

BS EN 12183:2014

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BSI Standards Publication

Manual wheelchairs — Requirements and test methods

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National foreword

This British Standard is the UK implementation of EN 12183:2014. It supersedes BS EN 12183:2009 which is withdrawn.

Since the drafting of this standard and its subsequent publication, it has come to the UK committee's attention that the needs of children under 22 kg seated in a wheelchair during road transport are out of the scope of the documents referred to in this standard.

The UK committee therefore wishes to bring the following important information to the attention of readers of this standard.

When a child of mass less than 22 kg is to be transported in a road vehicle, it is recommended that they be transferred from their wheelchair to a UNECE Regulation 44 compliant child restraint system, which may provide a more effective occupant restraint system than a vehicle mounted three-point lap and diagonal restraint system. There are child restraint systems available that include additional postural supports to assist in maintaining the position of the child when seated.

The UK committee recognizes that parents or care providers may consider that the best option for their child is to remain in their wheelchair whilst in transport due to the level of posture control and comfort provided by the support surface of the wheelchair. A risk management process may be required, preferably carried out by a multi-disciplined team including, such as, parent, carer and transport provider, supported by a clinical professional involved in the wheelchair prescription process.

The UK participation in its preparation was entrusted by Technical Committee CH/173, Assistive products for persons with disability, to Subcommittee CH/173/1, Wheelchairs.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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English Version

Manual wheelchairs - Requirements and test methods

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

Muskelkraftbetriebene Rollstühle - Anforderungen und Prüfverfahren

This European Standard was approved by CEN on 27 December 2013.

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Foreword

This document (EN 12183:2014) 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 September 2014 and conflicting national standards shall be withdrawn at the latest by March 2017.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 12183:2009, which is to be withdrawn (dow) three years after the date of availability of this edition. See CEN/TC 293 resolution 492.

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 14 June 1993 concerning medical devices.

For relationship 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 editions of 1999, 2006 and 2009.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Introduction

This is the fourth edition of this European Standard. The first edition was published in 1999, the second in 2006 (withdrawn in 2007) and the third in 2009.

Where this European Standard does not apply to particular wheelchairs, contracting parties should consider whether appropriate parts of this European Standard can be used. Manufacturers might also wish to consider whether appropriate parts of this European Standard can be used to assess the performance of their products against the Essential Requirements of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

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

1 Scope

This European Standard specifies requirements and test methods for manual wheelchairs intended to carry one person of mass not greater than 250 kg.

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 or toileting,
- manual wheelchairs with handrim-activated power-assisted propulsion,
- custom-made wheelchairs,
- stand-up wheelchairs, and
- manual wheelchairs with add-on power kits used for propulsion.

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

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 1021-2:2006, *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*

EN 12184, *Electrically powered wheelchairs, scooters and their chargers — Requirements and test methods*

EN ISO 14971:2012, *Medical devices — Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)*

ISO 7176-1:1999, *Wheelchairs — Part 1: Determination of static stability*

ISO 7176-3:2012, *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 7176-11:2012, *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 7176-19:2008, *Wheelchairs — Part 19: Wheeled mobility devices for use as seats in motor vehicles*

ISO 7176-22:2000, *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*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 7176-26:2007 (with the exception of the definition of wheelchair which is replaced by 3.2 below), EN 12182:2012 and the following apply.

3.1

loaded wheelchair

wheelchair loaded with a dummy as specified in 4.8

3.2

wheelchair

wheeled personal mobility device incorporating a body support system for a disabled occupant that is manually propelled by the occupant and/or an assistant 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 occupant is a disabled person or a person not having the full capacity to walk unaided.

4 Test apparatus

4.1 Adjustable test plane, a flat, rigid plane having an adjustable slope, with a coefficient of friction as specified in ISO 7176-13:1989, of sufficient size to accommodate the wheelchair during the tests specified in 9.2, 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 50 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 7176-13:1989, 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 50 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 $\pm 5\%$ and with a rate of application 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 distance in the range of 0 m to 5 m with an accuracy of ± 1 mm or $\pm 2\%$ whichever is the greater.

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

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

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 $\pm 0,05$ 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_0^{+2} 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, for example straps or bicycle inner tubes.

NOTE ISO 7176-8:1998, 10.3, provides guidance on restraining a test dummy.

5 General requirements

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

- intended performance and technical documentation;
- 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 the human body;
- folding and adjusting mechanisms;
- surfaces, corners and edges;
- clinical evaluation;
- ergonomics.

A risk analysis shall also be carried out in accordance with EN ISO 14971:2012.

6 Preparation for testing

6.1 General

Unless otherwise specified in Clauses 7, 8, 9, 10 and 11, the wheelchair shall be prepared for testing as specified in ISO 7176-22:2000 with the following modification.

If a test procedure requires the use of a test dummy, it shall be selected and fitted as specified in 6.2.

NOTE This instruction supersedes instructions for loading the wheelchair in the referenced standards.

6.2 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 7176-22:2000.

7 Wheelchair performance

7.1 Static stability

7.1.1 Requirements

The wheelchair shall have provision for anti-tip devices if the static stability is less than 10°.

7.1.2 Test method

Test the loaded wheelchair as specified in ISO 7176-1:1999. Use the angles recorded in Table 4 of ISO 7176-1:1999 to establish whether provision for anti-tip devices is required, and, if so, determine whether the wheelchair has such provision.

7.2 Static, impact and fatigue strength

7.2.1 Requirements

The wheelchair shall conform to the requirements of ISO 7176-8:1998.

Arm supports shall conform to the static loading requirements of ISO 7176-8:1998 in all intended operating positions.

Where the manufacturer specifies a maximum occupant mass greater than 100 kg the forces specified in Table 2 shall apply.

7.2.2 Test

Test the wheelchair in accordance with ISO 7176-8:1998 with modifications as stated in 7.2.1.

7.3 Tilting fatigue strength

7.3.1 General

Occupied wheelchairs can often be tipped backwards by assistants when manoeuvring them. The tipping action can put considerable stress on the back support and related components. It is important that a manual wheelchair that can be tipped in this way is able to withstand repeated tipping without damage.

7.3.2 Requirement

This requirement applies only to wheelchairs where the maximum occupant mass is not greater than 150 kg and where the intended use includes tipping the occupied wheelchair backwards about the rear wheel axles by use of the push handles.

After the wheelchair has been subjected to the test specified in 7.3.3, no part of the back support shall have moved from the pre-set position and no component or assembly of parts shall show visible signs of cracks, breakages, gross deformations, free play, loss of adjustment or any other damage that adversely affects the function of the wheelchair.

7.3.3 Test method

- a) If the position of the rear wheels is adjustable, set them to the most rearward position in accordance with the manufacturer's instructions for use. If the position of the front wheels is adjustable, set them to the most forward position in accordance with the manufacturer's instructions.
- b) If the position of the back support and/or push handles is adjustable, set them to the maximum height in accordance with the manufacturer's instructions.
- c) Ensure that the rear wheels are free to rotate, for example by disengaging parking brakes.
- d) Restrain the rear wheels using appropriate means (4.12) so that the wheelchair can be tipped about the axles of the rear wheels without the wheels moving.
- e) Attach the means to tip the wheelchair (4.13) to the push handles so that it will apply forces in a vertical plane parallel to the forward direction of travel that bisects the wheelchair. Make sure the means of attachment cannot apply any lateral forces to the push handles.
- f) Secure the dummy in the wheelchair using appropriate means (4.14) so that it will remain in position as the wheelchair is tipped and returned to the upright position.
- g) Using the means to tip the wheelchair (4.13), smoothly tip the loaded wheelchair backwards to the point of balance (where the centre of mass of the loaded wheelchair is directly above the rear axles), $\pm 1^\circ$, or to the angle where the front wheels are lifted to a height of $120 \begin{smallmatrix} +10 \\ 0 \end{smallmatrix}$ mm above the test surface, whichever angle is greater. Then smoothly return the loaded wheelchair to the upright position. Ensure the push handles are not pushed forward when the wheelchair is upright.
- h) Repeat g) for 20 000 cycles at a rate of $10 \begin{smallmatrix} +2 \\ 0 \end{smallmatrix}$ cycles per minute.
- i) Inspect the wheelchair and determine whether it has met the requirement.

7.4 Wheelchairs for use as seats in motor vehicles

If the manufacturer specifies that the intended use of the wheelchair includes use as a seat in a motor vehicle by an occupant of mass not less than 22 kg, the wheelchair shall conform to the performance requirements of ISO 7176-19:2008 with the following modifications.

4.1.2 is replaced by the following:

If a wheelchair is intended by the manufacturer to also be secured by a docking securement device in public transportation and/or different private vehicles, the securement points on the wheelchair and/or of the wheelchair tiedown adaptors shall conform to the performance requirements in Clause 5.

5.2.1 a) is replaced by the following:

If the wheelchair has a head restraint, the horizontal excursions of the ATD and the wheelchair, with respect to the impact sled, shall not exceed the limits in Table 7 at any time during the test.

