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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, Scooters 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	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

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

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European foreword

This document (EN 12184:2022) has been prepared by Technical Committee CEN/TC 293 “Assistive products and accessibility”, 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of an identical text or by endorsement, at the latest by March 2023, and conflicting national standards shall be withdrawn at the latest by May 2024.

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

This document supersedes EN 12184:2014.

Annex H provides details of the significant technical changes between this document and EN 12184:2014.

Requirements and test methods for manual wheelchairs are specified in EN 12183.

Any feedback and questions on this document should be directed to the users’ national standards body. A complete listing of these bodies can be found on the CEN website.

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Introduction

This is the fifth edition of this European Standard. 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 can also 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 [21] of 5 April 2017 on medical devices.

1 Scope

This document specifies requirements and test methods for electrically powered wheelchairs, with a maximum speed not exceeding 20 km/h, intended to carry one person of mass not less than 25 kg and not greater than 300 kg, including

— electrically powered scooters with three or more wheels,

— manual wheelchairs with an add-on electrically powered drive system,

— handrim-activated power-assisted wheelchairs,

— electrically powered stand-up wheelchairs,

— wheelchairs with a pivot drive wheel unit, and

— push-assist wheelchairs.

This document does not apply to balancing wheelchairs, custom-made electrically powered wheelchairs or electrically powered 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 614-1:2006+A1:2009, *Safety of machinery - Ergonomic design principles - Part 1: Terminology and general principles*

EN 1021-2:2014, *Furniture - Assessment of the ignitability of upholstered furniture - Part 2: Ignition source match flame equivalent*

EN 12183:2022, *Manual wheelchairs - Requirements and test methods*

EN 15194:2017, *Cycles - Electrically power assisted cycles - EPAC Bicycles*

EN 60335-2-29:2004,[1] *Household and similar electrical appliances - Safety - Part 2-29: Particular requirements for battery chargers (IEC 60335-2-29:2002)*

EN 60601-1:2006,[2] *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005)*

EN 62133-2:2017,[3] *Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems*

[1] EN 60335-2-29:2004 is amended by EN 60335-2-29:2004/A2:2010 and EN 60335-2-29:2004/A11:2018.

[2] EN 60601-1:2006 is amended by EN 60601-1:2006/A2:2021, EN 60601-1:2006/A12:2014 and EN 60601-1:2006/A1:2013; and corrected by EN 60601-1:2006/corrigendum Mar. 2010.

[3] EN 62133-2:2017 is amended by EN 62133-2:2017/A1:2021.

EN 62304:2006,[4] *Medical device software - Software life-cycle processes (IEC 62304:2006)*

EN ISO 10993-1:2020, *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018, including corrected version 2018-10)*

EN ISO 14155:2020, *Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2020)*

EN ISO 14971:2019,[5] *Medical devices - Application of risk management to medical devices (ISO 14971:2019)*

EN ISO 20417:2021, *Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021, Corrected version 2021-12)*

EN ISO 22442-1:2020, *Medical devices utilizing animal tissues and their derivatives - Part 1: Application of risk management (ISO 22442-1:2020)*

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

ISO 7176-2:2017, *Wheelchairs — Part 2: Determination of dynamic stability of electrically powered 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 7176-6:2018, *Wheelchairs — Part 6: Determination of maximum speed of electrically powered wheelchairs*

ISO 7176-8:2014, *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 7176-14:2008, *Wheelchairs — Part 14: Power and control systems for electrically powered wheelchairs and scooters — Requirements and test methods*

ISO 7176-19:2008,[6] *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*

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4 EN 62304:2006 is amended by EN 62304:2006/A1:2015.

5 EN ISO 14971:2019 is amended by EN ISO 14971:2019/A11:2021.

6 ISO 7176-19:2008 is amended by ISO 7176-19:2008/AMD 1:2015.

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

ISO 7176-25:2013, *Wheelchairs — Part 25: Batteries and chargers for powered wheelchairs*

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*

ISO 16840-10:2021, *Wheelchair seating — Part 10: Resistance to ignition of postural support devices — Requirements and test method*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 7176-26:2007, ISO 7176-14:2008 and the following apply.

NOTE The definitions of wheelchair and electrically powered wheelchair in ISO 7176-26:2007 are replaced by 3.5 below.

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

3.2
loaded wheelchair
wheelchair loaded with a test dummy or loaded with a human test occupant

Note 1 to entry: Instructions for selecting and fitting a test dummy or a human test occupant are given in Clause 7.

