מכון התקנים הישראלי
The Standards Institution of Israel

תקן ישראלי - ת"י 1279 חלק 1

אב התשס"ב - אוגוסט 2002

כיסאות גלגלים : כיסאות מונעים ידנית

Wheelchairs: Hand propelled chairs

תקן זה בא במקום התקן הישראלי
ת"י 1279 חלק 1 ממרס 1999

תקן זה למעט השינויים והתוספות המצוינים בו,
זהה לתקן האירופי EN 12183-99

מילות מפתח: כיסאות גלגלים, ציוד להעברת מטופלים, התקנים מופעלים ידנית, עזרים לנכים, ציוד רפואי.
Descriptors: wheelchairs, patient transport equipment, manually operated devices, aids for disabled, medical equipment.

תקן זה הוכן על ידי ועדת מומחים בהרכב זה:
שלמה גרוס, שולה הן, יצחק מרקמן, ישראל סביש, צביקה סמולנסקי (יו"ר), נדב שפר

תקן זה אושר על ידי הוועדה הטכנית 1414 - אמצעי שינוע לנכים וחולים, בהרכב זה:

איגוד לשכות המסחר בישראל	-	זאב תורן
בתי חולים ממשלתיים	-	שולמית הן
הטכניון - הפקולטה להנדסה ביו-רפואית	-	צביקה סמולינסקי (סגן יו"ר)
המועצה הישראלית לצרכנות	-	פסח נדיר
התאחדות התעשיינים בישראל	-	יוסף איצקוביץ
חברת העובדים	-	אריה בקר
מגן דוד אדום	-	עדי ברקת
מכון התקנים הישראלי - אגף תעשייה	-	ישראל סביץ
משרד הביטחון	-	עזרא חובב
משרד הבריאות	-	נדב שפר
צבא ההגנה לישראל - חיל רפואה	-	גיא לסקובסקי

אתי גולן ריכזה את עבודת הכנת התקן

הקדמה לתקן ישראלי

תקן ישראלי זה הוא התקן האירופי EN 12183 משנת 1999, שאושר בשפתו האנגלית כתקן ישראלי בשינויים ובתוספות.

בשפה העברית מובאים:
- סעיף חלות התקן בשינויים ובתוספות
- פירוט השינויים והתוספות לסעיפי התקן האירופי

התקן האירופי מובא כלשונו בשפה האנגלית.

לנוחות הקורא מובא בשפה העברית נספח א - תרגום התקן לעברית.

תקן זה הוא חלק מסדרת תקנים הדנים בכיסאות גלגלים.
חלקי הסדרה הם:
ת"י 1279 חלק 1 - כיסאות גלגלים: כיסאות מונעים ידנית
ת"י 1279 חלק 2 - כיסאות גלגלים: כיסאות גלגלים מונעים חשמלית, קלנועיות והמַטענים שלהן

1. חלות התקן (סעיף 1 של התקן האירופי בשינויים ותוספות)

תקן זה מפרט דרישות ושיטות בדיקה לכיסאות גלגלים מונעים ידנית, המיועדים לשימוש על-ידי אדם אחד שמסתו אינה גדולה מ-114 ק"ג (250 פאונד).

כיסאות הגלגלים שתקן זה חל עליהם כוללים את מיני הכיסאות המפורטים בתקן EN ISO 9999:1998, כמפורט להלן:

122103 - Manual attendant-controlled wheelchairs

122106 - Bimanual rear-wheel-driven wheelchairs

122109 - Bimanual front-wheel-driven wheelchairs

122112 - Bimanual lever-driven wheelchairs

122115 - Single side driven non-powered wheelchairs

Wheelchairs driven by one arm or one arm and one leg

122118 - Foot-driven wheelchairs

תקן זה מפרט גם דרישות ושיטות בדיקה לכיסאות גלגלים מונעים ידנית בעלי ציוד עזר חשמלי.

תקן זה אינו חל על:
- כיסאות המיועדים למטרות מיוחדות כגון ספורט, מקלחות ושירותים;
- כיסאות המתוכננים תכנון מיוחד או המותאמים לצרכי אנשים בעלי מגבלות מסוימות;
- כיסאות עמידה;
- כיסאות גלגלים מונעים ידנית בעלי תוספת של ערכת הנעה.

הערה:

יישומו של תקן זה מוגבל לכיסאות גלגלים למשתמש שמסתו עד 114 ק"ג (250 פאונד), מכיוון שלבדיקת תוצאי השימוש על ידי משתמשים שמסתם גדולה יותר, נדרשת עבודת מחקר נוספת.

פירוט השינויים והתוספות לסעיפי התקן האירופי

2. Normative references

- ראו סעיף Normative references בתקן האירופי.

- במקום חלק מן התקנים האירופיים המפורטים בסעיף Normative references באים תקנים ישראליים, כלהלן:

התקן המוזכר בתקן האירופי	התקן הישראלי שבא במקומו
EN 12184 -1999	ת"י 1279 חלק 2 - כיסאות גלגלים: כיסאות גלגלים מונעים חשמלית, קלנועיות והמטענים שלהם
ISO 7176-1	ת"י 1799 חלק 1 - כיסאות גלגלים: קביעת יציבות סטטית
ISO 7176-3	ת"י 1799 חלק 3 - כיסאות גלגלים: קביעת יעילות המעצורים
ISO 7176-8 - 1998	ת"י 1799 חלק 8 - כיסאות גלגלים: דרישות ושיטות בדיקה לחוזק סטטי, לעמידות בחולם ולהתעיפות
ISO 7176-11	ת"י 1799 חלק 11 - כיסאות גלגלים: בובות הדגמה לבדיקה
ISO 7176-13	ת"י 1799 חלק 13 - כיסאות גלגלים: קביעת מקדם החיכוך של משטחי בדיקה
ISO 7176-15	ת"י 1799 חלק 15 - כיסאות גלגלים: דרישות לדפי מידע, לתיעוד ולסימון
ISO 7176-16	ת"י 1799 חלק 16 - כיסאות גלגלים: עמידות החלקים המרופדים בהצתה - דרישות ושיטות בדיקה

- לסעיף יוסף תקן ישראלי, כמפורט להלן:

ת"י 891 - עגלות ילדים

6. Design requirements

6.1.2 Test method for footrests

Table 1 - Force to be applied to footplates

הטבלה חלה בשינוי זה:

בשורה האחרונה הערך 100 ק"ג אינו חל, ובמקומו יחול הערך: 114 ק"ג.

