Date:03-11-2024

ISO/TC 173/WG 1

Secretariat: KATS SIS

Date: 2024-06-25

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

Part 4:

Walking sticks with three or more legs

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

Partie 4: Cannes à trois pieds ou plus

FDIS stage

© ISO 20222024

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office

CP 401 • Ch. de Blandonnet 8 CH-1214 Vernier, Geneva Phone: + 41 22 749 01 11 EmailE-mail: copyright@iso.org

Website: www.iso.org

Published in Switzerland

iTeh Standards (https://standards.iteh.ai) Document Preview

ISO/FDIS 11334-4

Contents

Forew	ord	v
Introd	uction	vi
1	Scope	1
2	Normative references	1
3	Terms and definitions	2
4	Apparatus	8
5	Test conditions	
_	General requirements and test methods	
6 6.1	Risk analysis	
6.2	Maximum user mass/load limits	
6.2 6.3	Structural requirements	
o.s 6.3.1	Handgrip	
6.3.1	0 1	
6.3.2	Adjustment mechanisms and locking devices	
6.3.4	Leg section and tips Leg height from the ground of the walking stick for outside use	
6.3.5	Shaft distance from the user	11
7	Materials	12
7.1	General	12
7.2	Biocompatibility and toxicity	12
7.3	Infection and microbiological contamination	13
7.3.1	General	13
7.3.2	Cleaning and disinfection	13
7.4	Resistance to corrosion	
8	Temperatures of parts that come in contact with human skin	
្នាំttps:/	Prevention of traps for parts of the human body	
9.1	Holes and clearances	
9.1 9.2		
9.2	V-shape openings	
10	Surfaces, corners and edges	14
11	Static stability	14
11.1	Requirements for static stability	14
11.1.1	Inward direction static stability	
	Outward direction, forward direction and backward direction static stability	
11.2	Test methods for static stability	
	Inward direction static stability test	
	Outward direction, forward direction and backward direction static stability test	
12	Static strength	17
12.1	Static strength of walking sticks	
	Requirements for static strength of walking sticks	
	Test method for static strength of walking sticks	
	Alternative test method for static strength of walking sticks	
12.1.3 12.2	Static strength for the legs and separation part	
	Requirements for static strength of the legs and separation part	
14.4.L	nequifements for static su englifor the legs and separation partpart	∠∪

12.2.2	Test methods for static strength of the legs and separation part	20
13	Durability	21
	Requirements for durability	
	Test method for durability	
	Alternative test method for durability	
14	Information supplied by the manufacturer	22
	General	
14.2	Information marked on the product	23
	Instructions for use	
14.4	Test report	24
Biblios	graphy	26

iTeh Standards (https://standards.iteh.ai) Document Preview

ISO/FDIS 11334-4

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 document 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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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 second edition cancels and replaces the first edition (ISO 11334-4:1999), which has been technically revised.

The main changes are as follows:

- the minimum requirements for stability have been removed and are replaced by requirements on disclosure of the stability performance level for the specified direction;
- the static strength test for the legs and separation part was added;
- <u>Clause 6</u>— <u>Clause 6</u> on general requirements for assistive products for walking was added.

A list of all parts in the ISO 11334 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.

© ISO 2024 - All rights reserved

Introduction

A walking stick with three or more legs can be used when a person needs assistance for walking. It provides more stability when walking and standing compared with other types of sticks and canes manipulated by one arm and can thus reduce the risk of falling.

iTeh Standards (https://standards.iteh.ai) Document Preview

ISO/FDIS 11334-4

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

Part 4:

Walking sticks with three or more legs

1 Scope

This document specifies requirements and test methods of walking sticks with three or more legs used as assistive products for walking, manipulated by one arm, without accessories, unless specified in the particular test procedure. This document also gives requirements related 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 walking sticks with three or more legs as assistive products for walking for a maximum user mass as specified by the manufacturer. This document is for walking sticks with three or more legs specified for a user mass of no less than 35 kg.

This document is not applicable to walking sticks with three or more legs with underarm or forearm support or with moving parts such as a universal joint.

2 Normative references tos://standards.iteh.ai)

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 7000, Graphical symbols for use on equipment — Registered symbols 33-a9406c62261a/iso-fdis-11334-4

ISO 10993-_1, Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process

ISO 10993--5, Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity

ISO 14971, Medical devices — Application of risk management to medical devices

<u>ISO 15223-1, Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements</u>

ISO 20417, Medical devices — Information to be supplied by the manufacturer

ISO 24415-_1, Tips for assistive products for walking — Requirements and test methods — Part 1: Friction of tips

ISO 7000, Graphical symbols for use on equipment—Registered symbols

ISO 15223-1, Medical devices—Symbols to be used with information to be supplied by the manufacturer—Part 1: General requirements

3 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at https://www.iso.org/obp
- IEC Electropedia: available at https://www.electropedia.org/

3.1

anatomic handgrip

handgrip (3.2) that is shaped in a way to match the shaped of the hand

Note 1 to entry: Anatomic handgrips exist in right-hand and left-hand types.

