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Manual wheelchairs - Requirements and test methods

Muskelkraftbetriebene Rollstühle - Anforderungen und Prüfverfahren

Fauteuils roulants à propulsion manuelle - Exigences et méthodes d'essai

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Manual wheelchairs - Requirements and test methods

Fauteuils roulants à propulsion manuelle - Exigences et méthodes d'essai

Muskelkraftbetriebene Rollstühle - Anforderungen und Prüfverfahren

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Contents

Page

European foreword 4

Introduction 5

1 Scope 6

2 Normative references 6

3 Terms and definitions 7

4 Test apparatus 8

5 General requirements 9
5.1 Risk management 9
5.2 Intended performance and technical documentation 9
5.3 Clinical evaluation and investigation 9
5.4 Wheelchairs that can be dismantled 9
5.5 Single-use fasteners 9
5.6 Biocompatibility and toxicity 10
5.7 Contaminants and residues 10
5.8 Infection and microbiological contamination 10
5.9 Overflow, spillage, leakage, and ingress of liquids 11
5.10 Safety of moving parts 12
5.11 Prevention of traps for parts of the human body 13
5.12 Folding and adjusting mechanisms 13
5.13 Surfaces, corners, edges and protruding parts 14
5.14 Ergonomic principles 14
5.15 Applicable provisions for specified types of wheelchair 15
5.16 Recommendations 15

6 Preparation for testing 15
6.1 General 15
6.2 Test dummy 15

7 Wheelchair performance 15
7.1 Static stability 15
7.2 Static, impact and fatigue strength 16
7.3 Tipping fatigue strength 16
7.4 Wheelchairs for use as seats in motor vehicles 17
7.5 Surface temperature 18

8 Component properties 19
8.1 Foot supports, lower leg support assemblies and arm supports 19
8.2 Component mass 20
8.3 Pneumatic tyres 20
8.4 Means for maintaining a sitting posture 20
8.5 Resistance to ignition 21

9 Propulsion and braking systems 21
9.1 Means for operating brakes 21
9.2 Braking functions 23
9.3 Pushing force 25

10 Operations 26

10.1 Operations intended to be carried out by the occupant and/or assistant 26
10.2 Controls intended for operation by the occupant 26
10.3 Controls intended for operation by an assistant 26
10.4 Push handles and handgrips 27
10.5 Operating forces 27
10.6 Seating adjustments for tilting and reclining 28
11 Electrical systems — Electrically powered ancillary equipment 29
12 Information supplied by the manufacturer 29
12.1 General 29
12.2 Pre-sale information 29
12.3 User information 29
12.4 Service information 30
12.5 Labelling 31
13 Test report and figures 31
Annex A (informative) Recommendations for dimensions and manoeuvring space of manual wheelchairs 37
Annex B (informative) Recommended design features 39
Annex C (informative) EN 12183 and rail interoperability 42
Annex D (informative) Recommendations for caster stem angle 43
Annex E (informative) Hazardous substances 44
Annex F (normative) Applicable requirements for particular types of manual wheelchair 49
Annex G (informative) Technical changes from the previous edition of EN 12183 51
Bibliography 52

European foreword

This document (EN 12183:2022) 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 12183:2014.

Annex G provides details of the significant technical changes between this document and EN 12183:2014.

Requirements and test methods for electrically powered wheelchairs are specified in EN 12184.

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 [18] of 5 April 2017 on medical devices.

1 Scope

This document specifies requirements and test methods for manual wheelchairs intended to carry one person of mass not less than 25 kg and not greater than 250 kg, including

— stand-up manual wheelchairs, and

— manual wheelchairs whose intended use includes showering and/or toileting.

This document does not apply to custom-made manual wheelchairs, manual wheelchairs intended for use in sports, or manual wheelchairs intended only for showering and/or toileting.

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 12184:2022, *Electrically powered wheelchairs, scooters and their chargers - Requirements and test methods*

EN ISO 14971:2019[1], *Medical devices - Application of risk management to medical devices (ISO 14971:2019)*

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 13732-1:2008, *Ergonomics of the thermal environment - Methods for the assessment of human responses to contact with surfaces - Part 1: Hot surfaces (ISO 13732-1:2006)*

EN ISO 14155:2020, *Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2020)*

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 7176-3:2012, *Wheelchairs — Part 3: Determination of effectiveness of brakes*

[1] EN ISO 14971:2019 is amended by EN ISO 14971:2019/A11:2021.