7. Performance requirements

הכתוב בסעיף חל בתוספת שלהלן, בתחילתו:

בבדיקות המפורטות להלן, שבהן נדרשת בובת הדגמה, בודקים כיסאות גלגלים המיועדים למשתמשים שמשקלם עד 114 ק"ג עם בובת הדגמה שמסתה 100 ק"ג.

7.1. Requirements for wheelchair static, impact and fatigue strength

הסעיף חל בתוספת זו:

למעט סעיף 10.5 - Drop test.

- לאחר סעיף 7.7 יוסף סעיף 7.8, כמפורט להלן:

7.8. עמידות במכשול

מכינים בובת הדגמה כמפורט בתקן הישראלי ת"י 1799 חלק 11, בשינויים אלה:

בובות שמסתן 100 ק"ג, 75 ק"ג ו- 50 ק"ג, מחליפים את החלק התחתון של הרגל בשני חלקים שצורתם מאפשרת מגע עם המדרכים, לדוגמה: בלוקי ברזל שמידותיהם 75 מ"מ × 150 מ"מ × 40 מ"מ, שמסת כל אחד מהם (3.5±0.5) ק"ג ומרכז הכובד שלהם נמצא בגובה של (20±2) מ"מ מעל משטח המדרך.

בכיסא המיועד למשתמש שמסתו עד 114 ק"ג , משתמשים בבובת הדגמה שמסתה 100 ק"ג.

אם לכיסא יש צמיגים פנימטיים, הם יהיו מנופחים בלחץ המרבי המומלץ.

בודקים את הכיסא במיתקן כמתואר בתקן הישראלי ת"י 891 בסעיף הדן בבדיקת כושר הפעולה, בשינוי זה:

מסובבים את הכיסא 500 סיבובים.

<u>בתום הבדיקה לא יופיעו בכיסא סדקים, שברים, קרעים או עיוויים נראים לעין, והכיסא יתפקד כיאות בנסיעה ובקיפול.</u>

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 12183

March 1999

ICS 11.180

Descriptors: disabled persons, wheelchairs, manual control, specifications, design, stability, perfomance evaluation, brakes, effectiveness, fatigue life, tests, safety, information, utilization

English version

Manually propelled wheelchairs — Requirements and test methods

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

Rollstühle mit Muskelkraftantrieb — Anforderungen und Prüfverfahren

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

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

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

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart 36, B-1050 Brussels

Foreword

This European Standard has been prepared by Technical Committee CEN/TC 293, Technical aids for disabled persons, the Secretariat of which is held by SIS.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 1999, and conflicting national standards shall be withdrawn at the latest by September 1999.

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

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

This standard provides one means to demonstrate that manually propelled wheelchairs, which are also medical devices, conform to the essential requirements outlined in general terms in annex I of the EU Directive 93/42/EEC. It is not intended to provide a means to show conformity with the requirements of any other Directive.

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

Level 1: General requirements for technical aids

Level 2: Particular requirements for families of technical aids

Level 3: Specific requirements for types of technical aids.

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

This is a combined level 2- and 3-standard (lowest possible) for manually propelled wheelchairs, which are also medical devices, as specified in the Scope.

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

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Introduction

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

1 Scope

This European Standard specifies requirements and test methods for manually propelled wheelchairs intended for use by one person whose mass does not exceed 100 kg including the following classifications from EN ISO 9999:1998:

12 21 03	Manual attendant-controlled wheelchairs
12 21 06	Bimanual rear-wheel-driven wheelchairs
12 21 09	Bimanual front-wheel-driven wheelchairs
12 21 12	Bimanual lever-driven wheelchairs
12 21 15	Single side driven non-powered wheelchairs
12 21 15	Wheelchairs driven by one arm or one arm and one leg
12 21 18	Foot-driven wheelchairs

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, toiletting;

— custom-made wheelchairs;

— wheelchairs specially designed or with adaptations for specific disabled persons;

— stand-up wheelchairs;

— add-on power kits for manual wheelchairs.

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

2 Normative references

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

EN 1041, *Information supplied by the manufacturer with medical devices.*

EN ISO 9999:1998, *Technical aids for disabled persons — Classification* (ISO 9999:1998).

prEN 12182:1999, *Technical aids for disabled persons — General requirements and test methods.*

EN 12184:1999, *Electrically powered wheelchairs, scooters and their chargers — Requirements and test methods.*

ISO 6440, *Wheelchairs — Nomenclature terms and definitions.*

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

ISO 7176-3, *Wheelchairs — Part 3: Determination of efficiency of brakes.*

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

ISO 7176-11, *Wheelchairs —Part 11: Test dummies.*

ISO 7176-13, *Wheelchairs — Part 13: Determination of coefficient of friction of test surfaces.*

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

ISO 7176-16, *Wheelchairs — Part 16: Resistance to ignition of upholstered parts — Requirements and test methods.*

3 Definitions

For the purposes of this standard the definitions in ISO 6440 and prEN 12182:1999 apply together with the following.

