SLOVENSKI STANDARD
SIST EN 12184:2000

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Električni invalidski vozički, skuterji in njihovo polnjenje - Zahteve in preskusne metode

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

Elektrorollstühle und -mobile und zugehörige Ladegeräte - Anforderungen und Prüfverfahren

Fauteuils roulants électriques, trottinettes 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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English version

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

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This European Standard was approved by CEN on 18 February 1999.

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

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Foreword

This European Standard has been prepared by Technical Committee CEN/TC 293 "Technical aids for disabled persons", 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of an identical text or by endorsement, at the latest by September 1999, and conflicting national standards shall be withdrawn at the latest by September 1999.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex Z, which is an integral part of this standard.

This standard provides one means to demonstrate that electrically powered wheelchairs and scooters, which are also medical devices, conform to the essential requirements outlined in general terms in Annex 1 of the EU Directive 93/42 EEC. It is not intended to provide a means to show conformity with the requirements of any other directive.

There are three levels of European Standards dealing with technical aids for disabled persons. These are as follows, with level 1 being the highest:

Level 1: General requirements for technical aids
Level 2: Particular requirements for families of technical aids
Level 3: Specific requirements for types of technical aids.

Where standards for particular aids or groups of aids exist (level 2 or 3), the requirements of lower level standards take precedence over higher level standards. Therefore, to address all requirements for a particular aid, it is necessary to start with standards of the lowest available standard.

This is a combined level 2 and level 3 standard (lowest possible) for electrically powered wheelchairs and scooters, which are also medical devices, as specified in the scope.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

Where this standard does not apply to particular wheelchairs, contracting parties should consider if appropriate parts of this standard can be used. Manufacturers may also wish to consider if appropriate parts of this standard can be used to assess the performance of their products against the Essential Requirements of the Medical Devices Directive.

1 Scope

This European Standard specifies requirements and test methods for electrically powered wheelchairs and scooters with a maximum speed not exceeding 15 km/h intended to carry one person whose mass does not exceed 100 kg, including the following classifications from EN ISO 9999:1998:

12 21 21	Powered attendant-controlled wheelchairs
12 21 24	Electric-motor-driven wheelchairs with manual steering
12 21 27	Electric-motor-driven wheelchairs with powered steering

It also specifies requirements and test methods for manual wheelchairs with add on power kits used for propulsion.

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;
- manually propelled wheelchairs with electrically powered ancillary equipment (only electrical features);
- custom-made wheelchairs;
- wheelchairs specially designed for, or with adaptations for, specific disabled persons;
- powered office chairs.

NOTE 1: The requirement for manually propelled wheelchairs with electrically powered ancillary equipment is specified in EN 12183:1999.

NOTE 2: Appropriate parts of the standard may be applied to the above products and other wheelchairs outside this scope.

NOTE 3: The application of the standard is limited to wheelchairs with a maximum occupant mass of 100 kg because this is the maximum mass of dummy available in ISO 7176-11. Further work is needed to investigate the effects of people with larger body masses.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN 1041	Information supplied by the manufacturer with medical devices
EN ISO 9999:1998	Technical aids for disabled persons - Classification (ISO 9999:1998)
prEN 12182:1999	Technical aids for disabled persons - General requirements and test methods
EN 55022	Limits and methods of measurement of radio disturbance characteristics of information technology equipment
ISO 6440	Wheelchairs - Nomenclature, terms and definitions
ISO/FDIS 7176-1:1998	Wheelchairs - Part 1: Determination of static stability
ISO 7176-2	Wheelchairs - Part 2: Determination of dynamic stability of electric wheelchairs
ISO 7176-3	Wheelchairs - Part 3: Determination of efficiency of brakes
ISO 7176-4	Wheelchairs - Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance
ISO 7176-5	Wheelchairs - Part 5: Determination of overall dimensions, mass and turning space
ISO 7176-6	Wheelchairs - Part 6: Determination of maximum speed, acceleration and retardation of electric wheelchairs
ISO 7176-8:1998	Wheelchairs - Part 8: Requirements and test methods for static, impact and fatigue strengths
ISO 7176-9	Wheelchairs - Part 9: Climatic test for electric wheelchairs