ISO 7176-8:2014, *Wheelchairs — Part 8: Requirements and test methods for static, impact and fatigue strengths*

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 7176-19:2008[2], *Wheelchairs — Part 19: Wheeled mobility devices for use as seats in motor vehicles*

ISO 7176-22:2014, *Wheelchairs — Part 22: Set-up procedures*

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*

ISO 17966:2016, *Assistive products for personal hygiene that support users — Requirements and test methods*

3 Terms and definitions

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

NOTE The definitions of wheelchair and manual wheelchair in ISO 7176-26:2007 are replaced by 3.2 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
loaded wheelchair
wheelchair loaded with a test dummy

Note 1 to entry: Instructions for selecting and fitting a test dummy are given in Clause 6.

3.2
wheelchair
manual wheelchair
wheeled mobility device, intended to transport a seated occupant who has impaired mobility, that is manually propelled by the occupant and/or an assistant

3.3
pre-sale information
publicly available information provided by the manufacturer about the wheelchair

Note 1 to entry: A specification sheet is part of the pre-sale information.

[2] ISO 7176-19:2008 is amended by ISO 7176-19:2008/AMD 1:2015.

3.4
custom-made manual wheelchair
manual wheelchair designed and manufactured for use by a named individual occupant that is not an adaptation of a mass-produced design

4 Test apparatus

4.1 Horizontal test plane, a continuous, flat, rigid surface with a coefficient of friction as specified in ISO 7176-13:1989, inclined to the horizontal at less than 0,5°. The surface 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 horizontal test plane shall be dry, free from ice, free from loose material (such as gravel), and shall be of sufficient size to accommodate the wheelchair under test.

4.2 Inclined test plane, 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 ± 0,5°. The surface 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 inclined test plane shall be dry, free from ice, free from loose material (such as gravel), and shall be of sufficient size to accommodate the wheelchair during the tests specified in 9.2.2.

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

4.3 Means to apply a force between 25 N and 200 N with an accuracy of ±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 ±5 %.

4.5 Means to measure distance in the range 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 in the range 0,5 Nm to 10 Nm with an accuracy of ±2 %.

4.8 Test dummy, of appropriate mass, as specified in ISO 7176-11:2012.

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 a 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 the range 0 s to 30 s with an accuracy of ±1 s.

4.12 Means to restrain the rear wheels of a wheelchair so that the wheelchair can be tipped backwards about the axles of the rear wheels without the wheels moving.

EXAMPLE Chocks attached to the horizontal test plane.

4.13 Means to tip a wheelchair backwards smoothly about the axles of the rear wheels and return it to the upright position for 20 000 cycles, at a rate of $10\,^{+2}_{0}$ cycles per minute, that can be attached to the push handles of the wheelchair in a manner that does not cause any lateral forces to be applied to them.

EXAMPLE Pneumatic cylinder at an angle of 45° to the horizontal when the wheelchair is upright, attached by a sliding bearing to a bar connecting the push handles.

4.14 Means to restrain the test dummy in a wheelchair, as specified in ISO 7176-22:2014.

5 General requirements

5.1 Risk management

A risk management process shall be performed in accordance with EN ISO 14971:2019[1]. For conformity with this document, all elements of the risk management process specified in EN ISO 14971:2019[1] shall be applied except:

— the planning for, and execution of, production and post-production monitoring (EN ISO 14971:2019[1], 4.1 fourth indent, 4.4 item g), and Clause 10); and

— periodic reviews of the suitability of the risk management process (EN ISO 14971:2019[1], 4.2 third paragraph).

5.2 Intended performance and technical documentation

a) The wheelchair shall have sufficient strength and durability to sustain all loads expected during intended use. This shall be confirmed by using, where appropriate, references to relevant clinical and scientific literature, strength and/or durability calculations, appropriate test standards and their test results, in addition to the requirements given in this document.

b) The intended performance of the wheelchair, including, where appropriate, strength, durability and tipping stability, shall be described in technical documentation which sets out its functional characteristics, its application(s) and conditions of use.

c) The technical documentation shall include, where appropriate, references to relevant clinical and scientific literature, any strength and/or life calculations, appropriate test standards and their test results.

5.3 Clinical evaluation and investigation

A clinical evaluation shall be conducted for the wheelchair.

If, as part of the product conformity assessment, the clinical evaluation requires a clinical investigation, the clinical investigation shall conform to the requirements of EN ISO 14155:2020. A clinical evaluation shall always be conducted before performing a clinical investigation.