3.1

anti-tip device

a device to prevent the wheelchair tipping over completely when reaching its limit of stability

3.2

seat belt

strap to help maintain the occupant's position in the wheelchair during normal operation

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

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

3.3

user manual

post sale information normally provided with the wheelchair to inform the user about the assembly, operation, maintenance, repair and warranty aspects of wheelchair ownership

3.4

wheelchair(s)

abbreviation to represent the manually propelled wheelchair covered by the scope of this standard, to which the requirements and test methods are applied

4 Test equipment

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

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

4.2 *Weights, dynamometer*, or similar means, to apply forces of between 1 N and 100 N with an accuracy of ±2 %.

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

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

4.5 *Test ramp*, a hard, smooth ramp at least 1,2 m broad, 2,5 m long and with a total inclination of 200 mm ± 10 mm such that the whole surface lies between two imaginary parallel planes 5 mm apart throughout the test when loaded with the test wheelchair (see Figure 2). The surface of the plane shall have a coefficient of friction as defined in ISO 7176-13.

4.6 *Adjustable test plane*, a flat and hard test plane which can be set to sufficient size to enable the test indicated in **7.2.1** to be performed and with a surface of sufficient coefficient of friction to allow minimal wheel slippage during the performance of the test.

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

5 General requirements

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

- — risk analysis;
- — intended performance and technical documentation;
- — clinical evaluation;
- — aids that can be dismantled;
- — single use fasteners;
- — biocompatibility and toxicity;
- — contaminants and residues;
- — infection and microbiological contamination;
- — overflow, spillage, leakage and ingress of liquids;
- — safety of moving parts;
- — prevention of traps for parts of human body;
- — folding and adjusting mechanisms;
- — surfaces, corners and edges.

6 Design requirements

6.1 Footrests and legrests

6.1.1 *Requirements for footrests and legrests*

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

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

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

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

a) the gap between the footrests shall not exceed:

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

when tested as specified in **6.1.2**; or

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

6.1.2 *Test method for footrests*

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

Table 1 — Force to be applied to footplates

Max. intended user mass	Force on centroid of footplate
25 kg	25 N ± 5 %
50 kg	50 N ± 5 %
75 kg	75 N ± 5 %
100 kg	100 N ± 5 %

6.2 Requirement for pneumatic tyres

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

6.3 Requirement for fitting a seat belt

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

6.4 Requirement for armrests and backrests

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

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

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

NOTE ISO/TC 173/SC1 develops standards for WTORS and wheelchairs intended for use in motor vehicles. Manufacturers should consider if the resulting standards can be applied to their products.

6.6 Brakes

6.6.1 *Requirements for parking brakes*

The wheelchair shall be fitted with a parking brake.

The parking brakes shall have provision for adjustment to compensate for any wear to any friction surfaces, tyres etc. that have worn to the point of replacement as recommended in the manufacturer's documentation and for any wear occurring during the tests specified in **7.2.2** and **7.2.4**.

6.6.2 *Requirements for service brakes*

If the wheelchair has a propulsion system that does not include provision to stop the wheelchair, a service brake shall be fitted.

NOTE 1 For example lever operated wheelchairs.

NOTE 2 Manual wheelchairs propelled by the occupant using a circular hand rim attached to the wheels and wheelchairs propelled by an attendant, are considered to have provision to stop the wheelchair, as the user or attendant can slow it down.

NOTE 3 Service brake is also called running brake.

6.7 Requirement for component weight

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

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

or

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

6.8 Requirements for the fitting of anti-tip devices

If the minimum rearward static stability as measured by the method specified in ISO 7176-1 is less than 10°, there shall be provision for fitting anti-tip devices.

Anti-tip devices shall not move from their preset position when engaged by the loaded wheelchair.

7 Performance requirements

7.1 Requirements for wheelchair static, impact and fatigue strength

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

NOTE Further requirements and tests beyond those specified in ISO 7176-8:1998 are considered to be necessary and may be considered for a future development of this standard. These include e.g. impact strength of anti-tip levers.

7.2 Parking brake performance and strength

7.2.1 *Requirements for performance of parking brakes*

When the parking brakes have been adjusted by the method specified by the manufacturer to give operating forces that do not exceed the following values when measured as in **7.2.3**:

a) the force required to apply hand operated brakes shall not exceed 60 N;

b) the force required to apply foot push operated brakes shall not exceed 100 N;

c) the force required to apply foot pull operated brakes shall not exceed 60 N.

The wheelchair shall not slide, nor the wheels rotate when tested as in ISO 7176-3 facing up and down a slope of 7° from the horizontal.

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

7.2.2 *Requirements for fatigue strength of parking brakes*

When:

— the wheelchair has been tested as specified in ISO 7176-8:1998;

— the parking brake has been operated 60 000 times as specified in **7.2.4**;

the brake-to-frame connections shall not have moved from its preset position.

When:

— the parking brake has been adjusted as specified by the manufacturer within the requirements of **7.2.1**;

— the wheelchair has been tested as specified in ISO 7176-3, on a slope of 7°, with the wheelchair facing:

a) up the slope;

b) down the slope;

the wheelchair shall not slide, nor the wheels rotate.

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

7.2.3 *Test method for determination of brake lever operating forces*

Adjust the brakes as specified by the manufacturer within the requirements of **7.2.1.**

Use a device capable of measuring forces with an accuracy of ±2 N in increments of 1 N in the range of 0 N to 200 N.

Select the part of the lever through which the force is to be applied from the following (see Figure 1).

a) If the lever is fitted with a generally spherical knob apply the force through the centre of the knob.

b) If the lever is tapered, apply the force through the point where the largest cross-section intersects the centre line of the lever.

c) 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.

d) 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.

e) If the brake is operated by pushing or pulling a bar or pad, apply the force to the centroid of the bar or pad.