3.3
non-spillable battery
battery from which the electrolyte cannot escape whatever its orientation

3.4
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

3.5
wheelchair
electrically powered wheelchair
wheeled mobility device, intended to transport a seated occupant who has impaired mobility, that is propelled by one or more electric motors controlled by the occupant or by an assistant

Note 1 to entry: An electrically powered wheelchair can have electronic control of speed and electronic or manual control of direction.

Note 2 to entry: The definition includes scooters.

3.6
pre-sale information
publicly available information provided by the manufacturer about the wheelchair

Note 1 to entry: A specification sheet is part of the pre-sale information.

3.7
push-assist wheelchair
wheelchair intended to be partly propelled, braked, and/or steered by the manual effort of an assistant

EXAMPLE Wheelchair propelled by an electric motor and steered by forces applied to the push handles.

3.8
pivot drive wheel unit
integrated propulsion system comprising a pivot drive wheel, a battery and a controller

3.9
custom-made electrically powered wheelchair
electrically powered wheelchair designed and manufactured for use by a named individual occupant that is not an adaptation of a mass-produced design

4 Test apparatus

4.1 Horizontal test plane, of sufficient length that the wheelchair can reach its maximum speed and decelerate to a stop. The horizontal test plane shall be dry, free from ice, and free from loose material (such as gravel). The horizontal test plane shall include a test area consisting of a continuous, flat, rigid surface with a coefficient of friction as specified in ISO 7176-13:1989, inclined to the horizontal at less than 0,5°. The surface of the test area 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 test area shall be of sufficient size to complete the specified manoeuvres, except for acceleration and deceleration, which may occur outside the test area when they do not affect the test results.

The requirements for the test area do not apply to the parts of the horizontal test plane outside it, but the properties of all parts of the horizontal test plane, including any transitions at the edges of the test area, shall be sufficiently similar that the test results are not affected.

4.2 Inclined test plane, of sufficient length that the wheelchair can reach its maximum speed and decelerate to a stop. The inclined test plane shall be dry, free from ice, and free from loose material (such as gravel). The inclined test plane shall include a test area consisting of 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 of the test area 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 test area shall be of sufficient size to complete the specified manoeuvres, except for

acceleration and deceleration, which may occur outside the test area when they do not affect the test results.

The requirements for the test area do not apply to the parts of the inclined test plane outside it, but the properties and slope of all parts of the inclined test plane, including any transitions at the edges of the test area, shall be sufficiently similar that the test results are not affected.

See Figure 6.

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

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 speed between 0 km/h and 25 km/h to an accuracy of ±5 %.

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

4.7 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 3 '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 in the range 0,5 Nm to 10 Nm with an accuracy of ±2 %.

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, depending upon their intended use:

— Class A: wheelchairs intended for driving on flat horizontal surfaces and gentle slopes;

— Class B: wheelchairs intended for driving on moderately uneven surfaces and on moderate slopes, in addition to the intended use described for Class A;

— Class C: wheelchairs intended for driving on uneven terrain and on steeper slopes, in addition to the intended uses described for Classes A and B.

Requirements specific to each class are given in Table 3.

NOTE 1 Scooters are included within the classes above.

NOTE 2 Some requirements and exceptions specific to Class A are given in the text.

6 General requirements

6.1 Risk management

A risk management process shall be performed in accordance with EN ISO 14971:2019[5]. For conformity with this document, all elements of the risk management process specified in EN ISO 14971:2019[5] shall be applied except:

— the planning for, and execution of, production and post-production monitoring (EN ISO 14971:2019[5], 4.1 fourth indent, 4.4 item g) and Clause 10); and

— periodic reviews of the suitability of the risk management process (EN ISO 14971:2019[5], 4.2 third paragraph).

6.2 Intended performance and technical documentation

a) The wheelchair shall have sufficient strength and durability to sustain all loads expected during intended use. This shall be confirmed by using, where appropriate, references to relevant clinical and scientific literature, strength and/or durability calculations, appropriate test standards and their test results, in addition to the requirements given in this document.

b) The intended performance of the wheelchair, including, where appropriate, strength, durability and tipping stability, shall be described in technical documentation which sets out its functional characteristics, its application(s) and conditions of use.

c) The technical documentation shall include, where appropriate, references to relevant clinical and scientific literature, any strength and/or life calculations, appropriate test standards and their test results.

6.3 Clinical evaluation and investigation

A clinical evaluation shall be conducted for the wheelchair.

If, as part of the product conformity assessment, the clinical evaluation requires a clinical investigation, the clinical investigation shall conform to the requirements of EN ISO 14155:2020. A clinical evaluation shall always be conducted before performing a clinical investigation.

NOTE Guidance for clinical evaluation is given in MEDDEV 2.7/1 [22].

