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Invalidski voziļ ki na elektriļ ni 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, scooters et leurs chargeurs - Exigences et méthodes d'essai

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11.180.10	Pripomoļ ki in prilagoditve za gibanje	Aids and adaptation for moving

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

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Foreword

This document (EN 12184:2009) 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of an identical text or by endorsement, at the latest March 2010, and conflicting national standards shall be withdrawn at the latest by March 2010.

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 12184:2006.

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, as amended by Directive 2007/47/EC.

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

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

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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

This is the third edition of this European Standard which was originally issued in 1999. The second edition was published in 2006 but was withdrawn in 2007.

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 concerning medical devices 93/42/EEC of 14 June 1993, as amended by Directive 2007/47/EC.

This European Standard contains requirements for ergonomic design related to the ease of wheelchair operation. They are intended to be applicable to at least 80 % of adult occupants and are based upon:

— the body size of occupants within the range 5th percentile adult female to 95th percentile adult male,

— the abilities and restrictions of a 65-year-old 50th percentile female, and

— the wheelchair being equipped with operating devices which are not custom-made for individual occupants.

1 Scope

This European Standard specifies requirements and test methods for electrically powered wheelchairs with a maximum speed not exceeding 15 km/h intended to carry one person of mass not greater than 100 kg, which includes:

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

— electrically powered wheelchairs, and

— electrically powered scooters with three or more wheels.

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

This European Standard does not apply in total to:

— wheelchairs intended for special purposes, such as sports,

— custom-made wheelchairs,

— handrim activated power assisted wheelchairs and

— powered office chairs.

NOTE 1 The application of this standard is limited to wheelchairs with a maximum occupant mass of 100 kg because the maximum mass of dummy specified in ISO 7176-11:1992 is 100 kg. Annex A (informative) provides guidance for construction of dummies of mass 125 kg and 150 kg. At the time of publication, a new edition of ISO 7176-11 was under development, including test dummies with masses above 100 kg.

NOTE 2 Requirements for manually propelled wheelchairs are specified in EN 12183.

2 Normative references

The following referenced documents are indispensable for the application 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 1021-1:2006, *Furniture — Assessment of the ignitability of upholstered furniture — Part 1: Ignition source smouldering cigarette*

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

EN 12182, *Technical aids for disabled persons — General requirements and test methods*

EN 50272-3:2002, *Safety requirements for secondary batteries and battery installations — Part 3: Traction batteries*

EN 60335-1:2002, *Household and similar electrical appliances — Safety — Part 1: General requirements (IEC 60335-1:2001, 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 61000-3-2:2006, *Electromagnetic compatibility (EMC) — Part 3-2: Limits — Limits for harmonic current emissions (equipment input current ≤ 16 A per phase) (IEC 61000-3-2:2005)*

EN ISO 14971:2009, *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 7176-3:2003, *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 7176-9:2001, *Wheelchairs — Part 9: Climatic test for electric wheelchairs*

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

ISO 7176-11:1992, *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 7176-19:2001, *Wheelchairs — Part 19: Wheeled mobility devices for use in motor vehicles*

ISO 7176-21:2003, *Wheelchairs — Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and motorized scooters*

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

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

ISO 10542-5:2004, *Technical systems and aids for disabled or handicapped persons — Wheelchair tiedown and occupant-restraint systems — Part 5: Systems for specific wheelchairs*

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 3.7 below), ISO 7176-14:2008, EN 12182 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
maximum safe slope
maximum slope specified by the manufacturer on which the wheelchair meets all the requirements of dynamic stability, static stability, braking performance and slope climbing, traversing and descending

3.5
non-spillable battery
battery from which the electrolyte can not escape whatever its orientation

3.6
spillable battery
battery from which the electrolyte can escape in some orientations

3.7
wheelchair
wheeled personal mobility device incorporating a seating 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 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.

NOTE 3 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 8.4 and 8.8, 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 25 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 25 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 to be used as 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 size, as specified in ISO 7176-11:1992.

NOTE Annex A gives guidance on construction of dummies with masses larger than those specified in ISO 7176-11:1992.

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 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;

— electronic programmable systems;

— clinical evaluation;

— ergonomics.

A risk analysis shall also be carried out in accordance with EN ISO 14971:2009.

7 Design requirements

7.1 Foot supports, lower leg supports and arm supports

The wheelchair shall be fitted with foot supports that have a means of positioning the occupant's feet at the required height, that prevent the occupant's feet from sliding backwards and that meet the performance requirements specified in 8.2.

Where fitted, lower leg supports and arm supports shall meet the performance requirements specified in 8.2.

