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Invalidski vozički na električni pogon, skuterji in njihovi polnilniki - Zahteve in preskusne metode

Electrically powered wheelchairs, scooters and their chargers - Requirements and test methods

Elektrorollstühle und -mobile und zugehörige Ladegeräte - Anforderungen und Prüfverfahren

Fauteuils roulants électriques, trottinettes et leurs chargeurs - Exigenes et méthodes d'essai

Ta slovenski standard je istoveten z: **EN 12184:2014**

ICS:

11.180.10	Pripomočki in prilagoditve za gibanje	Aids and adaptation for moving

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Electrically powered wheelchairs, scooters and their chargers - Requirements and test methods

Fauteuils roulants électriques, scooters et leurs chargeurs - Exigences et méthodes d'essai

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Contents

Page

Foreword

This document (EN 12184:2014) 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of an identical text or by endorsement, at the latest by September 2014 and conflicting national standards shall be withdrawn at the latest by March 2017.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This document supersedes EN 12184:2009, which is to be withdrawn (dow) three years after the date of availability (dav) of this edition. See CEN/TC 293 resolution 493.

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 Council 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 G 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 electrically powered wheelchairs, including electrically powered scooters with three or more wheels, with a maximum speed not exceeding 15 km/h intended to carry one person of mass not greater than 300 kg.

It also specifies requirements and test methods for battery chargers for wheelchairs and scooters.

This European Standard does not apply in total to:

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

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

— custom-made electrically powered wheelchairs,

— electrically powered stand-up wheelchairs,

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

— electrically powered office chairs.

NOTE Requirements for manually propelled wheelchairs are specified in EN 12183.

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 60335-1:2012, *Household and similar electrical appliances — Safety — Part 1: General requirements (IEC 60335-1:2010, modified)*

EN 60529:1991, *Degrees of protection provided by enclosures (IP Code) (IEC 60529:1989)*

EN 60601-1:2006, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005)*

EN 62304:2006, *Medical device software — Software life-cycle processes (IEC 62304:2006)*

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 7176-2:2001, *Wheelchairs — Part 2: Determination of dynamic stability of electric wheelchairs*

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

ISO 7176-4:2008, *Wheelchairs — Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range*

ISO 7176-6:2001, *Wheelchairs — Part 6: Determination of maximum speed, acceleration and deceleration of electric wheelchairs*

ISO 7176-8:1998, *Wheelchairs — Part 8: Requirements and test methods for static, impact and fatigue strengths*

ISO 7176-9:2009, *Wheelchairs — Part 9: Climatic tests for electric wheelchairs*

ISO 7176-10:2008, *Wheelchairs — Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs*

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 7176-14:1997, *Wheelchairs — Part 14: Power and control systems for electric wheelchairs — Requirements and test methods*

NOTE ISO 7176-14:1997 is used only for requirements and test methods for battery chargers.

ISO 7176-14:2008, *Wheelchairs — Part 14: Power and control systems for electrically powered wheelchairs and scooters — Requirements and test methods*

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 7176-21:2009, *Wheelchairs — Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers*

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 3.6 below), ISO 7176-14:2008, EN 12182:2012 and the following apply.

3.1
audible warning device
device for making a warning sound or noise

EXAMPLE A horn.

3.2
freewheel device
means for disengaging the parking brake and/or the drive of a wheelchair to allow it to be manoeuvred manually

3.3
loaded wheelchair
wheelchair loaded with a dummy as specified in 4.9 or loaded with a human test occupant

3.4
non-spillable battery
battery from which the electrolyte cannot escape whatever its orientation

3.5
rated slope
maximum slope specified by the manufacturer on which the wheelchair meets the requirements for dynamic stability, static stability, braking performance and slope climbing, traversing and descending

3.6
wheelchair
wheeled personal mobility device incorporating a body support system for a disabled occupant that is propelled by one or more electric motors controlled by the occupant or by an assistant, and that has electronic control of speed and electronic or manual control of direction

Note 1 to entry: Definition is adapted from the definition given in the Global Medical Devices Nomenclature (GMDN).

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

Note 3 to entry: The definition includes scooters.

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 8.1 and 10.2, 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 specified 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 speed between 0 km/h and 20 km/h to an accuracy of ± 5 %.

4.6 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.