Apply the parking brakes using the force measuring device aligned in the direction of travel of the point of application of the force to measure the maximum force required.

If the wheelchair is fitted with two identical brakes (e.g. left and right) only one of the brakes needs to be tested.

If the wheelchairs have adjustable stability or if the manufacturer declares that the wheelchair static stability is less than 7° a minimum force shall be applied to the footrest so that the castors remain in contact with the test plane during the test procedure.

Perform the test three (3) times and calculate the arithmetic mean value of the forces measured.

7.2.4 *Test method for parking brake fatigue strength*

Carry out this fatigue test with the parking brake mounted on the wheelchair. If the wheelchair is fitted with pneumatic tyres inflate them to the maximum pressure recommended by the manufacturer.

Move the brake operating device smoothly from the brake off position to the brake on position and return to the brake off position 60 000 times at a frequency not exceeding 0,5 Hz.

Ensure that the means for moving the brake operating device does not apply forces in excess of those intended by the manufacturer.

If the wheelchair is fitted with two identical brakes (e.g. left and right) only one of the brakes needs to be tested.

If the wheelchair is fitted with more than one type of parking brake test one of each type.

7.3 Resistance to ignition

If the wheelchair is equipped with upholstered parts it shall conform to the requirements of ISO 7176-16.

7.4 Resistance to corrosion

NOTE For further guidance, see annex D.

7.5 Pushing force

7.5.1 *Requirements for pushing force*

When determined in accordance with **7.5.2**, the pushing force required to start and keep the loaded wheelchair moving at constant speed on a horizontal surface shall not exceed 40 N.

7.5.2 *Test method for measuring the pushing force*

Prepare the wheelchair as specified in ISO 7176-8:1998, **6.1**, **6.2**, **6.3** and **6.4.**

Select one of the dummies specified in ISO 7176-11 of mass equal to, or, if there is no dummy of equal mass, the next size greater than, the maximum mass of occupant recommended by the manufacturer. Position the dummy as specified in ISO 7176-8:1998, **6.5**;

or

make provision for a wheelchair driver of the same mass ±1 kg as the dummy specified above.

NOTE 1 Weights may be added on the seat of the wheelchair to supplement the mass of a small driver (sandbags or similar items are recommended).

If the wheelchair has two push handles, make provision for them to be joined together in a way that permits a horizontal force to be applied to them on the centre line of the wheelchair.

Make provision for applying a horizontal force along the longitudinal centre line of the wheelchair in the forward direction to any push handles;

or

where push handles are not fitted, to a point 15 mm ± 5 mm below the top of any backrest supports in the case of wheelchairs with a flexible backrest;

or

to a point 15 mm ± 5 mm below the top of any rigid backrest.

NOTE 2 A bar may be fitted across push handles or backrest supports to permit a push force to be applied, or a string may be fastened to each push handle or backrest support to permit a pull force to be applied.

Place the wheelchair on the horizontal test plane.

Set up a means to apply a force to start the wheelchair moving and to move the wheelchair in a forward direction at a speed of 1 m/s ± 0,1 m/s so that the direction of the force is maintained to the following throughout the test:

— horizontal ±5°;

— along the longitudinal centre line of the wheelchair ±5°;

— lateral displacement ±5 mm about the centre line.

Apply the force to the push handles or backrest, increasing the force gently until the wheelchair starts to move.

NOTE 3 The increasing rate of the force is recommended not to exceed 5 N/s.

Gently accelerate the wheelchair to a speed of 1 m/s ± 10 % during a distance not less than 2,5 m. Measure and record the force needed to move the wheelchair at a constant speed of 1 m/s ± 10 % during a distance not less than 2,5 m after the acceleration.

Maintain the direction of the force within the limits specified above during the whole test procedure.

The test shall be performed six (6) times, three in one direction and three in the opposite direction. All tests shall be performed on the same area of the test surface.

Calculate the arithmetic mean value of the forces measured.

7.6 Tracking characteristic

7.6.1 *Requirement for tracking characteristics*

This requirement does not apply to wheelchairs propelled by levers.

The deviation of the wheelchair from the straight tracking line shall not be more than 500 mm when tested as specified in **7.6.2**.

7.6.2 *Test method for tracking characteristics*

Frontwheel propelled wheelchairs shall be tested propelled in a rearward direction.

Prepare the test wheelchair as specified in ISO 7176-8:1998, **6.1**, **6.2**, **6.3** and **6.4**.

Select one of the dummies specified in ISO 7176-11 of mass equal to, or, if there is no dummy of equal mass, the next size greater than, the maximum mass of occupant recommended by the manufacturer. Position the dummy as specified in ISO 7176-8:1998, **6.5**.

Make provision for the rear wheels of the wheelchair to mark their track on the horizontal test plane.

NOTE 1 An acceptable method of marking the track of the wheels is to wet them with water and note the resulting tyre tracks.

Position the wheelchair on the ramp as shown in Figure 2 with one wheel on the "zero line". Ensure that the distance from the furthest back point of the rear wheel to the 0 m mark is 2 m ± 50 mm and that any castors are aligned with the "zero line" of the test surface.

NOTE 2 For example: a plate mounted on the ramp perpendicular to the "zero line" and to the surface, 2 m from the 0 m mark can be used to facilitate the alignment of the wheelchair in the correct position.

Release the wheelchair so that it rolls down the ramp and onto the horizontal test plane.

Measure and record the amount and direction of any deviation from the "zero line" when the wheelchair reaches the 0 m, 1 m and 4 m marks to an accuracy of ±10 mm (see Figure 2).

Perform the test seven (7) times.

The deviation of the wheelchair is the difference between the point where the wheelchair crosses the 4 m line and the intersection between the 4 m line and the straight line that goes through the points where the wheelchair crosses the 0 m and 1 m lines.

