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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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## 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 draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 293.

If this draft becomes a European Standard, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

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EUROPÄISCHES KOMITEE FÜR NORMUNG

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

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## European foreword

This document (prEN 12184:2020) has been prepared by Technical Committee CEN/TC 293 “Assistive products and accessibility”, the secretariat of which is held by SIS.

This document is currently submitted to the CEN Enquiry.

This document will supersede EN 12184:2014.

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

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

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## Introduction

This is the fifth edition of EN 12184. 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 might also wish to 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 of 5 April 2017 medical devices.

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

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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 greater than 300 kg, including:

- electrically powered scooters with three or more wheels,
- manual wheelchairs with an add-on drive system,
- handrim-activated power-assisted wheelchairs,
- electrically powered stand-up wheelchairs,
- balancing wheelchairs,
- wheelchairs with a pivot drive wheel unit, and
- assistant-guided wheelchairs.

This document does not apply to 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 1021-2:2014, *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*

prEN 12183:2020, *Manual wheelchairs - Requirements and test methods*

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

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

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

EN 62133-2:2017, *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 (IEC 62133-2:2017)*

EN 62304:2006<sup>2</sup>, *Medical device software - Software life-cycle processes (IEC 62304:2006)*

<sup>1</sup> A impacted by EN 60601-1:2006/A12:2014.

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EN ISO 14971:2012, *Medical devices — Application of risk management to medical devices*

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 7176-15:1996, *Wheelchairs — Part 15: Requirements for information disclosure, documentation and labelling*

ISO 7176-19:2008<sup>3</sup>, *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 7176-22:2014, *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 16840-3:2014, *Wheelchair seating — Part 3: Determination of static, impact and repetitive load strengths for postural support devices*

<sup>2</sup> As impacted by EN 62304:2006/A1:2015.

<sup>3</sup> As impacted by ISO 7176 19:2008/A1:2015.

ISO 16840-10:2014, *Wheelchairs — Resistance to ignition of non-integrated seat and back support cushions — Part 10: Requirements and test methods*

### 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 7176-26:2007, ISO 7176-14:2008, EN 12182:2012 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <http://www.iso.org/obp>

NOTE An exception to the terms given in ISO 7176-26:2007 is made for the definition of wheelchair which is replaced by 3.6 below.

#### 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 test 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: A disabled occupant is a disabled person or a person not having the full capacity to walk unaided.

Note 2 to entry: The definition includes scooters.

[SOURCE: Global Medical Device Nomenclature (GMDN), modified]

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## 3.7

**pre-sale information**

publicly available information provided by the manufacturer about the wheelchair

## 3.8

**stand-up wheelchair**

wheelchair which enables the occupant to move between a seated posture and a standing posture and enables the occupant to maintain a standing posture

## 3.9

**assistant-guided wheelchair**

wheelchair partly propelled, braked, and/or steered by the muscular energy of an assistant

## 3.10

**pivot drive wheel unit**

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

## 4 Test apparatus

**4.1 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  $\pm 0,5^\circ$ . 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.

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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 8.

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

**4.2 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. 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.

**4.3 Means to apply a force** between 25 N and 200 N with an accuracy of  $\pm 5\%$  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  $\pm 5\%$ .

**4.5 Means to measure speed** between 0 km/h and 25 km/h to an accuracy of  $\pm 5\%$ .

**4.6 Means to measure distance** in the range 0 m to 5 m with an accuracy of  $\pm 1$  mm or  $\pm 2\%$  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  $200\text{ mm} \pm 10\text{ mm}$ , 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** in the range 0,5 Nm to 10 Nm with an accuracy of  $\pm 2\%$ .

**4.11 Means to measure angles** to an accuracy of  $\pm 0,1^\circ$ .

**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  $\pm 1$  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

### 6.1 General

The wheelchair shall conform to the requirements specified in EN 12182:2012 for the following:

- intended performance and technical documentation;
- aids that can be dismantled;
- single use fasteners;

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- 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.

**6.2 Risk management**

A risk management process shall be performed in accordance with EN ISO 14971:2012. For conformity with this document, all elements of the risk management process specified in EN ISO 14971:2012 shall be applied except:

- the planning for, and execution of, production and post-production monitoring (EN ISO 14971:2012, 3.1 fourth indent, 3.4 item f), and Clause 9), and
- periodic reviews of the suitability of the risk management process (EN ISO 14971:2012, 3.2 fourth indent).

**6.3 Speed limitation in normative references**

For the purposes of this document, the maximum speed range stated in the Scope of this document shall override any limitation on maximum speed in the Scopes of the documents listed in Clause 3. See also 7.1.

**6.4 Applicable provisions**

Annex G specifies the provisions in this document that apply to some types of wheelchair. See G.1.

**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 7176-22:2014 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.

If, due to the speed of the wheelchair, the test plane specified in a referenced document is of insufficient size to conduct the specified tests, use the horizontal test plane specified in 4.1 or an inclined test plane specified in 4.2 as applicable.

## 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 7176-22:2014.

## 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 7176-22:2014.

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 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.

The rated slope specified by the manufacturer shall be not less than that specified in Table 1 for the type class of the wheelchair.

#### 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, if it 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 method

Use an inclined test plane as specified in 4.1 and the means to measure speed specified in 4.5.

Starting on the inclined test plane, drive the loaded wheelchair up the slope using the maximum speed command.

When the wheelchair has travelled  $(5,0 \pm 0,1)$  m up the slope and is inside the test area, measure and record the speed to an accuracy of  $\pm 10$  %.