

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

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

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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 und -mobile und zugehörige Ladegeräte -
Anforderungen und Prüfverfahren

This European Standard was approved by CEN on 6 August 2006.

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. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

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Management Centre: rue de Stassart, 36 B-1050 Brussels

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Foreword

This document (EN 12184:2006) 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of an identical text or by endorsement, at the latest by March 2007, and conflicting national standards shall be withdrawn at the latest by March 2007.

This document supersedes EN 12184:1999.

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 June 1993 concerning medical devices.

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

Informative Annex E provides details of significant technical changes between this European Standard and the previous edition of 1999.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, 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 United Kingdom.

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Introduction

This is the first revision of this European Standard which was originally issued in 1999.

Where this European Standard does not apply to particular wheelchairs, contracting parties should consider if appropriate parts of this European Standard can be used. Manufacturers may also wish to consider if 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.

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 users and are based upon

- the body size of users 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 users.

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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 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 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; *Furniture — Assessment of the ignitability of upholstered furniture — Part 1: Ignition source smouldering cigarette*

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

EN 12182:1999, *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, *Household and similar electrical appliances — Safety — Part 1: General requirements (IEC 60335-1:2001)*

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

EN 60601-1, *Medical electrical equipment — Part 1: General requirements for safety (IEC 60601-1:1988)*

EN 60942:2004, *Electroacoustics — Sound calibrators (IEC 60942:2003)*

EN 61000-3-2, *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, *Medical devices — Application of risk management to medical devices (ISO 14971:2000)*

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 7176-4:1997, *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 7176-10:1988, *Wheelchairs — Part 10: Determination of obstacle-climbing ability of electric 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*

ISO 7176-15:1996, *Wheelchairs — Part 15: Requirements for informative 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/DIS 7176-26:2006, *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/DIS 7176-26:2006 (with the exception of the definition of wheelchair which is replaced by 3.12 below), ISO 7176-14:1997, EN 12182:1999 and the following apply.

3.1

audible warning device

device making a warning sound or noise

EXAMPLE horn

3.2**automatic brake**

means for holding a wheelchair stationary on the level or on a slope when the speed control input device is set for zero speed

3.3**carry-on battery charger**

off-board battery charger intended for transportation on a wheelchair

3.4**ground clearance**

height of free space below the loaded wheelchair

NOTE The ground clearance is an indication for the capability of the wheelchair to negotiate obstacles.

3.5**loaded wheelchair**

wheelchair loaded with a dummy as specified in 4.10 or loaded with a human test user

3.6**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

3.7**on-board charger**

charger that is built into the wheelchair that cannot be removed without the use of tools and cannot be disconnected from the battery without the use of tools.

3.8**seat reference point**

intersection of the seat reference plane and the back support reference plane at half the width of the seat (see Figure 1)

NOTE The seat reference plane is specified in 3.2 of ISO 7176-7:1998 and the back support reference plane is specified with the name backrest reference plane in 3.3 of ISO 7176-7:1998.

3.9**spillable battery**

battery from which the electrolyte can escape in some orientation

3.10**turn-around width**

minimum width in which the wheelchair can be turned through 180° by operation of its control input device and where applicable its manual steering system

3.11**unspillable battery**

battery from which the electrolyte can not escape whatever its orientation

3.12**wheelchair**

wheeled personal mobility device incorporating a seating support system for a disabled user is propelled by one or more electric motors controlled by the occupant or by an attendant, and 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 user is a disabled person or a person not having the full capacity to walk by him or herself.

NOTE 3 Definition includes scooters

4 Test apparatus

4.1 Adjustable test plane, a flat, rigid plane with an adjustable slope, with a coefficient of friction as defined in ISO 7176-13, of sufficient size to accommodate the wheelchair during the tests specified in 8.4 and 8.11 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 defined in ISO 7176-13, 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 of between 25 N and 200 N with an accuracy of $\pm 5\%$ and an application rate less than 5 N/s.

4.4 Means to measure force with an accuracy of $\pm 5\%$ in increments of 1 N in the range of 0 N to 200 N.

4.5 Means to measure sound pressure calibrated in accordance with the manufacturer's instructions, using an acoustic calibrator class 1 as described in EN 60942 with an accuracy of ± 3 dB(A).

4.6 Means to measure speed between 0 km/h and 20 km/h to an accuracy of $\pm 5\%$.

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

4.8 Supplementary weights to add to a human test driver to achieve the maximum user mass as specified by the manufacturer and to achieve a similar mass distribution to the dummy to be used as specified in 4.10.

4.9 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.