Figure 3 shows this calculation depending on how the wheelchair performs on the test track where:

L = the deviation of the wheelchair;

X_4 = the value of the deviation at the 4 m line;

X_1 = the value of the deviation at the 1 m line;

X_0 = the value of the deviation at the 0 m line.

Exclude the two tests that have given the extreme deviation (one to the right and one to the left).

For the five (5) remaining values of deviation calculate the arithmetic mean value.

7.7 Electrically powered ancillary equipment

If the wheelchair is fitted with electrically powered ancillary equipment, it shall conform to the relevant requirements and test methods of EN 12184:1999.

8 Information supplied by the manufacturer

8.1 General

The wheelchair shall be provided with the documentation and labelling that conform to the requirements in EN 1041 and ISO 7176-15, together with **8.2** and **8.3** below.

8.2 User manual

The user manual shall include descriptions of the following:

— the method of seat belt attachment;

— the method of attaching anti-tip devices, if they are available;

— the method of adjustments to axles and castor positions together with a warning of any instability characteristics with particular positions;

— a warning of any driving characteristics that can be adjusted outside safe limits;

— if the intended use of the wheelchair cannot be achieved without risk of squeezing, the risks shall be described and how they can be minimized;

— if the intended use of the wheelchair cannot be achieved without risk of surface temperatures exceeding 41 °C, the risks shall be described and how they can be minimized;

— if the manufacturer claims the wheelchair is for use as a seat in motor vehicles, the method of attaching wheelchair tie down and occupant restraints and recommendations about suitable tie down and restraint systems;

— if a wheelchair is fitted with special driving/braking adjustment devices, the recommended adjustment methods and settings of these devices.

8.3 Labelling

Means of adjustment that cause a minimum static stability less than 10° as measured by the method specified in ISO 7176-1 shall be clearly marked with a warning to the user and/or attendant of any appropriate precautions to be taken to ensure the safety of the user.