If the wheelchair does not have a head restraint, the horizontal excursions of the ATD and the wheelchair, with respect to the impact sled, shall not exceed the limits in Table 7 at any time during the test with the exception that the excursion of the back of the head of the ATD, $X_{\text{head, R}}$, shall not be measured.

5.2.2 e) is replaced by the following:

Primary occupant-load-carrying components of the wheelchair shall not show visible signs of failure, unless there is a backup system to provide support.

7.5 Surface temperature

Surfaces of the wheelchair that can come into direct contact with the occupant's skin and/or an assistant's skin during normal use and that are within the envelopes illustrated in Figure 1 and Figure 2 shall meet the requirements for surface temperature specified in EN 12182. If an ambient temperature is not specified, test at an ambient temperature of $20\text{ °C} \pm 2\text{ °C}$.

8 Component properties

8.1 Foot supports, lower leg support assemblies and arm supports

8.1.1 Requirements

The wheelchair shall be fitted with foot supports that have a means of positioning the occupant's feet at the required height and prevent the occupant's feet from sliding backwards.

Any swing away, movable or removable foot support, lower leg support assembly or arm support fitted on the wheelchair shall:

- a) incorporate a means to locate it securely in any intended operating position,
- b) be adjustable in increments not exceeding 25 mm,
- c) be accessible and operable by the occupant or an assistant or both in accordance with the manufacturer's intended use of the wheelchair,
- d) be within the reach space shown in Figure 1, and

- e) be operable without the use of tools.

NOTE The ability to make adjustments without the use of tools is not required.

Where the wheelchair has separate foot supports which have a gap between them or the possibility of a gap being formed when they are loaded,

- f) means to prevent the occupant's feet from sliding into the gap shall be provided, or
- g) when the foot supports are tested in accordance with 8.1.2.2, any gap between them shall meet the requirement for safe distances between stationary parts specified in EN 12182.

8.1.2 Test methods

8.1.2.1 Test for general performance

- a) Fit foot supports, lower leg support assemblies and arm supports in the operating position(s) specified in the manufacturer's instructions.
- b) Adjust the foot supports, lower leg support assemblies and arm supports as specified in the manufacturer's instructions.
- c) Record whether the foot supports, lower leg support assemblies and arm supports have met the requirements.

8.1.2.2 Test for foot support gap

- a) Simultaneously apply a force $F \pm 5$ N to the centroid of each foot support, normal to the plane of the unloaded foot support. In cases where the foot support has no identifiable plane, apply the force within 5° of vertical. The force F is calculated from the following equation:

$$F = 0,125 \times m \times g$$

where

F is the force applied to each foot support, expressed in newtons;

m is the maximum occupant mass specified by the manufacturer, expressed in kilograms;

g is the acceleration due to gravity, 9,81 m/s².

- b) Apply the force for 5 s to 10 s.
- c) While the force is being applied measure the shortest distance between the foot supports.
- d) Record whether the foot supports have met the requirements.

8.2 Component mass

If the wheelchair is intended to be dismantled for storage or transportation, any component that requires moving or handling that 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 such components can be lifted and describing how they shall be handled during disassembly, lifting, carrying, and assembly to reduce risks to the person or persons moving or handling them.

8.3 Pneumatic tyres

All pneumatic tyres on the wheelchair shall have the same type of valve connection. Valves should be readily accessible when using the intended inflating tool.

The tyres or the rims shall be marked with the maximum pressure in kPa, bar or PSI.

8.4 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.

NOTE The term 'support' is used in relation to occupant posture, and the term 'restraint' is used in relation to motor vehicle impacts.

8.5 Resistance to ignition

8.5.1 Upholstered composite parts

For upholstered parts which are composites of cover and filling, with or without a support base or interliner, the complete composite shall be tested by the methods specified in EN 1021-2:2006 or ISO 8191-2:1988. Progressive smouldering ignition and flaming ignition as defined in the Standard applied shall not occur.

8.5.2 Foam materials

For foam materials which form all or part of a seat, back support, postural support, arm support or lower leg support and which consist of foam material with or without an integral skin, the material of each part shall be tested with the source applied centrally to the surface intended to support the occupant by the methods specified in EN 1021-2:2006 or ISO 8191-2:1988 (see Figure 3). Progressive smouldering ignition and flaming ignition as defined in the Standard applied shall not occur.

8.5.3 Other parts

For sling seats, sling backs, belts, restraint harnesses, foot supports, and clothing guards, the material of each item shall be tested with the source applied centrally to the surface intended to contact or support the occupant by the methods specified in EN 1021-2:2006 or ISO 8191-2:1988. Progressive smouldering ignition and flaming ignition as defined in the Standard applied shall not occur.

Belts that are intended for use as restraints in motor vehicles may, as an alternative, meet the requirements of FMVSS 302 or equivalent.

NOTE It is not necessary to test components that are inherently resistant to ignition, e.g. steel frame tube.

9 Propulsion and braking systems

9.1 Means for operating brakes

9.1.1 Requirement

a) Means for operating brakes shall:

- 1) be accessible and operable by the occupant or an assistant or both in accordance with the manufacturer's intended use of the wheelchair;

- 2) be within the reach space shown in Figure 1, if the wheelchair is intended to be operated by the occupant;
- 3) be within the reach space shown in Figure 2, if the wheelchair is intended to be operated solely by an assistant;
- 4) have operating forces for engaging and disengaging that do not exceed those stated in Table 1 when tested in accordance with 9.1.2.

NOTE The brake lever type shown in Figure 4 has a whole hand operation.

- b) If one or more brake levers are fitted to a wheelchair in the form used on bicycles and mopeds:
 - 1) for wheelchairs with a maximum occupant mass not greater than 150 kg, the force applied to each lever to hold the loaded wheelchair stationary on the maximum slope specified by the manufacturer for parking brake use shall not exceed 60 N;
 - 2) for wheelchairs with a maximum occupant mass greater than 150 kg, the force applied to each lever to hold the loaded wheelchair stationary on the maximum slope specified by the manufacturer for parking brake use should not exceed 60 N;
 - 3) the handgrip width of such brake levers when no force is applied, measured 15 mm from the end of the brake lever, shall not be greater than 100 mm and should not be greater than 80 mm (see Figure 4).

9.1.2 Test method for determination of brake operating forces

- a) Adjust the brakes as specified by the manufacturer.
- b) Select the part of the lever through which the force is to be applied as shown in Figure 5.
 - 1) If the lever is fitted with a generally spherical knob, apply the force through the centre of the knob.
 - 2) If the lever is tapered, apply the force through the point where the largest cross section intersects the centre line of the lever.
 - 3) If the lever is parallel or any shape other than those above, apply the force through a point on the centre line of the lever 15 mm below the top.
 - 4) If the form of the lever is such that the lever is gripped by the whole hand apply the force through the centre line of the lever 15 mm from the end.
 - 5) If the brake is operated by pushing or pulling a bar or pad, apply the force to the centroid of the bar or pad.
- c) Apply the brakes while measuring the force with the device specified in 4.4 aligned in the direction of travel of the point of application of the force in order to measure the maximum application force required.
- d) Release the brakes and measure the force with the device as specified in 4.4 aligned in the direction of travel of the point of application of the force in order to measure the maximum releasing force required.
- e) Perform c) and d) three times in total and record the measurements.
- f) Calculate and record the arithmetic mean value of the application and the release forces measured separately.
- g) Determine whether the requirements for the operating forces stated in Table 1 have been met.

9.2 Braking functions

NOTE Wheelchairs operated by the occupant using a circular handrim attached to the wheels are considered to have provision to stop the wheelchair because the occupant can slow it down. Wheelchairs intended to be controlled by an assistant might require a running brake to allow an assistant to slow or stop the wheelchair.

9.2.1 Requirements

- a) The wheelchair shall have parking brakes that meet the parking brake effectiveness requirement in Table 1 when tested in accordance with 9.2.2.1.
- b) If they are subject to wear, parking brakes shall have provision for adjustment and/or replacement as specified by the manufacturer.
- c) If the wheelchair is fitted with arm supports that can be moved or removed to enable transfer, when tested in accordance with 9.2.2.2, engaged parking brakes shall not have parts that protrude above the level of the occupied seat.
- d) When parking brakes are tested in accordance with 9.2.2.3, no parking brake mechanism shall move from the pre-set position and no component or assembly of parts shall show visible signs of cracks, breakages, gross deformations, free play, loss of adjustment or any other damage that adversely affects the function of the wheelchair.
- e) Following testing of the parking brakes in accordance with 9.2.2.3, parking brakes shall meet the parking brake effectiveness requirement in Table 1 when tested again in accordance with 9.2.2.1.

9.2.2 Test methods

9.2.2.1 Test for determination of effectiveness of parking brakes

- a) Adjust the parking brake in accordance with the manufacturer's instructions without exceeding the operating force requirements stated in Table 1.
- b) Test the loaded wheelchair facing uphill in accordance with ISO 7176-3:2012, with the test plane inclined to the horizontal at $(7 \text{ }^{+1}_0)^\circ$, or at the maximum angle specified by the manufacturer for parking brake use if it is greater.