ISO 7176-10	Wheelchairs - Part 10: Determination of obstacle-climbing ability of electric wheelchairs
ISO 7176-11	Wheelchairs - Part 11: Test dummies
ISO 7176-13	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	Wheelchairs - Part 15: Requirements for informative disclosure, documentation and labelling
ISO 7176-16	Wheelchairs - Part 16: Resistance to ignition of upholstered parts - Requirements and test methods
IEC 60073	Colours of indicator lights and push-buttons
IEC 60529:1989	Degrees of protection provided by enclosures (IP code)
IEC 60601-1	Medical Electrical Equipment - Part 1: General requirements for safety
IEC 61000-4-2:1995	Electromagnetic compatibility (EMC) - Part 4: Testing and measurement techniques - Part 2: Electrostatic discharge immunity test - Basic EMC publication
IEC 61000-4-3	Electromagnetic compatibility (EMC) - Part 4: Testing and measurement techniques - Part 3: Radiated radio frequency, electromagnetic field immunity test - Basic EMC publication

3 Definitions

For the purposes of this standard the definitions in ISO 6440, ISO 7176-14:1997 and prEN 12182:1999 apply together with the following:

3.1 **Anti-tip device**: A device to prevent the wheelchair tipping over completely when it exceeds its limit of stability.

3.2 **Automatic brake**: A means for holding a wheelchair stationary in a slope when the speed control input device set for zero speed.

3.3 **Control input device**: A device with which the user selects the desired speed and/or direction of movement of the wheelchair.

3.4 **Loaded wheelchair**: A wheelchair loaded with a dummy as specified in ISO 7176-11.

3.5 **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 ability.

3.6 **Seat belt**: A strap to help to maintain the occupant's position in the wheelchair during normal operation.

NOTE 1: This is a strap positioned over the occupant´s pelvis or waist.

NOTE 2: The seat belt is not necessarily intended for use as a safety restraint during transportation in vehicles.

3.7 **User manual**: Post sale information normally provided with the wheelchair to inform the user about the assembly, operation, maintenance, repair and warranty aspects of wheelchair ownership.

3.8 **Vertical plane**

Front vertical plane: A vertical plane which is normal to the forward direction of travel and tangential to the most forward point of the most forward wheel.

Rear vertical plane: A vertical plane which is normal to the forward direction of travel and tangential to the most rearward point of the most rearward wheel.

Side vertical plane: A vertical plane which is parallel to the forward direction of travel and tangential to the outer edge of the outermost wheel.

3.9 **Wheelchair(s)**: Abbreviation to represent the electrically powered wheelchair(s) and scooter(s) and other vehicles covered by the scope of this standard, to which the requirements and test methods are applied.

4 Test equipment

4.1 **Horizontal test plane**, comprising a flat horizontal surface large enough to accommodate the wheelchair under test, such that the whole surface lies between two imaginary horizontal planes 5 mm apart and have a coefficient of friction defined in ISO 7176-13.

NOTE: The requirement for the horizontal test plane to lie between two imaginary horizontal planes is a measure of flatness of the horizontal test plane.

4.2 **Weights, dynamometer**, or similar means, to apply a force of between 25 N and 100 N with an accuracy of ± 2%.

4.3 **Test dummies**, of appropriate sizes as specified in ISO 7176-11.

4.4 **Speedometer**, or similar means of measuring the speed of the wheelchair to an accuracy of ± 10%.

4.5 **Adjustable test plane**, a flat, hard plane of sufficient size and with an adjustable slope, which can enable the test indicated in 8.4.2.2. The surface of the plane shall have a coefficient of friction as defined in ISO 7176-13.

4.6 **Test track**, of sufficient length for the wheelchair to attain its maximum speed within the test area specified in Figure 2 marked on a horizontal test plane in a room with an ambient noise level not exceeding 45 dB(A).

4.7 **Sound pressure measurement device**, capable of measuring the sound pressure specified in 8.6.

NOTE: Further test equipment as descibed in the Normative references is needed.

5 Type classes

Electrically powered wheelchairs shall be classified in one or more of the following three classes, dependant 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 use indoors but capable of travelling over longer distances and negotiating outdoor obstacles.

NOTE: See 8.4 and Table 2 for details.

6 General requirements

The wheelchair shall conform to the requirements of prEN 12182:1999 for:

- Risk analysis;
- Intended performance and technical documentation;
- Clinical evaluation;
- 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.

7 Design requirements

7.1 Footrests and legrests

7.1.1 Requirements for footrests and legrests

The wheelchair shall be capable of being fitted with a means for preventing the user´s feet from sliding backwards.

If footrests and legrests can be adjusted or moved from one position to another they shall have provision to locate them securely in any operating position.

If the layout of footrests and legrests can be adjusted they shall have increment adjustments not exceeding 25 mm.