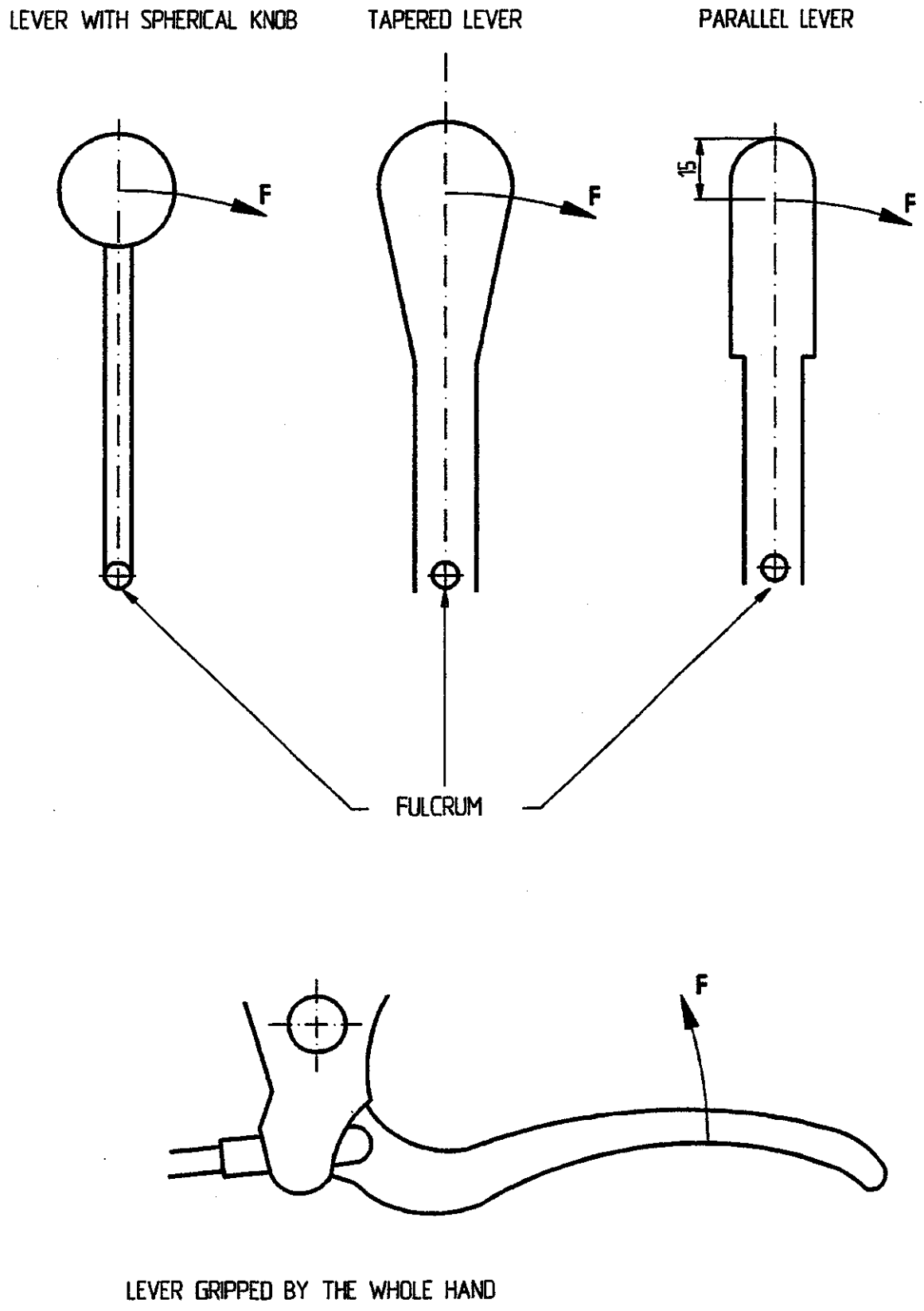


Figure 1 — Application of force on hand operated brakes

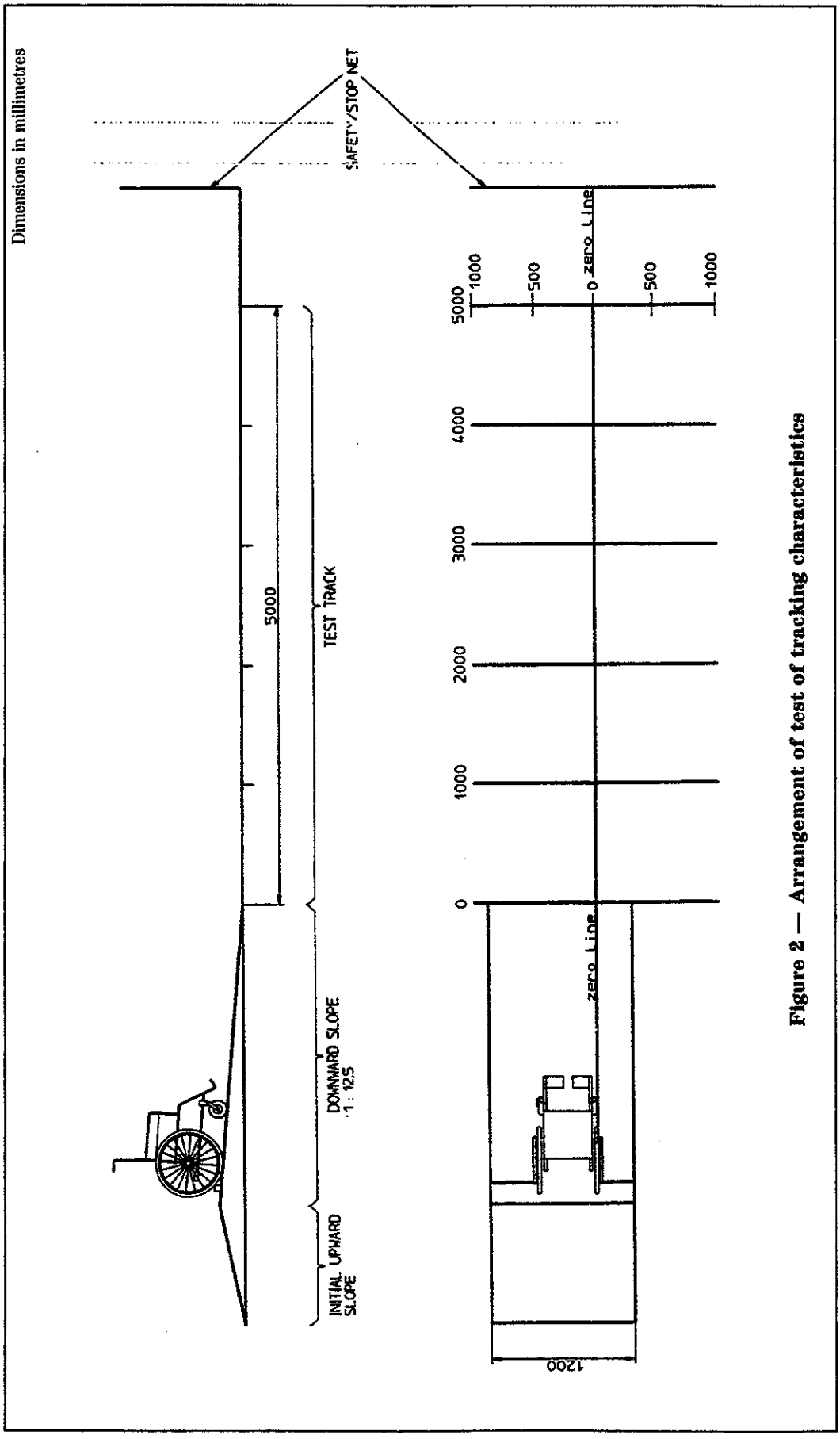
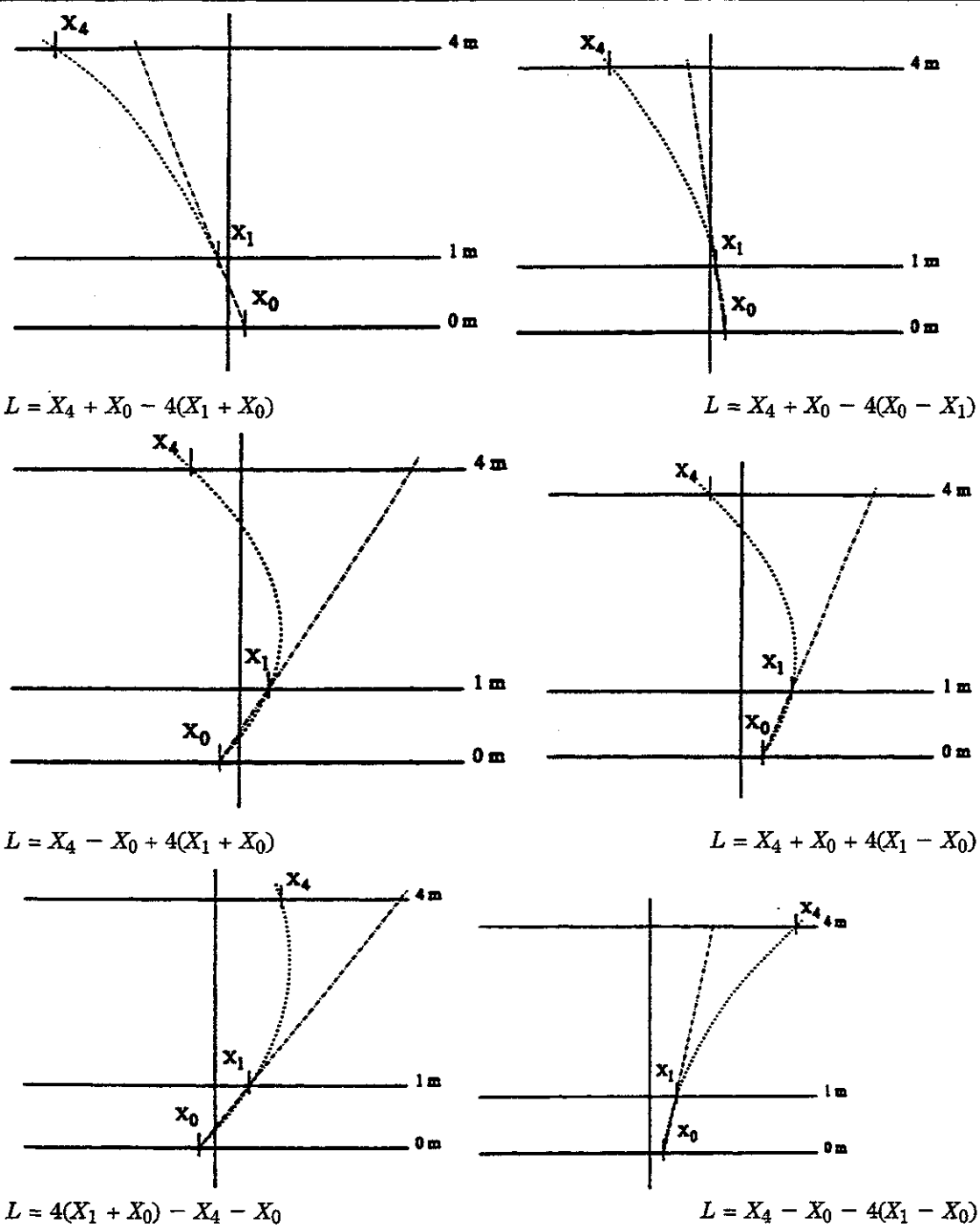


