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



EESTI STANDARDI EESSÕNA

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EUROPEAN STANDARD

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English Version

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

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

Elektrorollstühle, Scooters und zugehörige Ladegeräte
- Anforderungen und Prüfverfahren

This European Standard was approved by CEN on 17 July 2022.

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CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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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of an identical text or by endorsement, at the latest by March 2023, and conflicting national standards shall be withdrawn at the latest by May 2024.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.

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

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.

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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*

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