NOTE Guidance for clinical evaluation is given in MEDDEV 2.7/1 [19].

5.4 Wheelchairs that can be dismantled

If it is intended that the wheelchair can be dismantled for storage or transportation, it shall not be possible to reassemble the wheelchair in a manner that presents a hazard.

5.5 Single-use fasteners

If it is intended that the wheelchair can be dismantled for storage or transportation, the fasteners which are loosened or removed to allow this dismantling shall not be single-use fasteners.

EXAMPLE Single-use fasteners include wood screws and self-tapping screws.

5.6 Biocompatibility and toxicity

Materials which come into contact with the human body shall be evaluated for biocompatibility in accordance with EN ISO 10993-1:2020 as part of the risk management process (see 5.1).

The evaluation shall take into account the intended use, including, where appropriate, contact with the occupant, an assistant, those involved in care of the occupant, and those involved in transportation and storage of the wheelchair.

Wheelchairs shall be designed and manufactured to minimize the risks posed by substances leaking from them. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction and other substances of very high concern (SVHCs). The evaluation should follow the guidance given in Annex E.

NOTE See Annex E for additional guidance.

5.7 Contaminants and residues

5.7.1 General

The requirements given in 5.7.2 apply to substances which are an integral part of the wheelchair or are necessary for its function, such as oil and grease. The requirements do not apply to body fluids which the wheelchair is intended to collect (e.g. as a stoma-care product).

5.7.2 Substances which can leak in intended use or in a fault condition

Where a substance can leak from the wheelchair in intended use or in a fault condition:

a) the substance shall be assessed for biocompatibility in accordance with EN ISO 10993-1:2020 as part of the risk management process, and the assessment shall consider intended use, including, where appropriate, contact with the occupant, an assistant, those involved in care of the occupant, and those involved in transportation and storage of the wheelchair; or

b) the wheelchair shall have means of protection that minimizes the possibility of the substance becoming a biological hazard.

NOTE Substances that can leak include lubricants and hydraulic fluids.

EXAMPLE A method of protection from a hazardous substance is to place batteries in a container made from acid resistant material.

5.8 Infection and microbiological contamination

5.8.1 Cleaning and disinfection

If any parts of the wheelchair are intended to be cleaned, the method and suitable materials for cleaning shall be described in the instructions for use.

If any parts of the wheelchair are intended to be disinfected, the method and suitable materials for disinfection shall be described in the instructions for use.

NOTE For guidance, see B.2.5.

If any parts of the wheelchair are intended to be cleaned by automatic washing systems or hand-held jet stream or steam washing, the details of the procedure, such as temperature, pressure, flow and pH value of cleaning/rinsing solution, shall be described in the instructions for use. Where practicable, the wheelchair shall be labelled with appropriate symbols to represent the method of cleaning.

5.8.2 Animal tissue

Where the wheelchair has been manufactured utilizing tissues of animal origin or their derivatives, the process specified in EN ISO 22442-1:2020 shall be followed as part of the risk management process (see 5.1).

NOTE For guidance, see B.2.11.

5.9 Overflow, spillage, leakage, and ingress of liquids

5.9.1 Overflow

5.9.1.1 Requirements

If the wheelchair incorporates a reservoir or liquid storage chamber that can be overfilled or can overflow in intended use, liquid overflowing from the reservoir or chamber shall not wet electrical insulation or live parts which are liable to be adversely affected by such a liquid, nor shall a hazard be created. Unless indicated by a marking or by the instructions for use, no hazard shall be created if the wheelchair is tilted through an angle 15° greater than the maximum inclination that can occur during intended use.

5.9.1.2 Test method

Fill the reservoir to the maximum level specified by the manufacturer and, if possible, add further liquid equal to $15\,^{+1}_{0}$ % of the capacity of the reservoir or until the reservoir is full, whichever is the lesser quantity.

Tilt the wheelchair through an angle of $(a+15)\,^{+1}_{0}$ ° to the horizontal in each direction, where a is the maximum slope for use of parking brakes. If necessary, refill the reservoir between tests.

5.9.2 Spillage

5.9.2.1 Requirements

Wheelchairs requiring the handling of liquids in intended use shall be so constructed that spillage does not wet parts that creates a hazard.

5.9.2.2 Test method

Position the wheelchair on the horizontal test plane. Pour $200\,^{+5}_{0}$ ml of water steadily on an arbitrary point on the seat.

After the test, the wheelchair shall function as specified by the manufacturer.