If the wheelchair has adjustable stability or if the manufacturer declares that the wheelchair static stability is less than 7° , apply to the wheelchair the minimum force, perpendicular to the test plane, necessary for all wheels to remain in contact with the test plane during the test procedure.

- c) Repeat b) with the wheelchair facing downhill.
- d) Determine whether the parking brakes hold the loaded wheelchair stationary on the slope.

9.2.2.2 Test method for protrusion of parts of parking brakes

- a) Engage the parking brake.
- b) Move or remove the arm support to enable transfer.
- c) Check whether any part of the parking brake protrudes above the level of the occupied seat.

9.2.2.3 Test method for fatigue strength of parking brakes

- a) Carry out the test with the parking brake mounted on the wheelchair or mounted on a suitable test fixture that simulates mounting on the wheelchair. If the wheelchair is fitted with two identical brakes (left and right), test only one of the brakes.
- b) Adjust the parking brake in accordance with the manufacturer's instructions without exceeding the operating force requirement stated in Table 1.
- c) Move the lever of the brake smoothly from the non-braking position to the braking position for 60 000 cycles at a frequency not greater than 0,5 Hz (4.10). Carry out maintenance during testing only in accordance with the manufacturer's instructions.
- d) Inspect the brake mechanism and determine whether it has met the requirement.
- e) If a test fixture was used, return the brake mechanism to the wheelchair.

9.3 Pushing force

9.3.1 Requirements

When determined in accordance with 9.3.2, the pushing force required to start the loaded wheelchair moving and to maintain a constant speed on a horizontal surface shall not exceed the following limits:

- 40 N for $m \leq 100$ kg,
- 60 N for $100 \text{ kg} < m \leq 150$ kg,
- 70 N for $150 \text{ kg} < m \leq 200$ kg,
- 80 N for $200 \text{ kg} < m \leq 250$ kg,

where m is the maximum occupant mass specified by the wheelchair manufacturer.

9.3.2 Test

- a) Make provisions for applying a horizontal force in the forward direction of travel and along the longitudinal centreline of the wheelchair as follows:
 - 1) where push handles are fitted, to the push handles;
 - 2) where push handles are not fitted and the wheelchair has a flexible back support, to a point $15 \text{ mm} \pm 5 \text{ mm}$ below the top of the back support; or
 - 3) where the back support is rigid, to a point $15 \text{ mm} \pm 5 \text{ mm}$ below the top of the back support.A bar or string may be fitted across push handles or the back support to permit a pushing force to be applied.
- b) Place the loaded wheelchair on the horizontal test plane.
- c) Set up a means to apply a force to start the wheelchair moving and to maintain the wheelchair moving forwards at a speed of $1,0 \text{ m/s} \pm 0,1 \text{ m/s}$ so that the direction of the force is maintained within the following limits throughout the test:
 - 1) horizontal $\pm 5^\circ$;

- 2) at the height of the point to which the force is applied, and parallel to the forward direction of travel of the wheelchair $\pm 5^\circ$;
 - 3) within 5 mm of the longitudinal centre line of the wheelchair.
- d) Apply the force, and increase it at a rate not greater than 5 N/s until the wheelchair starts to move.
 - e) Accelerate the wheelchair to a speed of $1,0 \text{ m/s} \pm 0,1 \text{ m/s}$ over a distance not less than 0,5 m. After the acceleration is complete, measure and record the force needed to maintain the wheelchair in motion at a constant speed of $1,0 \text{ m/s} \pm 0,1 \text{ m/s}$ over a distance not less than 2,5 m.
 - f) Maintain the direction of the force within the limits specified above during the whole test procedure.
 - g) Perform the test six times in the forward direction of the wheelchair. Carry out the tests on the same area of the test track, three times in one direction and three times in the opposite direction.
 - h) Calculate the arithmetic mean value of the forces measured.

10 Operations

10.1 Operations intended to be carried out by the occupant and/or assistant

Wheelchairs shall be designed to facilitate ease of operation by the occupant and/or assistant as specified in the manufacturer's instructions.

Examples include:

- operation of adjustable seating;
- use of detachable components, including removable arm supports, lower leg support assemblies, etc., to facilitate safe transfers into and out of the wheelchair;
- use of folding mechanisms, including folding frames, etc., to facilitate storage and transportation of an unoccupied wheelchair;
- carrying out maintenance, including use of tools, etc.;
- use of braking systems;
- use of push handles; and
- use of electrical ancillary equipment.

10.2 Controls intended for operation by the occupant

Controls intended to be operated by the occupant while seated shall be within the occupant reach space shown in Figure 1.

The following controls, if fitted, are included:

- brakes;
- seating adjustments;

- detachable components, including removable arm supports, lower leg support assemblies, etc., to facilitate safe transfers into and out of the wheelchair;
- means of driving and steering; and
- electrical ancillary equipment.

10.3 Controls intended for operation by an assistant

Controls intended to be operated by an assistant shall be within the region specified in Figure 2.

Examples include:

- brakes,
- seating adjustments,
- detachable components, including removable arm supports, lower leg support assemblies, etc., to facilitate safe transfers into and out of the wheelchair,
- means of driving and steering,
- push handles, and
- electrical ancillary equipment.

10.4 Push handles and handgrips

10.4.1 Requirements

When push handles are fitted, no part of the wheelchair shall lie within a space to the rear of the wheelchair bounded by the following:

- a plane at 85° to the horizontal, that touches the rearmost points of the push handles as shown in Figure 6;
- two planes not less than 350 mm apart equidistant from a vertical plane parallel to the forward direction of travel that bisects the wheelchair, unless the intended occupant is a child;
- the horizontal test plane.

When the wheelchair is fitted with steering and/or manoeuvring handgrips for assistant use, the handgrips shall be at least 75 mm in length and between 20 mm and 50 mm in diameter.

When manoeuvring handgrips are fitted with controls that are intended to be used by being gripped by one hand, the handgrip width when no force is applied shall not be greater than 100 mm and should not be greater than 80 mm (see Figure 4).

10.4.2 Test method

- a) Place the wheelchair on the horizontal test plane.
- b) Project the planes specified in 10.4.1 and determine whether any part of the wheelchair lies within the enclosed space.
- c) Measure the dimensions of the steering and/or manoeuvring handgrips.

- d) Where applicable, measure the handgrip width of the controls fitted to the manoeuvring handgrips that are intended to be used by being gripped by one hand.
- e) Record whether the wheelchair has met the requirements.

10.5 Operating forces

10.5.1 Requirements

All controls, except for means to operate brakes, shall have operating forces for engaging and releasing that do not exceed those stated in Table 1 when tested in accordance with 10.5.2.

NOTE Requirements and test methods for means to operate brakes are given in 9.1.

In addition, to achieve the intended function of the system or device being operated, for knobs intended to be gripped and turned by one hand:

- where the diameter of the knob is greater than or equal to 25 mm and the force is transmitted by friction, the numerical value of the torque, expressed in Nm, shall not be greater than 0,05 times the numerical value of the diameter of the knob, expressed in mm, and
- where the diameter of the knob is less than 25 mm diameter, the numerical value of the torque, expressed in Nm, shall not be greater than 0,025 times the numerical value of the diameter of knob, expressed in mm.

10.5.2 Test

- a) Position a means to apply force or torque as applicable:
 - 1) where the operation is performed by pushing or pulling, position the means to apply force parallel to the direction of operation and in the middle of the knob or button;
 - 2) in the case of a lever of length 30 mm or greater, position the means to apply force at a distance of 15 mm from the end of the lever;
 - 3) in the case of a lever of length less than 30 mm, position the means to apply force at the midpoint of the lever;
 - 4) for a turning knob, use a suitable means (e.g. a force gauge) to measure torque concentrically on the knob.
- b) Gradually increase the force or torque until the intended function of the system or device as specified by the manufacturer's instructions is achieved.
- c) Measure and record the maximum operating force.
- d) Perform b) to c) three times in total.
- e) Calculate and record the arithmetic mean of the three recorded measurements.

10.6 Seating adjustments for tilt and recline systems

10.6.1 Requirements

If the manufacturer specifies that the seating can be adjusted by an assistant or the occupant or both while the occupant is seated, the assistant and/or the occupant shall not have to lift a mass (e.g. the combined mass of

the occupant and the seating) which presents a moving and handling safety hazard to the assistant and/or the occupant.

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

NOTE The lighter shaded region of Figure 1 shows the reach space for the occupant in relation to the position of the back support reference plane and the seat reference plane (see ISO 7176-7:1998).

10.6.2 Test method

- a) Adjust the seating in accordance with the manufacturer's instructions.
- b) Record whether the wheelchair has met the requirements.

11 Electrical systems — Electrically powered ancillary equipment

If the wheelchair is fitted with electrically powered ancillary equipment, the wheelchair combined with the ancillary equipment shall conform to the applicable requirements of EN 12184.

