SLOVENSKI STANDARD

SIST EN 12183:2006

01-december-2006

Nadomeġļa:

SIST EN 12183:2000

Invalidski voziļ ki z roļnim upravljanjem - Zahteve in preskusne metode

Manual wheelchairs - Requirements and test methods

Rollstühle mit Muskelkraftantrieb - Anforderungen und Prüfverfahren

Fauteuils roulants manuels - Exigences et méthodes d'essai

Ta slovenski standard je istoveten z: **EN 12183:2006**

ICS:

11.180.10	Pripomoļ ki in prilagoditve za gibanje	Aids and adaptation for moving

SIST EN 12183:2006 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 12183

September 2006

ICS 11.180.10

Supersedes EN 12183:1999

English Version

Manual wheelchairs - Requirements and test methods

Fauteuils roulants manuels - Exigences et méthodes d'essai

Rollstühle mit Muskelkraftantrieb - Anforderungen und Prüfverfahren

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Ref. No. EN 12183:2006: E

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Foreword

This document (EN 12183:2006) 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of an identical text or by endorsement, at the latest by March 2007, and conflicting national standards shall be withdrawn at the latest by March 2007.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 12183:1999.

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 EU Directive 93/42/EEC of June 1993 concerning medical devices.

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

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.

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.

1 Scope

This European Standard specifies requirements and test methods for manual wheelchairs intended to carry one person.

It also specifies requirements and test methods for manual wheelchairs with electrically powered ancillary equipment.

This European Standard does not apply in total to

— wheelchairs intended for special purposes, such as sports, showering, toileting,

— custom-made wheelchairs,

— stand-up wheelchairs and

— add-on power kits for the propulsion of manual wheelchairs.

NOTE Requirements for electrically powered wheelchairs are specified in EN 12184.

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 ignitability of upholstered furniture — Part 1: Ignition source smouldering cigarette*

EN 1021-2, *Furniture — Assessment of 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 12184, *Electrically powered wheelchairs, scooters and their chargers — Requirements and test methods*

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 7176-3:2003, *Wheelchairs — Part 3: Determination of effectiveness of brakes*

ISO 7176-8:1998, *Wheelchairs — Part 8: Requirements and test methods for static, impact and fatigue strengths*

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

ISO 7176-19:2001, *Wheelchairs — Part 19: Wheeled mobility devices for use in motor vehicles*

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 3.5 below), EN 12182:1999 and the following apply.

3.1
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.

3.2
loaded wheelchair
wheelchair loaded with a dummy as specified in 4.8 or loaded with a human test user

3.3
maximum safe slope
maximum slope specified by the manufacturer on which the wheelchair meets all the requirements of ability, static stability, braking performance and slope climbing, traversing and descending ability

3.4
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 term backrest reference plane in 3.3 of ISO 7176-7:1998.

3.5
wheelchair
wheeled personal mobility device incorporating a seating support system for a disabled user and is manually propelled by an attendant and/or the occupant whilst the occupant is seated.

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.

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 7.4 and 7.5 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 between 25 N and 200 N with an accuracy of ± 5 % and an application rate less than 5 N/s.

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

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

4.6 Means to measure angles to an accuracy of ± 0,1°.

4.7 Means to measure torque with an accuracy of ± 2 % in increments of 1 Nm in the range of 0,5 Nm to 10 Nm.

4.8 Test dummy

4.8.1 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.

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

$$0{,}857M - 85{,}7$$

4.8.1.2 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 cm ± 0,1 cm.

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

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

4.8.1.4 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:

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

4.8.1.5 When constructing the new mass dummy using the above calculations the additional mass shall be positioned within Y additional ± 0.1 cm and X additional ± 0.1 cm.

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

$$= 0{,}143M - 14{,}3$$

4.8.1.7 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.

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

4.9 Means to measure speed in the range 0,5 m/s to 1,5 m/s with an accuracy of ± 0,05 m/s.

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

4.11 Means to measure elapsed time in seconds in the range 0 to 30 s with an accuracy of ±1 s

5 General requirements

The wheelchair shall conform to the requirements as specified in EN 12182:1999 for the following:

— intended performance and technical documentation (4.2);

— aids that can be dismantled (4.4);

— single use fasteners (4.5);

— biocompatibility and toxicity (5.2);

— contaminants and residues (5.3);

— infection and microbiological contamination (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

6 Design requirements

6.1 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 7.2.

Where fitted leg supports and arm supports shall meet the performance requirements specified in 7.2.

6.2 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.

6.3 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.

6.4 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 10542-5:2005 and the ATD selection specified in Table A.1 of ISO 10542-5:2005 shall apply.

6.5 Braking systems

The wheelchair shall be fitted with a braking system that meets the performance requirements specified in 7.4.

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 2.

6.6 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.

6.7 Operations intended to be carried out by the user and/or attendant

Wheelchairs shall be designed to facilitate ease of operation by the user and/or attendant as specified in the manufacturer's instructions and meet the performance requirements of 7.2.1,7.6.1, 7.7.1,7.11, 7.12.1,and 7.15.1 or for brake levers the requirements of 7.4.1.

Examples include:

a) operation of adjustable seating,

b) use of detachable components; including removable arm supports, leg supports etc., to facilitate safe transfers into and out of the wheelchair,

c) use of folding mechanisms; including folding frames etc., to facilitate storage and transportation of unoccupied wheelchairs,

d) carrying out maintenance, including use of tools etc.,

e) use of braking systems and freewheel devices,

f) use of push handles, and

g) use of electrical ancillary equipment.

6.8 Controls operated when seated

6.8.1 General

Controls intended to be operated by the user while seated shall be within the user reach as shown in Figure 3.

The following controls, if fitted, are included:

— brakes intended to be operated by the user,

— seating adjustments,

— detachable components, including removable arm supports, leg supports etc., to facilitate safe transfers into and out of the wheelchair,

— propulsion devices, and

— electrical ancillary equipment.

If the manufacturer specifies that the seating can be adjusted by an attendant or the user or both while the user is seated,

— uncontrolled movement of the seating shall not exceed ± 5 mm, and

— the attendant and/or the user shall not have to lift a mass (e.g. the combined mass of the user and the seating) which presents a moving and handling safety hazard to an attendant and/or the user.

Controls for seating adjustments intended to be operated by the user shall be accessible to the user from all seating positions.

NOTE The shaded area of Figure 3 shows the maximum reach space for the user in relation to the actual wheelchair backrest position and seat reference point.