5.9.3 Leakage

Wheelchairs shall be so constructed that liquid which can escape in single fault condition does not create a hazard.

5.9.4 Ingress of liquids

5.9.4.1 Requirements

If liquid can enter an enclosure unintentionally, either there shall be a means for the liquid to escape from the enclosure, or the liquid shall not create a hazard.

Hazards that can be caused by the ingress of liquids shall be addressed in the risk management process (see 5.1).

NOTE See B.2.12.

5.9.4.2 Test method

Test whether the liquid can escape from an enclosure by adding liquid and then tilting the wheelchair 10° in each direction. If any liquid remains in the enclosure, test the wheelchair to determine whether it is still functional, and determine whether the liquid can create a hazard.

5.10 Safety of moving parts

5.10.1 Squeezing

Unless the intended purpose of part of the wheelchair is to grip, cut, squeeze or provide a similar function, or if the intended use cannot be achieved without a risk of squeezing:

a) any moving parts that constitute a hazard shall be provided with guards that cannot be removed without the use of a tool; or

b) the gap between exposed parts of the wheelchair that move relative to each other shall be maintained throughout the range of movement at less than the relevant minimum value or more than the relevant maximum value specified in Table 1; or

c) if cords (ropes), chains or drive belts are used, either they shall be confined so that they cannot run off or jump out of their guiding devices, or a hazardous situation shall be prevented by other means; mechanical means used for this purpose shall not be removable without the use of a tool; or

d) the wheelchair shall incorporate a control device which enables the movement when it is operated and stops the movement when it is released (e.g. a spring-loaded device that returns to the stop position when released).

For moving parts that can cause squeezing, manufacturers shall take into consideration the part or parts of the body that are at risk. It is necessary to specify the characteristics of the persons involved in the intended use, so that the appropriate safe distances can be applied.

Table 1 — Safe distances between moving parts

To avoid	Safe distances for adults	Safe distances for children
Finger traps	Less than 8 mm or more than 25 mm	Less than 4 mm or more than 25 mm
Foot traps	Less than 35 mm or more than 120 mm	Less than 25 mm or more than 120 mm
Head traps	Less than 120 mm or more than 300 mm	Less than 60 mm or more than 300 mm
Genitalia traps	Less than 8 mm or more than 75 mm	Less than 8 mm or more than 75 mm

5.10.2 Mechanical wear

Parts subject to mechanical wear likely to create a hazard shall be accessible for inspection.

5.11 Prevention of traps for parts of the human body

5.11.1 Holes and clearances

Holes in, and clearances between stationary parts that are accessible to the occupant and/or assistant during the intended use of the wheelchair shall be as specified in Table 2.

Table 2 — Safe distances between stationary parts

To avoid	Safe distances for adults	Safe distances for children
Finger traps	Less than 8 mm or more than 25 mm	Less than 5 mm or more than 12 mm
Foot traps	Less than 35 mm or more than 100 mm	Less than 25 mm or more than 45 mm
Head traps	Less than 120 mm or more than 250 mm	Less than 60 mm or more than 250 mm
Genitalia traps	Less than 8 mm or more than 75 mm	Less than 8 mm or more than 75 mm

If the intended purpose of the wheelchair cannot be met without a hazard caused by the size of holes and the clearance between stationary parts, a warning and instructions on how to control the risk shall be provided in the instructions for use.

For stationary parts that can cause a trap, manufacturers shall take into consideration the parts of the body that are at risk. It is necessary to specify the characteristics of the persons involved in the intended use, so that the appropriate safe distances can be applied.

The design of parts that confine a hole or clearance shall take into consideration the forces that can be applied in normal use.

NOTE Forces can cause holes or clearances to widen, which can lead to loss of conformity with the requirements of Table 2.

The lower limits specified in Table 2 do not apply for holes with the shape of a keyhole, or for V-shaped openings. When inspecting the wheelchair for traps for body parts any flexibility and/or elasticity of adjacent parts shall be taken into account.

5.11.2 V-shaped openings

The risk of entrapment in V-shaped openings shall be addressed by the risk management process (see 5.1).

NOTE For guidance, see B.2.13.

5.12 Folding and adjusting mechanisms

5.12.1 General

Folding and adjusting mechanisms can present a hazard if parts of the body can enter a gap between parts and be trapped when the gap is closed.

If the wheelchair incorporates folding and/or adjusting mechanisms it shall conform to 5.12.2 and 5.12.3.