12 Information supplied by the manufacturer

12.1 General

Each wheelchair shall be provided with documentation and labelling that conform to the requirements in EN 12182 and ISO 7176-15:1996.

In addition, the manufacturer shall provide the documentation in three separate sections: pre-sale, user and servicing information as specified in 12.2, 12.3 and 12.4 respectively. These may be provided as separate printed documents or in other forms of media to meet the needs of individual occupants or their assistants.

For the requirements in 12.2 and 12.3, unless otherwise specified, all linear dimensions shall be expressed in millimetres and all masses shall be expressed in kilograms.

12.2 Pre-sale information

In addition to the requirements of 12.1, pre-sale information shall include the following:

- a) information on how to obtain the user information in a format appropriate for use by visually impaired people;
- b) a description of the intended occupant of the wheelchair, including the occupant's mass and any specific requirements for the occupant's functional capability, visual ability and cognitive ability suitable for operating the wheelchair safely in its intended environment;
- c) the intended operator (occupant, assistant or both);
- d) a description of the intended use and the intended environment;
- e) the overall dimensions (width, length and height) of the wheelchair and its mass when it is ready for use and, if applicable, when it is folded or dismantled;
- f) if the overall dimensions of the wheelchair when it is ready for use exceed the values recommended in A.1.1, a clear statement that the wheelchair is larger than the recommended dimensions;

- g) the pivot width;
- h) the maximum slope for use of parking brakes, expressed in degrees;
- i) the standard options that are available for the wheelchair;
- j) the type(s) of tyres that can be used on the wheelchair;
- k) operator adjustments;
- l) if the wheelchair can be dismantled or has any removable parts; the mass of the heaviest part;
- m) information concerning whether the removal of parts or accessories intended by the manufacturer to be removed without the use of tools will have adverse or beneficial effects on the wheelchair;
- n) information on whether or not the wheelchair is intended to be used as a seat in a motor vehicle, and whether and how this depends on the standard options referred to in i);
- o) information on whether the unoccupied wheelchair is suitable for land and/or air transport.

12.3 User information

User information shall be provided by the manufacturer with each wheelchair. Further copies shall also be available for any subsequent user of the wheelchair. User information shall contain all pre-sale information and the following:

- a) the unique identification number of the wheelchair or information on the location of the unique identification number on the wheelchair;
- b) any adjustment or settings required before the wheelchair can be used and warnings of how adjustments or settings affect stability;
- c) where applicable, information on any adjustments that can be made and the competency required to carry out these adjustments;
- d) instructions on operation of all controls, including brakes;
- e) the wheelchair manufacturer's recommended tyre pressure(s), expressed in kPa, bar or PSI;
- f) instructions for dealing with tyre punctures, where pneumatic tyres are fitted;
- g) a warning that surface temperatures can increase when the wheelchair is exposed to external sources of heat (e.g. sunlight);
- h) a warning for trapping hazards (e.g. pinch points);
- i) the level of resistance to ignition of materials and assemblies;
- j) instructions on how to engage and disengage the drive system, if applicable;
- k) instructions on whether and how the wheelchair can be folded to assist in storage or transport;
- l) instructions on dismantling and re-assembly of the wheelchair or any removable parts;
- m) instructions regarding transport of the wheelchair when it is unoccupied (e.g. in a car or aeroplane);

- n) the masses of parts of the wheelchair that are expected to be handled during dismantling, reassembly, or carrying;
- o) the positions of points where the component parts can be gripped for safe moving and handling and/or a method for handling during dismantling, assembly or carrying;
- p) if the manufacturer specifies that the wheelchair is intended for use as a seat in a motor vehicle, the method of attaching wheelchair tiedown and occupant restraints, and recommendations about suitable tiedown and restraint systems;
- q) if the manufacturer specifies that the wheelchair is not intended for use in the motor vehicle, a warning to that effect, together with the symbol shown in Figure 7;
- r) instructions on how to obtain and fit the optional anterior pelvic support (see 8.4) if it is not supplied with the wheelchair;
- s) the positions of points intended to carry additional loads;

EXAMPLE Grocery basket, backpack hook.

- t) instructions for preparing the wheelchair for long-term storage (e.g. longer than four months) and for preparing it for use afterward;
- u) information on the recycling of the wheelchair;
- v) a warning, if the adjustments of seating or wheel positions can be set outside safe limits;
- w) if the overall width or overall length of the wheelchair when it is ready for use exceed the applicable values recommended in A.1.1, a warning concerning access to emergency escape routes;
- x) if the characteristics of the wheelchair (including occupant as applicable) exceed the limits specified in Annex M of the Technical Specification for Interoperability relating to Accessibility for Persons with Reduced Mobility (PRM-TSI), a statement to that effect (see Annex C);
- y) information on how to find out about product safety notices and product recalls, for example by ensuring the supplier has up-to-date contact details;
- z) the expected service life of the wheelchair;
- aa) the name and address of the manufacturer;
- bb) the name and address of the authorized representative, where the manufacturer does not have a registered place of business in the European Union.

12.4 Service information

The service information shall contain all the pre-sale, user information and instructions necessary for the maintenance, adjustment and repair of the wheelchair and for the replacement of parts.

12.5 Labelling

In addition to the requirements of 12.1, the manufacturer shall apply permanent labelling for the following:

- a) devices for disengagement of the drive system, showing engaged and disengaged positions, including a warning that the drive system should be re-engaged before an occupant is left unattended or attempts to operate the wheelchair;

- b) for wheelchairs where the intended use includes use as a seat in a motor vehicle, the position of attachment points for wheelchair tie-down and occupant restraint systems (WTORS);
- c) for wheelchairs not intended to be used as a seat in a motor vehicle, a warning to that effect, including the symbol shown in Figure 7 with a diameter not less than 15 mm, in the same location as the labelling required by ISO 7176-15:1996.

13 Test report

The test report shall contain the following information:

- a) a unique report number;
- b) the name and address of the testing institution;
- c) the date of issue of the test report;
- d) a reference to this edition of this European Standard, i.e. EN 12183:2014;
- e) the name and address of the manufacturer of the wheelchair;
- f) a description of the sample including the manufacturer's or vendor's trade mark, model or type, unique identification number and any variations or accessories fitted;
- g) the source of the sample;
- h) details of the set-up of the wheelchair as specified in ISO 7176-22:2000, including details of how it is equipped and details of adjustments;
- i) the ambient temperature at which each test was carried out;
- j) the mass of the dummy used;
- k) a photograph of the sample equipped as during testing;
- l) the results of the tests;
- m) if this document does not apply in total to the wheelchair (see Clause 1), a list of the requirements that have been applied and those that have not;
- n) a statement as to whether or not the tested sample has met all of the applicable requirements of this European Standard and a list of all the applicable requirements it has not met.

14 Tables

Table 1 — Requirements and tests for operating characteristics

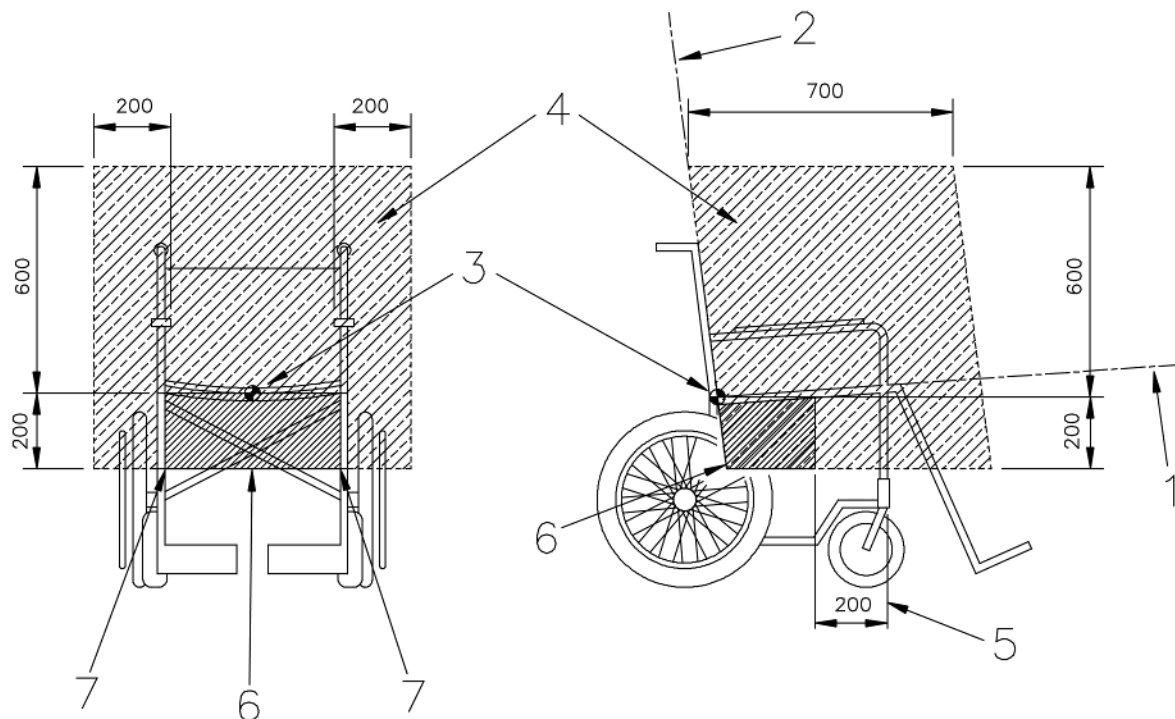
Wheelchair characteristics	Test	Requirements
Static stability	7.1.2	
- all directions		Provision for anti-tip devices if less than 10°.
Maximum operating forces	9.1.2 10.5.2	
- single finger operation		5 N
- more than one finger operation		13,5 N
- whole hand operation		60 N
- combined hand and arm operation		60 N
- foot operation, pushing operation		100 N
- foot operation, pulling operation		60 N
Parking brake effectiveness	9.2.2.1	The wheelchair shall not slide nor shall its wheels rotate when tested in accordance with ISO 7176-3:2012 with the loaded wheelchair on a slope of 7° from the horizontal or at the maximum slope specified by the manufacturer for use of parking brakes, if greater.