Figure 2 — Arrangement of test of tracking characteristics



$L = X_4 + X_0 - 4(X_1 + X_0)$

$L = X_4 + X_0 - 4(X_0 - X_1)$

$L = X_4 - X_0 + 4(X_1 + X_0)$

$L = X_4 + X_0 + 4(X_1 - X_0)$

$L = 4(X_1 + X_0) - X_4 - X_0$

$L = X_4 - X_0 - 4(X_1 - X_0)$

Figure 3 — Calculation of the deviation of the wheelchair

Annex A (informative)

Recommended design features — Introduction

This annex contains recommendations on design features for manually propelled wheelchairs. Since wheelchairs have to serve many different users with many different wishes for use, it is not possible to make the recommendations of this annex mandatory for every wheelchair. Manufacturers are recommended to follow the recommendations as far as possible and applicable, depending on the intended use of the wheelchair.

It includes features which are either:

not necessary for meeting the essential requirements of the Medical Devices Directive;

or

not necessary for all wheelchairs;

or

have no valid test method for verification of the requirement.

A.1 General recommendations

A.1.1 *Anti-tip devices*

Some wheelchairs may benefit from the facility of fitting anti-tip devices, even though the rearward static stability as measured by the method specified in ISO 7176-1 is greater than 10°.

Anti-tip devices should not move from their preset position when engaged by the loaded wheelchair.

Anti-tip devices should be positioned so that the maximum overall length of the wheelchair does not exceed 1 200 mm and the anti-tip device should not interfere with mounting or dismounting a 120 mm kerb.

Anti-tip devices may be positioned so that the wheelchair is able to be reclined.

A.1.2 *Component weight*

If the wheelchair parts are demountable, the maximum mass of such components should not exceed 10 kg.

A.1.3 *Fittings and tools*

It is strongly recommended that all screws, fasteners and similar fittings should be of metric sizes as specified in ISO 68. A minimum of tools should be required for operation and maintenance.

A.1.4 *Tyres*

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

A.1.5 *Pneumatic valves*

Pneumatic tyre valves should be readily accessible and an appropriate means of inflating the tyres should be supplied.

A.1.6 *Surface temperature*

The heat reflecting performance of materials that come in direct contact with the user, e.g. for upholstered parts, should be considered when selecting these materials to avoid excessive surface temperatures.

A.1.7 *Recommendations related to the user transferring into or out of the wheelchair*

The brake should not protrude above the seat in the braked position.

Legrests should not impede transfer.

Footrests should not impede forward transfer.

The armrests should be designed to facilitate sitting down and rising-from-sitting movements.

A.2 Overall dimensions

Wheelchairs should have maximum overall dimensions within the limits specified in ISO 7193.

Minimum turning radius should not exceed 1 000 mm or minimum turn around width should not exceed 1 300 mm when measured as specified in ISO 7176-5.

The ground clearance of the loaded wheelchairs with correctly inflated tyres should be at least 40 mm. This is tested by measurement of the distance between the floor and the lowest fixed part of the wheelchair excluding anti-tip device, when loaded with the appropriate dummy.

Annex B (informative)

Recommended seating design

B.1 Care should be taken to minimize the likelihood of seating producing pressure sores.

B.2 The seat angle, measured as specified in ISO 7176-7, should be between +4° and +14°.

B.3 The angle between the backrest plane and the seat plane should not be less than 80° when measured as specified in ISO 7176-7.

B.4 Combined seats and backrest units which can be pivoted ("tilt-in-space") should have not less than 6° of adjustment and be capable of operation by the user or attendant.

Annex C (informative)
Recommendations for ease of operation

C.1 Introduction

The following recommendations for ergonomic design relate to the ease of wheelchair operation.