4.7 Supplementary weights to add to a human test occupant to achieve the maximum occupant mass specified by the manufacturer and to achieve a similar mass distribution to the dummy specified in 4.9.

4.8 Test block, capable of supporting the loaded wheelchair under each of its wheels, with length and width 200 mm ± 10 mm, thickness given in Table 1 'ground unevenness' and corner radii greater than 2,0 mm. For the two large surfaces, the whole of each surface shall lie between two imaginary horizontal planes 1 mm apart. The coefficient of friction shall be as specified in ISO 7176-13:1989.

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

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

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

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

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

5 Type classes

Wheelchairs shall be classified in one or more of the following three classes, dependent upon their intended use:

— Class A: compact, manoeuvrable wheelchairs not necessarily capable of negotiating outdoor obstacles;

— Class B: wheelchairs sufficiently compact and manoeuvrable for some indoor environments and capable of negotiating some outdoor obstacles;

— Class C: wheelchairs, usually large in size, not necessarily intended for indoor use but capable of travelling over longer distances and negotiating outdoor obstacles.

NOTE Scooters are included within the classes above.

6 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 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.

7 Preparation for testing

7.1 General

Unless otherwise specified in Clauses 8, 9, 10, 11 and 12, 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 or human test occupant, they shall be selected and fitted as specified in 7.2 or 7.3.

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

7.2 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.

7.3 Human test occupant

Select a human test occupant whose mass, in combination with any supplementary weights as specified in 4.7, is equal to the maximum occupant mass specified by the wheelchair manufacturer, with a tolerance of 0 kg to + 5 kg.

Seat the occupant in the wheelchair and position and secure the supplementary weights to give substantially the same mass distribution as the test dummy when fitted as specified in ISO 7176-22:2000.

WARNING – This testing is potentially hazardous to a human test occupant and other test personnel. Appropriate safety precautions should be taken to avoid injury.

8 Wheelchair performance

8.1 Performance of driving characteristics

8.1.1 General

The loaded wheelchair shall meet the driving performance requirements specified in Table 1 and Table 2 for the type class of the wheelchair as specified in Clause 5.

8.1.2 Ability to climb rated slope

8.1.2.1 Requirements

The wheelchair shall be capable of climbing at a speed not less than 2 km/h:

— the applicable rated slope for the type class of wheelchair specified in Table 1, or

— the rated slope specified by the manufacturer, whichever is greater.

The wheelchair passes the test specified in 8.1.2.2 if it achieves or exceeds a speed of 2 km/h after travelling 5 m up the slope.

8.1.2.2 Test

Adjust the gradient of the adjustable test plane specified in 4.1 to the required angle, ± 0,5°.

Starting on the adjustable test plane, drive the loaded wheelchair up the adjustable test plane using the maximum speed command. Use the means to measure speed specified in 4.5.

When the wheelchair has travelled (5,0 ± 0,1) m up the slope, measure and record the speed to an accuracy of ± 10 %.

8.1.3 Ground unevenness

8.1.3.1 Principle

It is important that a wheelchair is able to drive on uneven terrain without stopping even if one wheel is at a higher level than the others.

8.1.3.2 Requirement

The wheelchair shall be capable of driving when any of its wheels is raised to a height specified in Table 1 for ground unevenness.

8.1.3.3 Test

a) Place the loaded wheelchair on the horizontal test plane.

b) Place the test block specified in 4.8 under one wheel, such that one of its largest faces is flat on the test plane with the centre of the block beneath the point of contact with the wheel.

c) Attempt to drive the loaded wheelchair off the test block.

d) Record the result of the test.

e) Repeat for the remaining wheels, one at a time.

f) The test is passed if the wheelchair is able to drive off the test block for each wheel.

8.1.4 Maximum downhill speed

8.1.4.1 Requirement

The wheelchair shall not exceed 125 % of its maximum speed on the horizontal, when driving down

— the applicable rated slope for the type class of wheelchair specified in Table 1, or

— the rated slope specified by the manufacturer, whichever is greater.

8.1.4.2 Test

a) Drive the loaded wheelchair at maximum speed down a gradient with the required slope, ± 0,5°.

b) Measure the speed achieved using the means specified in 4.5.

c) Record the measured speed and record whether the wheelchair has met the requirement.