Table 2 — Forces for static loading relating to occupant mass greater than 100 kg

Test	Equation	Maximum force applied
Arm support downward ^a	$F = \frac{m_d \times g \times S}{2 \times \cos 15^\circ}$	950 N
Foot support downward ^a	$F = m_d \times g$	1 230 N
Tipping lever downward ^a	$F = \frac{20}{15} (m_d + m_w)g$	1 000 N
Handgrip pull off ^b	Limited by maximum force that can be applied by one hand	750 N
Arm support upward ^a	$F = \frac{S(m_d + m_w)g}{2 \times \cos 10^\circ}$	1 000 N
Foot support upward: Two single foot supports ^a	$F = \frac{S(m_d + m_w)g}{4}$	500 N
Foot support upward: One-piece foot support ^a	$F = \frac{S(m_d + m_w)g}{2}$	1 000 N
Push handle upward: Two single handles ^a	$F = \frac{S(m_d + m_w)g}{3}$	1 000 N
Push handle upward: One cross bar handle ^a	$F = \frac{2 \times S(m_d + m_w)g}{3}$	2 000 N
Key		
m_d dummy mass in kg		
m_w wheelchair mass in kg		
S safety factor equal to 1,5		
^a Result of the calculation or the maximum force, whichever is lower.		
^b Maximum force to be applied.		

15 Figures

Dimensions in millimetres

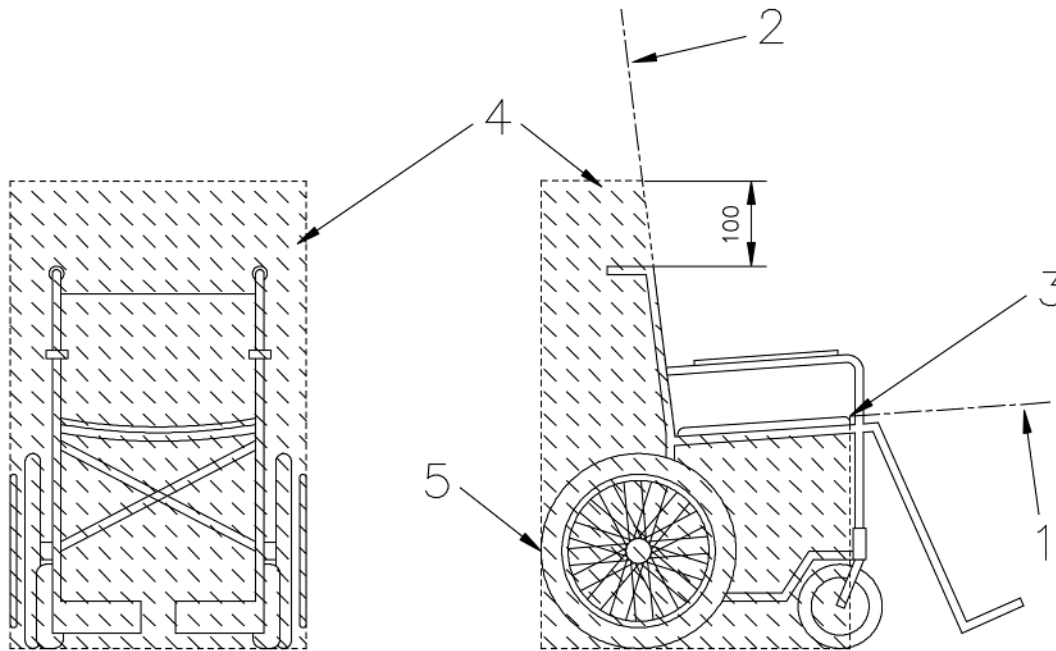


Key

- 1 seat reference plane
- 2 back support reference plane
- 3 seat reference point
- 4 occupant reach space
- 5 vertical line from the centre of the front edge of the seat
- 6 region below the rear of the seat that is excluded from the reach space
- 7 lateral extent of excluded region delimited by vertical lines from the sides of the seat

Figure 1 — Occupant reach space

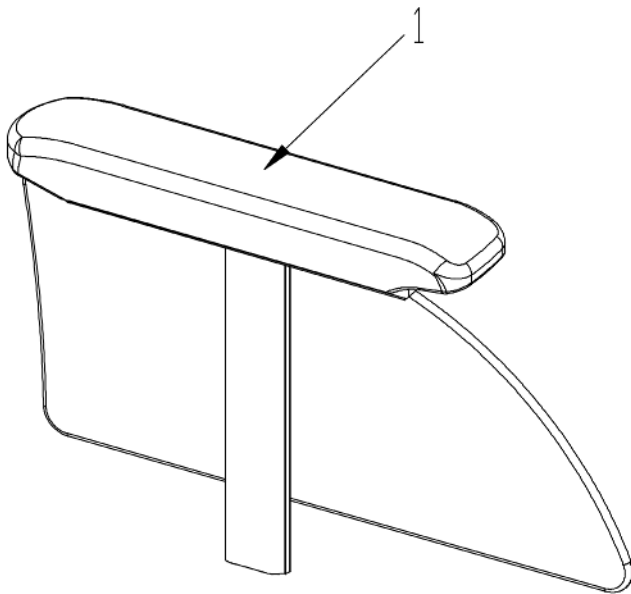
Dimensions in millimetres



Key

- 1 seat reference plane
- 2 back support reference plane
- 3 front edge of seat
- 4 assistant reach space for controls
- 5 most rearward point on wheelchair

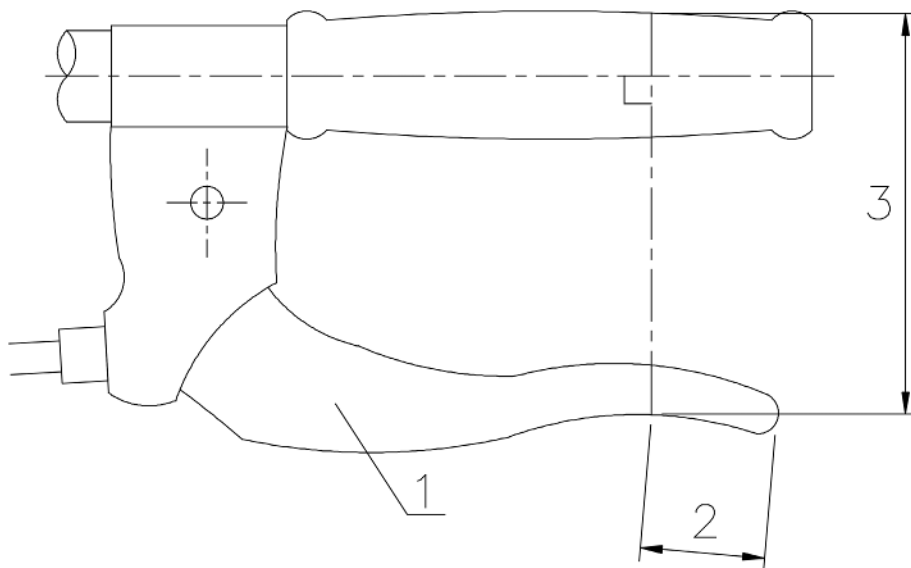
Figure 2 — Assistant reach space for controls



Key

- 1 application of source to the centre of the surface intended to support the occupant

