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Invalidski vozički z ročnim upravljanjem - Zahteve in preskusne metode

Manual wheelchairs - Requirements and test methods

Rollstühle mit Muskelkraftantrieb - 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 European Standard was approved by CEN on 27 December 2013.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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Foreword

This document (EN 12183:2014) has been prepared by Technical Committee CEN/TC 293 “Assistive products for persons with disability”, 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of an identical text or by endorsement, at the latest by September 2014 and conflicting national standards shall be withdrawn at the latest by March 2017.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 12183:2009, which is to be withdrawn (dow) three years after the date of availability of this edition. See CEN/TC 293 resolution 492.

This document 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 of 14 June 1993 concerning medical devices.

For relationship with the applicable EU Directive(s), see informative Annex ZA, which is an integral part of this document.

Informative Annex E provides details of significant technical changes between this European Standard and the previous editions of 1999, 2006 and 2009.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Introduction

This is the fourth edition of this European Standard. The first edition was published in 1999, the second in 2006 (withdrawn in 2007) and the third in 2009.

Where this European Standard does not apply to particular wheelchairs, contracting parties should consider whether appropriate parts of this European Standard can be used. Manufacturers might also wish to consider whether appropriate parts of this European Standard can be used to assess the performance of their products against the Essential Requirements of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

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

1 Scope

This European Standard specifies requirements and test methods for manual wheelchairs intended to carry one person of mass not greater than 250 kg.

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

This European Standard does not apply in total to:

— wheelchairs intended for special purposes, such as sports, showering or toileting,

— manual wheelchairs with handrim-activated power-assisted propulsion,

— custom-made wheelchairs,

— stand-up wheelchairs, and

— manual wheelchairs with add-on power kits used for propulsion.

NOTE Requirements for electrically powered wheelchairs are specified in EN 12184.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 1021-2:2006, *Furniture — Assessment of the ignitability of upholstered furniture — Part 2: Ignition source match flame equivalent*

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

EN 12184, *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, Corrected version 2007-10-01)*

ISO 7176-1:1999, *Wheelchairs — Part 1: Determination of static stability*

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

ISO 7176-8:1998, *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, *Wheelchairs — Part 19: Wheeled mobility devices for use as seats in motor vehicles*

ISO 7176-22:2000, *Wheelchairs — Part 22: Set-up procedures*

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

ISO 8191-2:1988, *Furniture — Assessment of ignitability of upholstered furniture — Part 2: Ignition source: match-flame equivalent*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 7176-26:2007 (with the exception of the definition of wheelchair which is replaced by 3.2 below), EN 12182:2012 and the following apply.

3.1
loaded wheelchair
wheelchair loaded with a 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 Definition is adapted from the definition given in the Global Medical Devices Nomenclature (GMDN).

NOTE 2 A disabled occupant is a disabled person or a person not having the full capacity to walk unaided.

4 Test apparatus

4.1 Adjustable test plane, a flat, rigid plane having an adjustable slope, with a coefficient of friction as specified in ISO 7176-13:1989, of sufficient size to accommodate the wheelchair during the tests specified in 9.2, and such that the whole surface lies 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.

4.2 Horizontal test plane, a flat, rigid plane, with a coefficient of friction as defined in ISO 7176-13:1989, of sufficient size to accommodate the wheelchair under test, and such that the whole surface lies between two imaginary horizontal 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.

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

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

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 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 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, for example straps or bicycle inner tubes.

NOTE ISO 7176-8:1998, 10.3, provides guidance on restraining a test dummy.

5 General requirements

The wheelchair shall conform to the requirements specified in EN 12182 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.

A risk analysis shall also be carried out in accordance with EN ISO 14971:2012.

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 7176-22:2000 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

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 7176-22:2000.

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 7176-1:1999. Use the angles recorded in Table 4 of ISO 7176-1:1999 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 7176-8:1998.

Arm supports shall conform to the static loading requirements of ISO 7176-8:1998 in all intended operating positions.

Where the manufacturer specifies a maximum occupant mass greater than 100 kg the forces specified in Table 2 shall apply.

7.2.2 Test

Test the wheelchair in accordance with ISO 7176-8:1998 with modifications as stated in 7.2.1.

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 maximum occupant mass is not greater than 150 kg and 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.

7.3.3 Test method

a) If the position of the rear wheels is adjustable, set them to the most rearward position in accordance with the manufacturer's instructions for use. If the position of the front wheels is adjustable, set them to the most forward position in accordance with the manufacturer's instructions.

b) If the position of the back support and/or push handles is adjustable, set them to the maximum height in accordance with the manufacturer's instructions.

c) Ensure that the rear wheels are free to rotate, for example by disengaging parking brakes.

d) Restrain the rear wheels using appropriate means (4.12) so that the wheelchair can be tipped about the axles of the rear wheels without the wheels moving.

e) Attach the means to tip the wheelchair (4.13) to the push handles so that it will apply forces in a vertical plane parallel to the forward direction of travel that bisects the wheelchair. Make sure the means of attachment cannot apply any lateral forces to the push handles.

f) Secure the dummy in the wheelchair using appropriate means (4.14) so that it will remain in position as the wheelchair is tipped and returned to the upright position.

g) Using the means to tip the wheelchair (4.13), smoothly tip the loaded wheelchair backwards to the point of balance (where the centre of mass of the loaded wheelchair is directly above the rear axles), ± 1°, or to the angle where the front wheels are lifted to a height of $120\ ^{+10}_{0}$ mm above the test surface, whichever angle is greater. Then smoothly return the loaded wheelchair to the upright position. Ensure the push handles are not pushed forward when the wheelchair is upright.

h) Repeat g) for 20 000 cycles at a rate of $10\ ^{+2}_{0}$ cycles per minute.

i) Inspect the wheelchair and determine whether it has met the requirement.

7.4 Wheelchairs for use as seats in motor vehicles

If the manufacturer specifies that the intended use of the wheelchair includes use as a seat in a motor vehicle by an occupant of mass not less than 22 kg, the wheelchair shall conform to the performance requirements of ISO 7176-19:2008 with the following modifications.