SLOVENSKI STANDARD
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Invalidski vozički z ročnim upravljanjem - Zahteve in preskusne metode

Manual wheelchairs - Requirements and test methods

Muskelkraftbetriebene Rollstühle - Anforderungen und Prüfverfahren

Fauteuils roulants à propulsion manuelle - Exigences et méthodes d'essai

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Manual wheelchairs - Requirements and test methods

Fauteuils roulants à propulsion manuelle - Exigences et méthodes d'essai

Muskelkraftbetriebene Rollstühle - Anforderungen und Prüfverfahren

This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 293.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (prEN 12183:2020) has been prepared by Technical Committee CEN/TC 293 “Assistive products and accessibility”, the secretariat of which is held by SIS.

This document is currently submitted to the CEN Enquiry.

This document will supersede EN 12183:2014.

Annex G provides details of the significant technical changes between this document and the previous edition of 2014.

Requirements and test methods for electrically powered wheelchairs are specified in EN 12184.

Introduction

This is the fifth edition of EN 12183. The previous editions were published in 1999, 2006, 2009 and 2014.

Where this document does not apply to particular wheelchairs, contracting parties should consider whether appropriate parts of this document can be used. Manufacturers might also wish to consider whether appropriate parts of this document can be used to assess the performance of their products against the general safety and performance requirements of Regulation (EU) 2017/745 of 5 April 2017 on medical devices.

This document contains requirements for ergonomic design related to the ease of wheelchair operation.

1 Scope

This document specifies requirements and test methods for manual wheelchairs intended to carry one person of mass not greater than 250 kg, including:

— stand-up manual wheelchairs, and

— manual wheelchairs for showering and/or toileting.

This document does not apply to custom-made manual wheelchairs or manual wheelchairs intended for use in sports.

This document also specifies requirements and test methods for manual wheelchairs with electrically powered ancillary equipment.

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.

EN 12182:2012, *Assistive products for persons with disability - General requirements and test methods*

prEN 12184:2020, *Electrically powered wheelchairs, scooters and their chargers - Requirements and test methods*

EN ISO 14971:2012, *Medical devices — Application of risk management to medical devices (ISO 14971:2007)*

ISO 7176-1:2014, *Wheelchairs — Part 1: Determination of static stability*

ISO 7176-3:2012, *Wheelchairs — Part 3: Determination of effectiveness of brakes*

ISO 7176-8:2014, *Wheelchairs — Part 8: Requirements and test methods for static, impact and fatigue strengths*

ISO 7176-11:2012, *Wheelchairs — Part 11: Test dummies*

ISO 7176-13:1989, *Wheelchairs — Part 13: Determination of coefficient of friction of test surfaces*

ISO 7176-15:1996, *Wheelchairs — Part 15: Requirements for information disclosure, documentation and labelling*

ISO 7176-19:2008,[1] *Wheelchairs — Part 19: Wheeled mobility devices for use as seats in motor vehicles*

ISO 7176-22:2014, *Wheelchairs — Part 22: Set-up procedures*

ISO 7176-26:2007, *Wheelchairs — Part 26: Vocabulary*

ISO 16840-3:2014, *Wheelchair seating — Part 3: Determination of static, impact and repetitive load strengths for postural support devices*

[1] As impacted by ISO 7176-19:2008/A1:2015.

ISO 16840-10:2014, *Wheelchairs — Resistance to ignition of non-integrated seat and back support cushions — Part 10: Requirements and test methods*

ISO 17966:2016, *Assistive products for personal hygiene that support users — Requirements and test methods*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 7176-26:2007, EN 12182:2012 and the following apply.

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

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

NOTE Exceptionally, the definition of wheelchair in ISO 7176-26:2007 is replaced by 3.2 below.

3.1
loaded wheelchair
wheelchair loaded with a test dummy as specified in 4.8

3.2
wheelchair
wheeled personal mobility device incorporating a body support system for a disabled occupant that is manually propelled by the occupant and/or an assistant whilst the occupant is seated

Note 1 to entry: A disabled occupant is a disabled person or a person not having the full capacity to walk unaided.

[SOURCE: Global Medical Device Nomenclature (GMDN), modified]

3.3
pre-sale information
publicly available information provided by the manufacturer about the wheelchair

3.4
stand-up wheelchair
wheelchair which enables the occupant to move between a seated posture and a standing posture and enables the occupant to maintain a standing posture

4 Test apparatus

4.1 Inclined test plane, a continuous, flat, rigid surface with a coefficient of friction as specified in ISO 7176-13:1989, inclined to the horizontal at the specified angle ± 0,5°. The surface shall lie between two imaginary parallel planes 5 mm apart per 1 000 mm of extension in any direction and 50 mm apart per 6 000 mm of extension in any direction. The inclined test plane shall be dry, free from ice, free from loose material (such as gravel), and shall be of sufficient size to accommodate the wheelchair during the tests specified in 9.2.

The inclined test plane may have a fixed or adjustable slope. Where the slope is fixed it could be necessary to use more than one inclined test plane.

4.2 Horizontal test plane, a continuous, flat, rigid surface with a coefficient of friction as specified in ISO 7176-13:1989. The surface shall lie between two imaginary parallel planes 5 mm apart per 1

000 mm of extension in any direction and 50 mm apart per 6 000 mm of extension in any direction. The horizontal test plane shall be dry, free from ice, free from loose material (such as gravel), and shall be of sufficient size to accommodate the wheelchair under test.