Figure 3 — Application of ignition source to a postural support

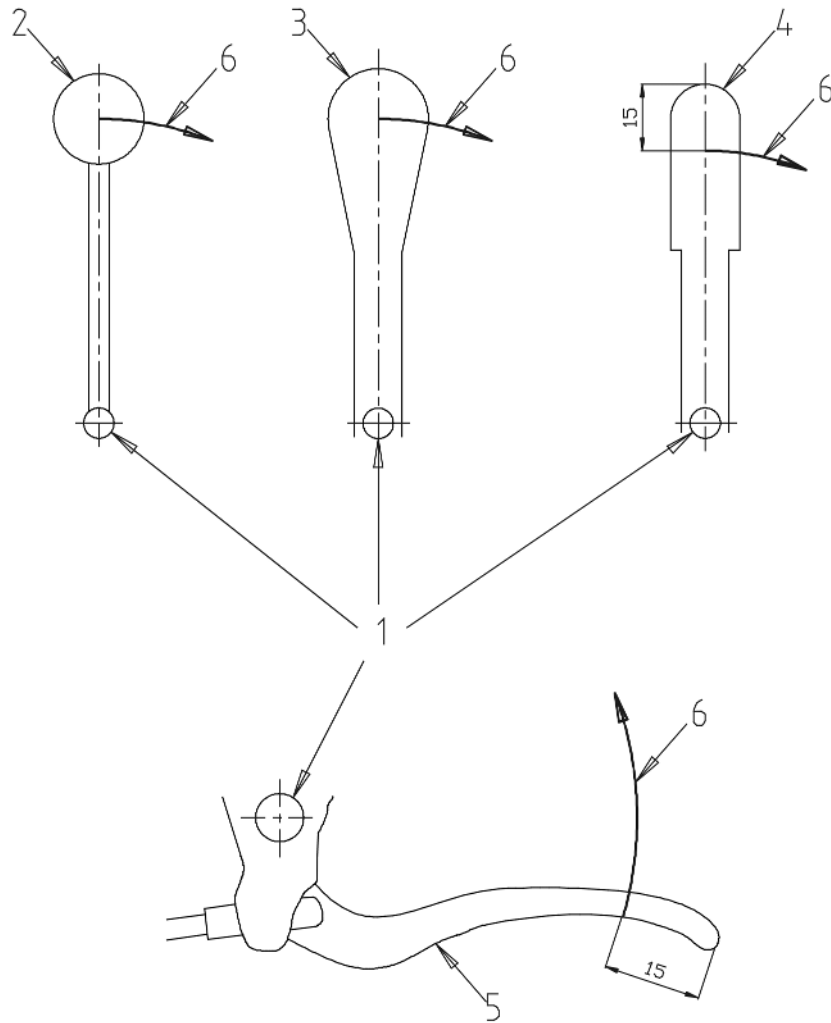


Key

- 1 lever gripped by the fingers of one hand
- 2 15 mm
- 3 handgrip width

Figure 4 — Handgrip width

Dimensions in millimetres



Key

- 1 fulcrum
- 2 generally spherical knob
- 3 tapered lever
- 4 parallel lever
- 5 bicycle-style lever
- 6 path of the point of application of the operating force

Figure 5 — Application of forces to levers

Dimensions in millimetres

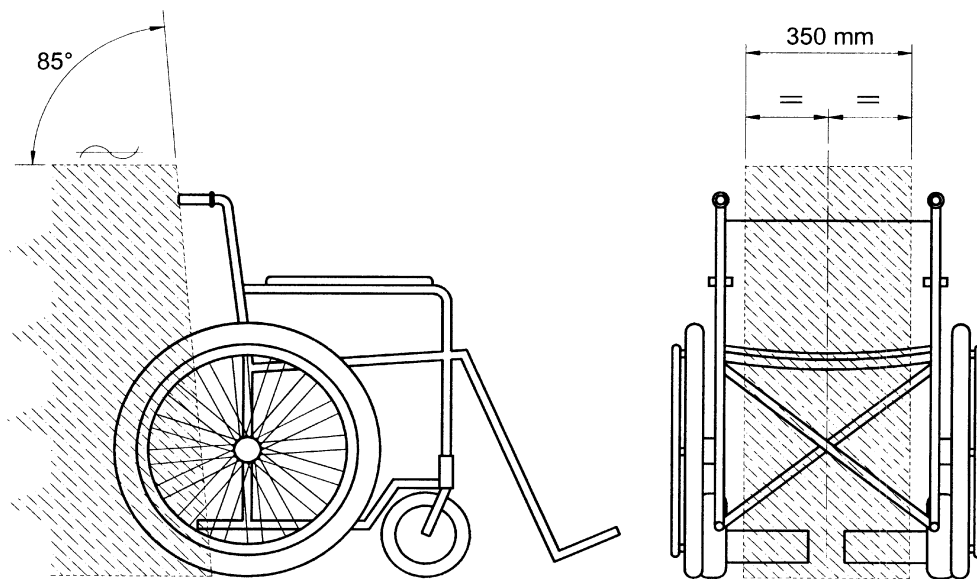


Figure 6 — Space for assistant movement



Figure 7 — Symbol for wheelchair not intended to be used as a seat in a motor vehicle

Annex A (informative)

Recommendations for dimensions and manoeuvring space of manual wheelchairs

A.1 Specific dimensions

A.1.1 Dimensions when ready for use and when folded and/or dismantled

The overall width, overall height and full overall length, when measured in accordance with ISO 7176-5:2008, should not be greater than the values specified in Table A.1.

If the wheelchair can be folded and/or dismantled for transport or stowage, the stowage width, stowage height and stowage length, when measured in accordance with ISO 7176-5:2008, should not be greater than the values specified in Table A.1.

A.1.2 Push handle height

The height of push handles, if fitted, should be between 900 mm and 1 200 mm when the wheelchair is set up as specified in ISO 7176-22:2000.

A.1.3 Ground clearance

The ground clearance, when measured in accordance with ISO 7176-5:2008, should not be less than the value specified in Table A.1. This recommendation does not apply to wheelchairs designed for special purposes that are incompatible with the recommendation, e.g. stand-up wheelchairs and wheelchairs with a seat that lowers to ground level.

A.2 Manoeuvring space

A.2.1 Turning diameter

The turning diameter, when measured in accordance with ISO 7176-5:2008, should not be greater than the value specified in Table A.1.

A.2.2 Pivot width

The pivot width, when measured in accordance with ISO 7176-5:2008, should not be greater than the value specified in Table A.1.

Table A.1 — Dimensions and manoeuvring space of manual wheelchairs

Dimensions	when ready for use mm	when folded and/or dismantled mm
Overall length – maximum	1 200 (full overall length)	900 (stowage length)
Overall width – maximum	700	350 (folded) (stowage width)
Overall height – maximum	1 200	1 200 (stowage height)
Turning diameter – maximum	1 000	No recommendation
Pivot width – maximum	1 300	No recommendation
Ground clearance – minimum	30	No recommendation

Annex B (informative)

Recommended design features

B.1 Introduction

Since wheelchairs serve many different users who have many different requirements and demands, it is not possible to make the recommendations contained in this annex mandatory for every wheelchair. Manufacturers should follow the recommendations as far as possible and when applicable, depending on the intended use of the wheelchair.

B.2 General recommendations

B.2.1 Fittings and tools

All screws, fasteners and similar fittings should be of metric size as specified in ISO 68-1:1998. The number of tools required for their operation should be a minimum.

B.2.2 Tyres

The wheelchairs should be fitted with tyres that do not mark indoor floors.

B.2.3 Means to inflate tyres

An appropriate means to inflate the tyres should be supplied with the wheelchair if it is fitted with pneumatic tyres.

B.2.4 Surface temperature

The thermal properties of materials that come into direct contact with the occupant, e.g. handrims or upholstered parts, should be considered when selecting these materials to avoid excessive surface temperatures when they are exposed to external sources of heat (e.g. sunlight).

B.2.5 Occupant transfer into or out of the wheelchair

When the manufacturer specifies that a sideways transfer can be made:

- arm supports should be movable or removable;
- lower leg support assemblies should be removable, and when they are removed, swung to the side or retracted, their mountings should not protrude more than 50 mm in front of the occupied seat nor protrude more than 20 mm above it, and no sharp edges or protrusions should be present.

When the manufacturer specifies that the occupant can make a sideways step to a standing position in front of the wheelchair, lower leg support assemblies should be removable.

When lower leg support assemblies are not removable, foot supports should be movable or removable so that the occupant has room to rise from a seated position in the wheelchair to a standing position. The underside of a movable foot support should not present any sharp edges or protrusions that can contact the occupant's lower legs or feet when the foot supports are raised.

B.2.6 Resistance to contamination from urine incontinence

Contamination resistance and methods for cleaning and decontamination should be considered when selecting materials that can come in contact with urine (e.g. upholstered parts) in order to avoid the occurrence of unhygienic conditions, odours and degradation of materials.

B.2.7 Head support

If the use of the wheelchair requires the seat or the back support to be reclined to an angle of more than 25° to the vertical, the wheelchair should have a head support or provision to attach a head support.

The manufacturer of a wheelchair that has such provision should offer a head support as an option.

The “head support height above seat” dimension (see ISO 7176-7:1998, dimension 10) of the wheelchair should cover the range 680 mm to 844 mm in order to be appropriate for the body size of various occupants.