7.2 Pneumatic tyres

If the wheelchair is fitted with pneumatic tyres, they shall have the same type of valve connection on all tyres.

The tyres or the rims shall be marked with the maximum pressure in kPa or bar.

7.3 Fitting an anterior pelvic support

The wheelchair shall have provision for an anterior pelvic support to be fitted. The manufacturer of the wheelchair shall have available as an option an anterior pelvic support which can be used with that provision.

7.4 Wheelchairs for use as seats in motor vehicles

If the manufacturer specifies that the intended use of the wheelchair includes use by an adult as a seat in a motor vehicle, the wheelchair shall conform to the performance requirements of ISO 7176-19:2001.

If the manufacturer specifies that the intended use of the wheelchair includes use as a seat in a motor vehicle by a child of mass greater than 22 kg, the wheelchair shall conform to the performance requirements of ISO 7176-19:2001 with the exception of the horizontal excursion limits and the selection of the Anthropomorphic Test Device (ATD). The horizontal excursion limits specified in Table 1 of ISO 10542-5:2004 and the ATD selection specified in Table A.1 of ISO 10542-5:2004 shall apply.

7.5 Braking systems

The wheelchair shall be fitted with a braking system that meets the performance requirements specified in 8.4.

If one or more brake levers are fitted to a wheelchair in the form used on bicycles and mopeds, the hand-grip width of such brake levers, measured 15 mm from the end of the brake lever, shall not be greater than 75 mm before a force is applied. See Figure 1.

7.6 Freewheel device

The wheelchair shall be fitted with a freewheel device that shall

— be accessible and operable by the occupant or an assistant or both in accordance with the manufacturer's intended use,

— be within the reach specified in Figure 2, if it is intended to be operated by the occupant,

— have operating forces for engaging and disengaging that do not exceed those stated in Table 1,

— be operable without detaching any parts,

— not depend on the battery power supplying the motor drive system,

NOTE 1 A battery independent from the motor drive battery may be used to supply energy to enable freewheel mode.

— have two defined positions including clear indication of freewheel mode and drive mode,

NOTE 2 An audible alarm activated when the freewheel device is in operation and deactivated when the drive and braking systems are fully operational would assist the occupant and/or assistant.

— prevent use of the wheelchair's drive system, if any part of the freewheel device is activated.

NOTE 3 These requirements apply in addition to those concerning non-powered mobility stated in ISO 7176-14:2008.

7.7 Component mass

If the wheelchair is intended to be dismantled for storage or transportation, any component that requires moving or handling that has a mass greater than 10 kg shall be provided with suitable handling devices (e.g. handles). The manufacturer shall provide information indicating the points where such components can be lifted and describing how they shall be handled during disassembly, lifting, carrying, and assembly to reduce risks to the person or persons moving or handling them.

7.8 Battery enclosures and containers

Battery enclosures and containers shall

a) allow accessibility without the use of tools for inspection and service specified by the wheelchair manufacturer,

b) provide protection so that it should not be possible for liquids dropping from above to enter into them and onto any cell or battery they contain,

c) provide protection to stop any objects contacting the terminals of batteries and/or cells and the connections between them, to prevent a short circuit.

Battery enclosures shall be ventilated at the side near to the highest point by an opening or openings which have a total area not less than 100 mm² or as specified in 6.6.2 of EN 50272-3:2002 whichever is the greater.

NOTE The openings are intended to permit escape of gases.

Battery containers shall

d) be used where spillable batteries are fitted to the wheelchair,

e) be resistant to corrosion caused by battery gases and acid.

7.9 Operations intended to be carried out by the occupant and/or assistant

Wheelchairs shall be designed to facilitate ease of operation by the occupant and/or assistant as specified in the manufacturer's instructions and meet the performance requirements of 8.2.1, 8.5, 8.6.1, 8.7.1, 8.9, 8.12.1, 9.2 and 9.3. In addition, brake levers shall meet the applicable requirements of 8.4.1.

Examples include:

— operation of adjustable seating,

— use of detachable components, including removable arm supports, lower leg supports etc., to facilitate safe transfers into and out of the wheelchair,

— use of folding mechanisms, including folding frames etc., to facilitate storage and transportation of unoccupied wheelchairs,

— carrying out maintenance, including use of tools etc.,

— use of manual steering controls,

— use of braking systems and freewheel devices,

— use of assistant controls,

— use of control devices.

7.10 Controls intended for operation by the occupant

Controls intended to be operated by the occupant while seated shall be within the occupant reach as shown in Figure 2.

The following controls, if fitted, are included:

— on/off switch or key,

— speed regulator,

— speed pre-setting,

— running brake,

— parking brake,

— audible warning device,

— direction indicator,

— direction switch,