **7.1**, Table B.1 below gives recommended values for testing walking aids where no specific standard (level 3 standard) exists.

Table B.1 — Recommended values for testing walking aids where no specific standard exists

Classification according to EN ISO 9999:1998	Type of aid	Fatigue test: Force (N)/ number of cycles	Static test force (N)	Forwards stability test angle	Backward stability test angle	Sideways stability test angle	Temperature test
120303	Walking stick	250	_	5°	5°	_	−25 °C
		825 000					
120309	Forearm support	550	1 000	_	_	_	−25 °C
	crutches	1 000 000					
120312	Axillary crutches	550	1 000	_	_	_	−25 °C
		1 000 000					
120609	Walking chairs	800	+	10°	$4^{\circ}$	3,5°	_
		200 000					
120612	Walking tables	800	+	10°	4°	3,5°	_
		200 000					

- **B.5.2** All adjustment mechanisms should have a physical stop at their critical adjustment.
- **B.5.3** A walking aid should not have mechanisms on which the user or the attendant may be injured by scissoring or pinching action, e.g. braking, adjusting, locking, folding or reciprocating mechanisms. These mechanisms should be easy to understand and easy to use without the use of tools.
- **B.5.4** A walking aid should not rattle when in use.
- **B.5.5** The materials used in a walking aid should as far as possible be easy to recycle when the walking aid can no longer be used for its prime purpose.

#### Annex Z (informative)

#### Clauses of this European Standard addressing essential requirements or other provisions of EU Directives

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association and supports essential requirements of EU Directive 93/42/EEC concerning medical devices.

WARNING: Other requirements and other EU Directives  $\underline{may}$  be applicable to the product(s) falling within the  $\underline{scope}$  of this standard.

The following clauses of this standard, as detailed in Table Z.1, are likely to support requirements of Directive 93/42/EEC.

Compliance with the clauses of this standard provides one means of conforming with the specific essential requirements of the Directive concerned and associated EFTA regulations.

Table Z.1 — Correspondence between this European Standard and EU Directives

Clauses/subclauses of this European Standard	Corresponding annexes/paragraphs of Directive 93/42/EEC concerning medical devices — Annex I, Essential requirements	Comments
Requirements: <b>4</b> ; <b>5</b> ; <b>6</b> ; <b>7</b> Testing: level 3 standards:	I.1	EN 1441 applies
EN ISO 11334-1 prEN ISO 11334-4 prEN ISO 11199-1 prEN ISO 11199-2		Equivalent clauses of prEN 12182:1997 apply
Requirements: 4; 7.1; 7.3 Testing: level 3 standards:	I.2	EN 1441 applies
EN ISO 11334-1 prEN ISO 11334-4 prEN ISO 11199-1 prEN ISO 11199-2		
Requirements: <b>7.1</b> Testing: level 3 standards:	L3	Annex B, recommendations only
EN ISO 11334-1 prEN ISO 11334-4 prEN ISO 11199-1 prEN ISO 11199-2		
Requirements: <b>7.1</b> Testing: level 3 standards:	I.4	
EN ISO 11334-1 prEN ISO 11334-4 prEN ISO 11199-1 prEN ISO 11199-2		

Table Z.1 — Correspondence between this European Standard and EU Directives (continued)

-	-			
Clauses/subclauses of this European Standard	Corresponding annexes/paragraphs of Directive 93/42/EEC concerning medical devices — Annex I, Essential requirements	Comments		
Requirements: 4; 6.2; 6.3	I.6	EN 1441 applies Equivalent clauses of prEN 12182:1997 apply		
Requirements: 5.2	II.7.1	Equivalent clauses of prEN 12182:1997 apply		
Requirements: 5.4	II.7.2			
Requirements: 5.2; 5.4	II.8.1	Equivalent clauses of prEN 12182:1997 apply		
Requirements: 6.1	II.9.1			
Requirements: 5.5; 6.2; 6.3; 7.3	II.9.2	Equivalent clauses of prEN 12182:1997 apply		
Requirements: 8	II.13.1			
Requirements: 8	II.13.2			
Requirements: 8	II.13.3.a); b); d); j); k); l)			
Requirements: 8.3; 8.4; 8.5	II.13.4			
Requirements: 8.4	II.13.6.b)	Maximum user weight		

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