If a wheelchair is available with a head support, and the seat or the back support can be reclined to an angle of more than 25° to the vertical, the operator’s manual should contain an instruction to use the head support when the seat or back support is reclined.

B.2.8 Tipping device

At least one tipping device should be present to enable an assistant to tip the wheelchair.

The height of each tipping device, from the top of the device to the floor, should be less than 175 mm.

The distance between the centre of each tipping device and the inside of the nearest tyre should be greater than 50 mm.

The width of the surface used to operate each tipping device should be greater than 20 mm.

B.2.9 Anti-tip devices

If the wheelchair is fitted with anti-tip devices, they should not move from their pre-set positions or lose their function when preventing a loaded wheelchair from tipping.

Anti-tip devices should be positioned so they will not cause the wheelchair to exceed the full overall length limit specified in Table A.1, and they should not interfere with mounting or dismounting kerbs when in non-working position.

Anti-tip devices should be labelled with a warning that the occupant should be informed when an anti-tip device is fitted or removed.

B.2.10 Accidental release of parking brakes

Means for releasing parking brakes should be protected against release caused by accidental contact.

B.2.11 Continuous operating forces

Appropriate measures should be adopted wherever practicable to minimize the forces applied for extended periods of time by operators in normal use of the wheelchair.

Annex C (informative)

EN 12183 and rail interoperability

C.1 Background

Directive 2008/57/EC concerns the interoperability of the European rail network. It provides for mandatory Technical Specifications for Interoperability (TSIs) to cover particular subsystems of the rail network. One such TSI deals with rail infrastructure and passenger rolling stock subsystems in relation to 'persons with reduced mobility' (PRM). This document, usually referred to as the PRM-TSI, was adopted by the European Commission on 21 December 2007 (2008/164/EC).

The PRM-TSI defines 'persons with reduced mobility' as including wheelchair users. It goes on to specify several aspects of rail infrastructure and rolling stock in relation to a notional wheelchair that meets limits for characteristics, including dimensions and mass, specified in Annex M of that document. These limits appear to be based on the results of the European COST 335 study, with some modifications. The COST 335 study in turn made use of ISO 7193:1985, which only specifies maximum overall dimensions for wheelchairs primarily intended for indoor use.

The PRM-TSI specifies the following aspects in relation to the limits in Annex M:

- boarding aids at stations;
- level track crossings;
- universal toilet compartments;
- dimensions of clearways;
- wheelchair-accessible sleeping accommodation.

The PRM-TSI specifies other aspects in relation to wheelchairs, but without reference to the limits in Annex M.

The PRM-TSI does not make any statement concerning access to rail travel for passengers whose wheelchairs have characteristics exceeding the limits specified in Annex M.

C.2 Related provisions in this document

Wheelchairs are used in many situations, only some of which will involve travel by rail. Their characteristics are usually determined by the clinical needs and preferences of the occupant. Some wheelchairs will, of necessity, exceed the limits specified in the PRM-TSI. On the other hand, many wheelchair users will want to travel by rail at some point. It would be useful for them to know whether their wheelchair could present difficulties when they are travelling. Therefore, to assist prescribers, purchasers and users of wheelchairs, this document specifies a requirement for disclosure if the wheelchair characteristics exceed the engineering limits specified in the PRM-TSI.

Annex D (informative)

Recommendations for castor stem angle

D.1 Recommendations

The castor rake should be $(0 \text{ }_0^{+2})^\circ$ and the difference between the rake of the left and right castors should not exceed 1° .

The castor cant should be $(0 \pm 1)^\circ$ and the asymmetry between left and right castor cant should not exceed 1° .

If the positions of the rear wheels and/or the positions of the castor assemblies are adjustable, and the castor rake is affected by the movement of these adjustable parts, the castor rake should be adjustable to $(0 \text{ }_0^{+2})^\circ$ for all positions of the manoeuvring wheels and/or the castor assemblies.

D.2 Test method

Position the loaded wheelchair on the horizontal test plane.

Measure all castor rakes and castor cants to an accuracy of $0,1^\circ$ in accordance with ISO 7176-5:2008.

If the positions of the rear wheels and/or the positions of the castor assemblies are adjustable, and the castor rake is affected by the movement of these adjustable parts, verify that the castor rake can be adjusted to $(0 \text{ }_0^{+2})^\circ$ for all positions of the rear wheels and/or the castor assemblies.

Record whether the wheelchair has met the recommendations.

Annex E (informative)

Technical changes from previous editions of EN 12183

E.1 Technical changes between the first (1999) and second (2006) editions

In preparing the second edition, the content of the first edition was revised to incorporate numerous technical and editorial changes. All potential changes suggested by member bodies and working group members were considered by the working group. Where consensus could be achieved the changes were incorporated into the second edition. Where consensus could not be achieved, or the technical changes suggested were not of sufficient maturity to include in the second edition, the subject area was recommended to be put forward for a future revision. Some of these points were included in informative Annexes A, B, C and D (which correspond to Annexes B, C, D and E respectively in the third edition).

One major change from the first edition was the separation of design and performance requirements into two clauses. In some areas changes to the technical requirements of the previous edition were not incorporated, however others did incorporate updated technical content either in the design or the performance requirements or in both. This led to considerable changes in the format from the previous edition.

The list below includes the significant technical changes between the first and second editions, but it does not include all changes. Clause number references apply to the second edition.

- The scope of the second edition did not limit the applicability of the standard to wheelchairs with a maximum occupant mass of 100 kg, and the second edition specified a method of augmenting the 100 kg ISO test dummy to test wheelchairs with larger maximum occupant mass.
- The normative references included appropriate new or revised standards that had been issued by CEN, ISO and IEC since the first edition was published. The normative references were dated to ensure that any subsequent revisions of the normative reference standards could be considered for their potential effect on the content of this European Standard. Future issues of revised normative references might not apply in total without further revision being made to this European Standard.
- The test apparatus was revised and updated to incorporate brake lever test equipment.
- Design requirements in the second edition were extracted from the performance requirements clause in the first edition. Design and performance requirements were clearly separated between Clauses 6 and 7 in the second edition.
- Design requirements in the second edition incorporated new or updated specific requirements for: wheelchairs for use in motor vehicles (6.4), braking systems (6.5), component mass (6.6), operations intended to be carried out by the occupant and/or assistant (6.7) and control operation (6.8).
- Performance requirements in the second edition incorporated new or updated specific requirements for: foot, leg, and arm supports (7.2), static, impact and fatigue strength (7.3), braking systems (7.4), operating force (7.6), push handles and handgrips (7.7), surface temperature (7.9), resistance to ignition (7.10), seating adjustment (7.11), castor stem (7.12) and pushing force (7.14).
- The requirement for information to be supplied by the manufacturer (Clause 8) was considerably updated in the second edition following input from users, member countries and working group members.
- A new requirement for a test report was added in Clause 9 of the second edition.

- Revised and updated tables were placed into Clause 10 of the second edition.
- Revised and new figures referenced within the second edition were placed into Clause 11.
- The content of Annex ZA of the second edition was compiled taking into account the new and updated content.

E.2 Technical changes between the second (2006) and third (2009) editions

Following publication of the second edition, errors were discovered in the equations for augmenting the 100 kg ISO test dummy. These errors could have affected the evaluation of the stability of wheelchairs intended for occupants of mass greater than 100 kg, and hence have been potentially hazardous. This matter was raised officially, and in early 2007 CEN/BT circulated a resolution for the withdrawal of the second edition, together with EN 12184:2006, the related standard for powered wheelchairs, that contained the same errors.

After considering alternatives, the committee decided that the most suitable corrective action was to limit the scope of the standard to a maximum occupant mass of 100 kg, and to provide information on the construction of 125 kg and 150 kg test dummies to assist those wishing to evaluate the performance of wheelchairs with a larger occupant mass.

Revised editions of some normative reference documents had been published since the second edition was prepared. These were included in an appropriate manner. Generally their inclusion did not result in any technical changes unless noted below.

In the same intervening period, Council Directive 93/42/EEC was amended by Directive 2007/47/EC. Changes to the Essential Requirements were addressed, as were the implications of the link to Directive 2006/42/EC on machinery.

The list below includes the significant technical changes between the second and third editions, but it does not include all changes.

- The scope was limited to a maximum occupant mass of 100 kg. References to maximum occupant mass that exceeded that limit were removed from the normative content throughout the document.
- All normative references were dated and referred to the latest editions at the time of publication, apart from the references to EN 12182 and EN 12184, which were undated, and the reference to ISO 7176-19:2001.
- Some additional references were made to provisions in EN 12182 as required by the amendments to the Directive concerning medical devices.
- Ambiguous requirements for uncontrolled movement of seating were removed, since that topic was already covered by requirements in EN 12182 relating to adjustable parts.
- The reference to ISO 7176-8 was corrected.
- Annex ZA was updated to reflect the new content and changes to the Essential Requirements.

In addition, many minor editorial changes were made. In particular, definitions which appeared in ISO 7176-26:2007 were removed, and the third edition used its applicable terms.