If the wheelchair is fitted with a separate footrest for each foot :

a) the gap between the footrests shall not exceed

35 mm for wheelchairs intended for adults;
25 mm for wheelchairs intended for children;

when tested as specified in 7.1.2;

or

b) the footrests shall be fitted with means for preventing the user's feet from sliding into the gap.

7.1.2 Test method for footrests

Select a force appropriate to the intended user mass from Table 1. Apply the force to the centroid of each footrest normal to the plane of the unloaded footrest. Measure the minimum gap between the footrests in a transverse direction.

7.2 Requirement for pneumatic tyres

If the wheelchair is fitted with pneumatic tyres, they shall have identical valve connections.

7.3 Requirement for fitting a seat belt

The wheelchair shall have provision for a seat belt to be fitted.

7.4 Requirement for armrests and backrests

If armrests and backrests can be adjusted or moved from one position to another they shall have provision to locate them securely in any intended operating position.

7.5 Requirement for wheelchairs intended for use as seats in motor vehicles

If the manufacturer claims the wheelchair is intended for use as a seat in a motor vehicle, the manufacturer's information shall identify the wheelchair tiedown and occupant restraint systems (WTORS) that are suitable and the attachment points on the wheelchair.

> **NOTE:** At the time of drafting this European Standard, work is in hand in ISO/TC 173/SC1 to develop standards for WTORS and wheelchairs intended for use in motor vehicles. Manufactures should consider if the resulting standards can be applied to their products.

7.6 Requirements for braking systems

The wheelchair shall be fitted with a braking system that includes the following:

a) a service brake, which operates independently of tyre wear and inflation pressure and operation of which is possible by the user and/or the attendant;

b) an automatic brake, which operates independently of tyre wear and inflation pressure and is operated by putting the speed control input device set for zero speed;

c) a parking brake, which can be operated independently of tyre wear and inflation pressure and when there is no battery power and/or motor drive is disconnected (i.e. in freewheel mode) and which can be operated by the user and/or attendant.

NOTE: These braking functions may be combined in one device and/or operated by reconnection of the motor drive system.

d) if the wheelchair has no service brake operational when in free-wheel mode, parking brakes shall be operable during motion.

If parking brakes are subject to wear from any friction surfaces, tyres etc., they shall have provision for adjustment for any wear that have taken place to the point of replacement as recommended in the manufacturer´s documentation and for any wear occurring during the tests specified in 8.2.2.

7.7 Requirement for component weight

If the wheelchair is intended to be dismantled for ease of carrying

a) any component that has a mass greater than 10 kg, shall be provided with suitable handling devices (e.g. handles);

or

b) the user manual shall indicate the points where the component part can be lifted safely and/or a method for handling during assembly.

7.8 Requirements for battery enclosures

If batteries are used for the wheelchair propulsion

a) they shall be accessible without tools for inspection, service and replacement operations as recommended by the manufacturer;

and

b) all battery enclosures shall be ventilated at the highest point by an opening or openings which total not less than 100 mm^2 in area.

NOTE: The openings are to permit escape of gas.

7.9 Battery containers

7.9.1 Resistance to corrosion

Battery containers shall be resistant to corrosion caused by battery gases and acid.

7.9.2 Resistance to leakage from battery containers

If the wheelchair is fitted with batteries containing liquid electrolytes, the battery containers shall not leak when tested according to 7.9.3.

7.9.3 Test method for leakage from battery containers

Place the battery or batteries in the container. Fill the container with water to a depth of half of the total battery height, ± 3 mm. Tilt the container through 20° ± 3° from the horizontal in all directions.

Examine the container for visible evidence of leakage.

7.10 Audible warning device

The wheelchair shall be equipped with an audible warning device.

8 Performance requirements

8.1 Static, impact and fatigue strength - Requirements and test method for static, impact and fatigue strength

The wheelchair shall comply with the requirements specified in ISO 7176-8:1998. The wheelchair shall be tested as specified in ISO 7176-8:1998.

Wheelchairs of Type Class A (see 5) are excluded from the Drop Test, 10.5 of ISO 7176-8:1998.

NOTE: Further requirements and tests beyond those specified in ISO 7176-8:1998 are considered to be necessary and may be considered for a future development of this standard. These include the following:

- Impact strength of anti-tip levers;
- Impact strength of kerb climbers;
- Fatigue strength of brake mechanisms, other than manually operated brakes;
- Strength of steering mechanisms (e.g. manual handle bar steering systems for scooters).