3.2

handgrip

part of the walking stick which is normally held in the hand when the walking stick is in use

3.3

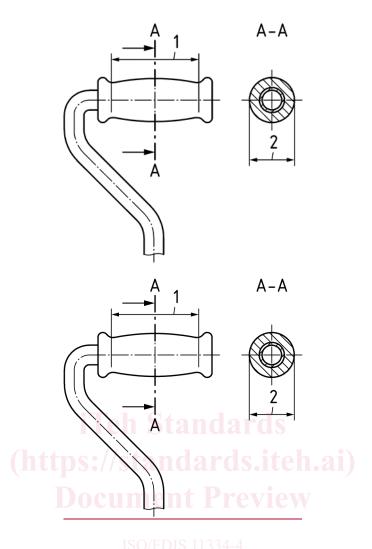
handgrip length

dimension of the handgrip (3.2) measured longitudinally where the hand rests

Note 1 to entry: See Figure 1 Figure, key 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 support the weight of the user is defined as the handgrip length.

ISO/FDIS 11334-4



Key

- 1 handgrip length https://sandards/iso/a8c366d1-9616-446d-9333-a9406e62261a/iso-fdis-11334-4
- 2 handgrip width

Figure 1 — Detail of handle and handgrip

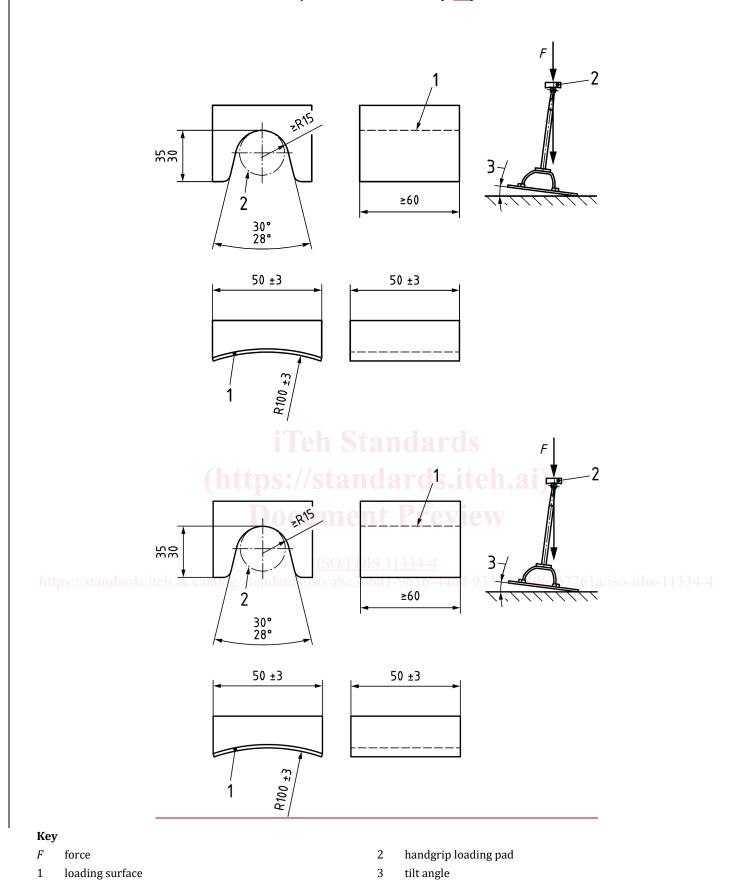
3.4

handgrip loading pad

device capable of applying the test force to the *handgrip* (3.2)

Note 1 to entry: See <u>Figure 2 Figure</u>, <u>key</u> 2.

Note 2 to entry: For some anatomically shaped handgrips, it <u>maycan</u> be necessary to design a custom loading pad.



 $Figure\ 2-Handgrip\ loading\ pad$

3.5

handgrip reference point

crossing point of vertical line through centre of shaft (3.11) and handgrip (3.2)

3.6

handgrip width

dimension of the *handgrip* (3.2) measured length cross-sectionally to longitudinal direction where the hand

Note 1 to entry: See Figure 1 Figure 1, key 12.

3.7

handle

part of walking stick to which the *handgrip* (3.2) is attached

Note 1 to entry: On most devices, the handgrip and the handle are part of the same piece.

3.8

leg

frame or rod separated from the *shaft* (3.11₇), which contacts the ground

3.9

locking device

part of a walking stick that provides locking of the height and/or other adjustment mechanisms

Note 1 to entry: See <u>Figure 4</u>Figure 4, key 7.

3.10

separation part

part of a shaft (3.11) to which separated legs (3.8) are attached

Note 1 to entry: See <u>Figure 9</u> Figure 8, key 1.

standards.iteh.ai/catalog/standards/iso/a8c366d1-9616-446d-9333-a9406e62261a/iso-fdis-11334-4

3.11

shaft

prop section of the walking stick

Note 1 to entry: In most types of walking sticks, the shaft is made of two telescopic tubes used for height adjustment.

3.12

tip

part of a walking stick leg(s) (3.8) which contacts the ground

Note 1 to entry: see Figure 4Figure 4, key 10.

3.13

maximum user mass

greatest permissible mass of the person using the product

Note 1 to entry: It is measured in kilograms (kg).

[SOURCE: ISO 21856:2022, 3.16.1]

© ISO 2024 - All rights reserved