6.4 Wheelchairs that can be dismantled

If it is intended that the wheelchair can be dismantled for storage or transportation, it shall not be possible to reassemble the wheelchair in a manner that presents a hazard.

6.5 Single-use fasteners

If it is intended that the wheelchair can be dismantled for storage or transportation, the fasteners which are loosened or removed to allow this dismantling shall not be single-use fasteners.

EXAMPLE Single-use fasteners include wood screws and self-tapping screws.

6.6 Biocompatibility and toxicity

Materials which come into contact with the human body shall be evaluated for biocompatibility in accordance with EN ISO 10993-1:2020 as part of the risk management process (see 6.1).

The evaluation shall take into account the intended use, including, where appropriate, contact with the occupant, an assistant, those involved in care of the occupant, and those involved in transportation and storage of the wheelchair.

Wheelchairs shall be designed and manufactured to minimize the risks posed by substances leaking from them. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction and other substances of very high concern (SVHCs). The evaluation should follow the guidance given in Annex F.

NOTE See Annex F for additional guidance.

6.7 Contaminants and residues

6.7.1 General

The requirements given in 6.7.2 apply to substances which are an integral part of the wheelchair or are necessary for its function, such as oil and grease. The requirements do not apply to body fluids which the wheelchair is intended to collect (e.g. as a stoma-care product).

6.7.2 Substances which can leak in intended use or in a fault condition

Where a substance can leak from the wheelchair in intended use or in a fault condition:

a) the substance shall be assessed for biocompatibility in accordance with EN ISO 10993-1:2020 as part of the risk management process, and the assessment shall consider intended use, including, where appropriate, contact with the occupant, an assistant, those involved in care of the occupant, and those involved in transportation and storage of the wheelchair; or

b) the wheelchair shall have means of protection that minimizes the possibility of the substance becoming a biological hazard.

NOTE Substances that can leak include lubricants and hydraulic fluids.

EXAMPLE A method of protection from a hazardous substance is to place batteries in a container made from acid resistant material.

6.8 Infection and microbiological contamination

6.8.1 Cleaning and disinfection

If any parts of the wheelchair are intended to be cleaned, the method and suitable materials for cleaning shall be described in the instructions for use.

If any parts of the wheelchair are intended to be disinfected, the method and suitable materials for disinfection shall be described in the instructions for use.

NOTE For guidance, see B.2.7.

If any parts of the wheelchair are intended to be cleaned by automatic washing systems or hand-held jet stream or steam washing, the details of the procedure, such as temperature, pressure, flow and pH value of cleaning/rinsing solution, shall be described in the instructions for use. Where practicable, the wheelchair shall be labelled with appropriate symbols to represent the method of cleaning.

6.8.2 Animal tissue

Where the wheelchair has been manufactured utilizing tissues of animal origin or their derivatives, the process specified in EN ISO 22442-1:2020 shall be followed as part of the risk management process (see 6.1).

NOTE For guidance, see B.2.13.

6.9 Overflow, spillage, leakage, and ingress of liquids

6.9.1 Overflow

6.9.1.1 Requirements

If the wheelchair incorporates a reservoir or liquid storage chamber that can be overfilled or can overflow in intended use, liquid overflowing from the reservoir or chamber shall not wet electrical insulation or live parts which are liable to be adversely affected by such a liquid, nor shall a hazard be created. Unless indicated by a marking or by the instructions for use, no hazard shall be created if the wheelchair is tilted through an angle 15° greater than the maximum inclination that can occur during intended use.

6.9.1.2 Test method

Fill the reservoir to the maximum level specified by the manufacturer and, if possible, add further liquid equal to $15\,^{+1}_{0}$ % of the capacity of the reservoir or until the reservoir is full, whichever is the lesser quantity.

Tilt the wheelchair through an angle of $(a+15)\,^{+1}_{0}$ ° to the horizontal in each direction, where a is the rated slope specified by the manufacturer (see 8.1.1). If necessary, refill the reservoir between tests.

Inspect the wheelchair, including any electrical insulation and any uninsulated live parts, to determine whether the requirements have been met. For electrical insulation, in case of doubt, subject the wheelchair to the dielectric strength test specified in EN 60601-1:2006[2].

6.9.2 Spillage

6.9.2.1 Requirements

Wheelchairs requiring the handling of liquids in intended use shall be so constructed that spillage does not wet parts that creates a hazard.

6.9.2.2 Test method

Position the wheelchair on the horizontal test plane. Pour $200\,^{+5}_{0}$ ml water steadily on an arbitrary point on the seat.

After the test, the wheelchair shall function as specified by the manufacturer.

6.9.3 Leakage

Wheelchairs shall be so constructed that liquid which can escape in single fault condition does not create a hazard.