4.10 Test dummy

4.10.1 General

Select a test dummy (ISO 7176-11) of mass equal to or, if there is no dummy of equal mass, the next size greater than the maximum user mass recommended by the manufacturer.

If the maximum user mass specified by the manufacturer is greater than 100 kg use an augmentation to the 100 kg test dummy from ISO 7176-11 as specified below. The mass is added to the upper legs/seat section and trunk/back section in the ratio of 1:6.

The following will provide the required mass and position to augment a 100 kg dummy.

M is the total mass of the required dummy.

4.10.1.1 The additional trunk/back section mass is obtained from the following:

$$0,857M - 85,7.$$

4.10.1.2 The point on the Y axis for the centre of mass for the complete new trunk/back section is obtained from the following:

Point on Y (comp) axis measured from the pivot point of the dummy = $\frac{22,1M + 753}{M - 28,82} - 4,8 \text{ cm} \pm 0,10 \text{ cm}$.

4.10.1.3 The point on the Y axis of the centre of mass of the additional trunk/back section mass is obtained from the following:

$$\frac{\left[61 + \frac{6}{7}(M - 100) \times Y_{comp}\right] - (61 \times 29,8)}{\frac{6}{7}(M - 100)} = Y_{additional} \text{ in cm}$$

4.10.1.4 The point on the X axis of the centre of mass for the additional trunk/back section mass measured from the front face of the trunk/back section is obtained from the following:

$$\frac{(0,17M + 1,32)\left[\frac{6}{7}(M - 100) + 36,6\right] - 18,3(36,6)}{\frac{6}{7}(M - 100)} - 25,1 \text{ cm} = X_{additional} \text{ in cm}$$

4.10.1.5 When constructing the new mass dummy using the above calculations the additional mass shall be positioned within Y additional $\pm 0.1 \text{ cm}$ and X additional $\pm 0.1 \text{ cm}$.

4.10.1.6 The additional mass of the upper legs is obtained from the following:

$$= 0,143M - 14,3.$$

4.10.1.7 The additional mass for the upper leg/seat section is evenly distributed so as not to change the centre of mass for this segment.

NOTE This may be achieved by wrapping the leg/seat section in a sheet material e.g. lead of appropriate mass.

4.10.1.8 The mass of the lower legs/feet does not increase from the 100kg dummy.

4.11 Test track marked on a horizontal test plane with a hard, non-porous surface in a room with an ambient noise level not exceeding 45 dB(A) and of sufficient length for the wheelchair to attain its maximum speed, maintain its maximum speed and decelerate within the measuring distance specified in Figure 2.

4.12 Means to measure torque with an accuracy of $\pm 2 \%$ in increments of 1 Nm in the range of 0,5 Nm to 10 Nm.

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

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

4.15 Means to measure force applied to control devices (e.g. joystick) capable of measuring forces in a range of 0 N to 10 N in 0,1 N increments with an accuracy of $\pm 1 \%$ of the rated capacity.

4.16 Means to measure elapsed time in the range 0 to 30 s with an accuracy of $\pm 1 \text{ s}$.

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 as specified in EN 12182:1999 for the following:

- intended performance and technical documentation (Clause 4.2);
- aids that can be dismantled (Clause 4.4);
- single use fasteners (Clause 4.5);
- biocompatibility and toxicity (Clause 5.2);
- contaminants and residues (Clause 5.3);
- infection and microbiological contamination (Clause 5.4);
- overflow, spillage, leakage and ingress of liquids (Clause 9);
- safety of moving parts (Clause 12);
- prevention of traps for parts of human body (Clause 13);
- folding and adjusting mechanisms (Clause 14);
- surfaces, corners and edges (Clause 18).

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

7 Design requirements

7.1 Foot supports, leg supports and arm supports

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

Where fitted, 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.

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 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 3.

7.6 Freewheel device

The wheelchair shall be fitted with a freewheel device that shall

- be accessible and operable by the user or the attendant or both in accordance with the manufacturer's intended use, <https://standards.iteh.ai/catalog/standards/sist/a224e544-4ce2-4b44-8121-e9e2265c7220/sist-en-12184-2006>
- be within the reach specified in Figure 4, if it is intended to be operated by the user,
- have maximum operating forces for engaging and disengaging as 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 user and/or attendant.

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

NOTE 3 This requirement overrides 7.2 of ISO 7176-14:1997 concerning requirements for non-powered mobility.

7.7 Component mass

If the wheelchair is intended to be dismantled for storage or transportation, any component that requires moving or handling and 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 it can be lifted and describe how it shall be handled during disassembling, lifting, carrying, and assembling to reduce risks to the person or persons moving or handling the equipment.