4.3 Means to apply a force between 25 N and 200 N with an accuracy of ± 5 % and with a rate of application less than 5 N/s.

4.4 Means to measure force in increments of 1 N in the range 0 N to 200 N with an accuracy of ± 5 %.

4.5 Means to measure distance in the range 0 m to 5 m with an accuracy of ± 1 mm or ± 2 % whichever is the greater.

4.6 Means to measure angles to an accuracy of ± 0,1°.

4.7 Means to measure torque in the range 0,5 Nm to 10 Nm with an accuracy of ± 2 %.

4.8 Test dummy, of appropriate mass, as specified in ISO 7176-11:2012.

4.9 Means to measure speed in the range 0,5 m/s to 1,5 m/s with an accuracy of ± 0,05 m/s.

4.10 Means to move a brake lever smoothly for 60 000 cycles at a frequency of not more than 0,5 Hz.

4.11 Means to measure elapsed time in the range 0 s to 30 s with an accuracy of ± 1 s.

4.12 Means to restrain the rear wheels of a wheelchair so that the wheelchair can be tipped backwards about the axles of the rear wheels without the wheels moving.

EXAMPLE 1 Chocks attached to the horizontal test plane.

4.13 Means to tip a wheelchair backwards smoothly about the axles of the rear wheels and return it to the upright position for 20 000 cycles, at a rate of 10^{+2}_{0} cycles per minute, that can be attached to the push handles of the wheelchair in a manner that does not cause any lateral forces to be applied to them.

EXAMPLE 2 Pneumatic cylinder at an angle of 45° to the horizontal when the wheelchair is upright, attached by a sliding bearing to a bar connecting the push handles.

4.14 Means to restrain the test dummy in a wheelchair, as specified in ISO 7176-22:2014.

5 General requirements

5.1 General

The wheelchair shall conform to the requirements specified in EN 12182:2012 for the following:

— intended performance and technical documentation;

— aids that can be dismantled;

— single use fasteners;

— biocompatibility and toxicity;

— contaminants and residues;

— infection and microbiological contamination;

— overflow, spillage, leakage and ingress of liquids;

— safety of moving parts;

— prevention of traps for parts of the human body;

— folding and adjusting mechanisms;

— surfaces, corners and edges;

— clinical evaluation;

— ergonomics.

5.2 Risk management

A risk management process shall be performed in accordance with EN ISO 14971:2012. For conformity with this document, all elements of the risk management process specified in EN ISO 14971:2012 shall be applied except:

— the planning for, and execution of, production and post-production monitoring (EN ISO 14971:2012, 3.1 fourth indent, 3.4 item f), and Clause 9), and

— periodic reviews of the suitability of the risk management process (EN ISO 14971:2012, 3.2 fourth indent).

5.3 Applicable provisions

Annex F specifies the provisions in this document that apply to some types of wheelchair. See F.1.

6 Preparation for testing

6.1 General

Unless otherwise specified in Clauses 7, 8, 9, 10 and 11, the wheelchair shall be prepared for testing as specified in ISO 7176-22:2014 with the following modification.

If a test procedure requires the use of a test dummy, it shall be selected and fitted as specified in 6.2.

NOTE This instruction supersedes instructions for loading the wheelchair in the referenced standards.

6.2 Test dummy

Unless otherwise specified in this document, select a test dummy, as specified in ISO 7176-11:2012, of mass equal to the maximum occupant mass specified by the wheelchair manufacturer, with a tolerance of 0 kg to +5 kg.

Fit the test dummy in the wheelchair as specified in ISO 7176-22:2014.

7 Wheelchair performance

7.1 Static stability

7.1.1 Requirements

The wheelchair shall have provision for anti-tip devices if the static stability is less than 10°.

7.1.2 Test method

Test the loaded wheelchair as specified in ISO 7176-1:2014. Where the maximum occupant mass is greater than 100 kg, repeat the rearward static stability test with a 100 kg dummy fitted to the wheelchair.

If the wheelchair can be tested without anti-tip devices, use the results of tests without anti-tip devices recorded in ISO 7176-1:2014, Table 4, to establish whether provision for anti-tip devices is required, and, if so, determine whether the wheelchair has such provision.

7.2 Static, impact and fatigue strength

7.2.1 Requirements

The wheelchair shall conform to the requirements of ISO 7176-8:2014.

Arm supports shall conform to the static loading requirements of ISO 7176-8:2014 in all intended operating positions.

See also Annex E.

7.2.2 Test method

Test the wheelchair in accordance with ISO 7176-8:2014, with the following modification to preparation for the fatigue test.

Where the maximum occupant mass is greater than 100 kg and the position of the rear wheels is adjustable, adjust the position of the rear wheels so that the relative distribution of load on the front and rear wheels is as close as practicable to the relative distribution of load on the front and rear wheels when a 100 kg dummy is fitted in the wheelchair.

7.3 Tilting fatigue strength

7.3.1 General

Occupied wheelchairs can often be tipped backwards by assistants when manoeuvring them. The tipping action can put considerable stress on the back support and related components. It is important that a manual wheelchair that can be tipped in this way is able to withstand repeated tipping without damage.

7.3.2 Requirement

This requirement applies only to wheelchairs where the intended use includes tipping the occupied wheelchair backwards about the rear wheel axles by use of the push handles.

After the wheelchair has been subjected to the test specified in 7.3.3, no part of the back support shall have moved from the pre-set position and no component or assembly of parts shall show visible signs of cracks, breakages, gross deformations, free play, loss of adjustment or any other damage that adversely affects the function of the wheelchair.