E.3 Technical changes from the third (2009) edition

The list below includes the significant technical changes between the third and fourth editions, but it does not include all changes. Clause number references apply to the fourth edition.

- The upper limit for maximum occupant mass covered by the scope has been extended to 250 kg.
- The standard deals more clearly with wheelchairs, which come partially into its scope.
- The list of normative references has been brought up to date, most notably including the latest editions of ISO 7176-11 and ISO 7176-19.
- Wheelchairs are tested at the specified maximum user mass.
- The document has been extensively restructured to group related requirements and test methods together.
- The tilting fatigue strength requirement and test method have been added.
- Some sections of text in ISO 7176-19:2008 have been replaced, and the reference to ISO 10542-5 has been removed.
- The requirement for handgrip width has been relaxed.
- Static loading force limits for occupant mass above 100 kg have been provided in Table 2.
- The term 'maximum safe slope' is no longer used, since only parking brake performance is relevant.
- The criteria for footrest gaps has been improved.
- Either ISO 8191-2 or EN 1021-2 may be used for assessment of ignitability. ISO 8191-1 and EN 1021-1 are no longer used.
- A separate test rig can be used for the parking brake fatigue test.
- Pushing force limits for user mass above 100 kg have been added.
- The occupant reach space is extended beneath the front part of the seat.
- Requirements for brakes have been clarified.
- Recommended dummy designs have been removed.
- Guidance has been added concerning the PRM-TSI (see Annex C).
- Castor stem angle requirements have been changed to recommendations.
- Annexes concerning recommended seating design and manoeuvring forces have been removed.
- Annex ZA has been updated.
- CEN/TC 293 agreed a three-year transition period between the third and fourth editions.

Annex ZA (informative)

Relationship between this European Standard and the Essential Requirements of Council Directive 93/42/EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC concerning medical devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC

Clause(s)/ subclause(s) of this European Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
Clause 5, 8.5, Clause 11	7.1, first and second indents	Toxicity and biocompatibility are covered by reference to EN 12182. Flammability of upholstered parts, foam materials which support the occupant, sling seats, sling backs, belts, restraint harnesses and clothing guards are covered by 8.5. For wheelchairs with electrically powered ancillary equipment, flammability of polymeric components close to battery terminals, electrical enclosures, lamp housings and exposed housings for electrical connectors carrying battery charging current, motor current or lamp current are covered by reference to EN 12184. Flammability of other parts is not covered.
Clause 5	7.2	Contaminants and residues are covered by reference to EN 12182. Packaging is not covered.
Clause 5, Clause 11	7.5, first paragraph	Leakage of substances is covered by reference to EN 12182, and for wheelchairs with electrically powered ancillary equipment, by reference to EN 12184.
Clause 5, Clause 11	7.6	Ingress of liquids is covered by reference to EN 12182, and for wheelchairs with electrically powered ancillary equipment, by reference to EN 12184. Ingress of other substances is not covered.
Clause 5, 8.2, 9.1, 9.3, 10.4, 10.5.	9.2, first indent	Risks regarding the following physical features are covered by reference to EN 12182: <ul style="list-style-type: none"> • traps for parts of the human body; • surfaces, corners and edges.

Clause(s)/ subclause(s) of this European Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
		<p>Risks regarding the following ergonomic features are covered:</p> <ul style="list-style-type: none"> • means for handling heavy components, by 8.2; • forces applied to means for operating brakes, by 9.1; • pushing force, by 9.3; • handgrip dimensions, by 10.4; • operating forces for controls, by 10.5.
Clause 11	9.3	<p>For wheelchairs with electrically powered ancillary equipment, risk of fire due to the power and control system is covered by reference to EN 12184.</p> <p>The risk of explosion in single fault condition is not covered.</p>
Clause 11	12.1	<p>For wheelchairs with electrically powered ancillary equipment, risks due to single fault conditions in the control system are covered by reference to EN 12184.</p> <p>Other aspects of this essential requirement are not covered.</p>
Clause 11	12.1a	<p>For wheelchairs with electrically powered ancillary equipment, embedded or integral software introduced after the date of withdrawal of EN 12184:2009 is covered by reference to EN 12184.</p>
Clause 11	12.5	<p>For wheelchairs with electrically powered ancillary equipment, this is covered by reference to EN 12184.</p>
Clause 11	12.6	<p>For wheelchairs with electrically powered ancillary equipment, electrical risks from carry-on and on-board battery chargers, and isolation of the frame of the wheelchair from the battery in normal use are covered by reference to EN 12184.</p> <p>Other electrical risks are not covered.</p>
Clause 5, 7.1, Clause 11	12.7.1	<p>Risks due to moving parts, traps and adjusting mechanisms are covered by reference to EN 12182 and, for wheelchairs with electrically powered ancillary equipment, by reference to EN 12184.</p> <p>Static stability is covered by 7.1.</p>
Clause 11	12.7.3	<p>For wheelchairs with electrically powered ancillary equipment, noise is covered by reference to EN 12184.</p>
Clause 11	12.7.4	<p>For wheelchairs with electrically powered ancillary equipment, the following are covered by reference to EN 12184:</p> <ul style="list-style-type: none"> • the output connectors of battery chargers; • electrical connectors to supply mains for built-in battery chargers. <p>Gas, hydraulic and pneumatic connectors and terminals are not covered. Other electrical connections to supply mains</p>

Clause(s)/ subclause(s) of this European Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
		are not covered.
7.5, Clause 11	12.7.5	Temperatures of surfaces that can come into contact with the occupant or assistant during normal use and that are within the occupant reach space and assistant reach space shown in Figure 1 and Figure 2 respectively are covered by 7.5. For wheelchairs with electrically powered ancillary equipment, surface temperatures of parts within the occupant reach space shown in Figure 1 are covered by reference to EN 12184. Surface temperatures of other accessible parts are not covered.
Clause 11	12.9	For wheelchairs with electrically powered ancillary equipment, markings, visual indicators and displays are covered by reference to EN 12184.
Clause 12	13.1	
12.1, 12.3	13.3 a)	Labelling bearing the manufacturer's name and address are covered by reference to ISO 7176-15. Information concerning the authorized representative is covered by 12.3.
12.1	13.3 b)	Covered by reference to ISO 7176-15.
12.1	13.3 d)	Covered by reference to ISO 7176-15.
Clause 12	13.4	Requirements for the label are not covered.
Clause 12	13.6 a)	Details in 13.3 a), b), i), j) and k) are covered. Other details are not covered.
Clause 12	13.6 c)	Covered by reference to EN 12182.
Clause 12	13.6 d)	Covered by reference to EN 12182 and ISO 7176-15.
Clause 12	13.6 h), first paragraph	Covered by reference to EN 12182 and ISO 7176-15.
Clause 12	13.6 i)	Covered by reference to EN 12182 and ISO 7176-15.

For devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC on Machinery, in accordance with Article 3 of Directive 93/42/EEC the following Table ZA.2 details the relevant essential health and safety requirements (EHSRs) of Directive 2006/42/EC on Machinery to the extent to which they are more specific than those of Directive 93/42/EEC along with the corresponding clauses of this European Standard. Table ZA.2, however, does not imply any citation in the OJEU under the machinery directive and thus do not provide presumption of conformity for the machinery directive.

Determination of whether a certain EHSR is "relevant" and thus applies to a particular device, pertains to the responsible parties (e.g. manufacturer, notified bodies, competent authorities) in accordance with the applicable procedures.

Table ZA.2 — Relevant Essential Health and Safety Requirements from Directive 2006/42/EC on machinery that are addressed by this European Standard (according to article 3 of amended Directive 93/42/EEC)

Clause(s)/ subclause(s) of this European Standard	Essential Health and Safety Requirements (EHSRs) of Directive 2006/42/EC	Qualifying remarks/Notes
Clause 11	1.1.4	For wheelchairs with electrically powered ancillary equipment, this is covered by reference to EN 12184.
7.2	1.1.8	Resistance to operating stresses of seat mountings is covered by reference to ISO 7176-8.
	1.2.2	This relevant EHSR is not covered by this standard.
	1.2.3	This relevant EHSR is not covered by this standard.
	1.2.4.1	This relevant EHSR is not covered by this standard.
Clause 11	1.2.4.3	For wheelchairs with electrically powered ancillary equipment, this is covered by reference to EN 12184.
Clause 11	1.5.4	For wheelchairs with electrically powered ancillary equipment, risk of erroneous electrical connections are covered by reference to EN 12184.
	1.6.1	This relevant EHSR is not covered by this standard.
Clause 11	1.6.2	For wheelchairs with electrically powered ancillary equipment, access for operation and adjustment and access to batteries for maintenance are covered by reference to EN 12184. Safety of access is not covered.
Clause 11	1.6.3	For wheelchairs with electrically powered ancillary equipment, isolation of the battery set is covered by reference to EN 12184.
	3.6.2	This relevant EHSR is not covered by this standard.

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

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