The recommendations are intended to be applicable to at least 80 % of adult users and are based upon the assumption that the user has a body size within the range from the 5th percentile adult female to the 95th percentile adult male;

and

the abilities and restrictions of a 65 year old 50th percentile female;

and

the wheelchair is equipped with operating devices which are not custom-made for individual users.

The recommendations apply to the following features:

1) seating adjustments; including functions to change the posture of the user;

2) detachable components; including removable armrests, legrests etc., to facilitate safe transfers into and out of the wheelchair;

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

4) maintenance; includes operation of tools etc., for the periodic maintenance of wheelchairs.

C.2 Operating characteristics

1) Seating adjustments should be operable while the user is seated in the wheelchair and should operate in a safe manner.

2) All the above features should have an operating force as follows:

— combined arm and hand operation:	maximum force = 60 N;
— hand operation only:	maximum force = 13,5 N;

and be within easy reach of the user.

3) If fitted with braking lever(s) these should be easy to reach and to operate for the user and/or the attendant.

4) If fitted with legrests or armrests that are swinging or removable, the mechanisms should be easy to reach and to operate by the user and/or the attendant.

5) Removable and swinging armrests and footrests should be capable of being operated without the use of tools.

6) If fitted with push handles for attendant propulsion, the handles should be placed between 900 mm and 1 200 mm above the ground.

NOTE Figure C.1 gives guidance on the maximum reach of users seated in wheelchairs. The measurements are specified relative to the seat and reference planes defined in ISO 7176-7.

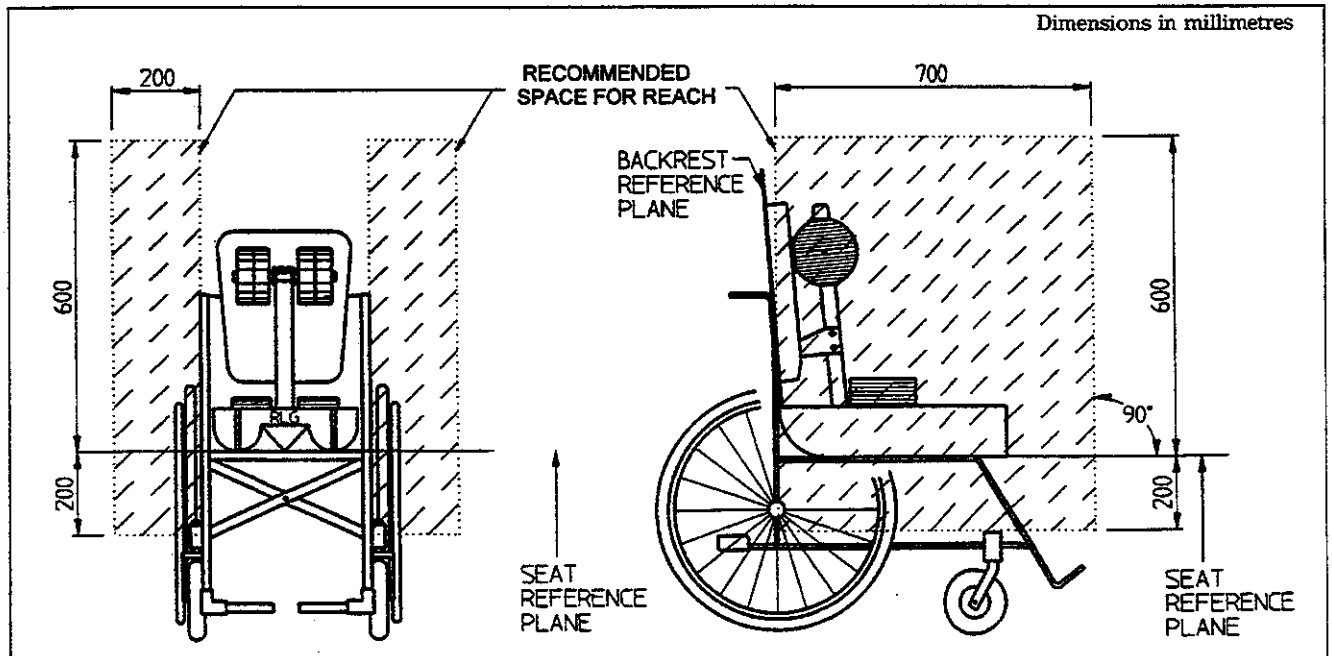


Figure C.1 — Maximum reach of users seated in wheelchairs

Annex D (informative)

Resistance to corrosion

As concerns component surfaces shifting over and against each other as a result of an adjustment facility and/or folding and components that get in direct contact with the user, the allowed maximum oxidation value has been set at Re 2, Ox 3. Other parts are also evaluated but without a test consequence (see DIN 53210 and ISO 4628).

Method: DIN 50021/DIN 52210.

NOTE Manufacturers and prescribers are encouraged to look at various international standards for corrosion on the various elements within the product.

Annex Z (informative)

Clauses of this European Standard addressing essential requirements or other provisions of EU Directives

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association and supports essential requirements of EU Directive 93/42/EEC concerning medical devices.

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

The following clauses of this standard, as detailed in Table Z.1, are likely to support requirements of Directive 93/42/EEC.

Compliance with the clauses of this standard provides one means of conforming with the specific essential requirements of the Directive concerned and associated EFTA regulations.

Table Z.1 — Correspondence between this European Standard and EU Directives

Clauses/subclauses of this European Standard	Corresponding annexes/paragraphs of Directive 93/42/EEC concerning medical devices — annex I, Essential requirements	Comments
Full or partial conformity with all clauses/subclauses	1	Each device needs to be considered against its intended use. prEN 12182:1999 is valid as a general reference document. EN 1441 (risk analysis) is generally valid. The ISO 7176 series is used as basic reference, in particular concerning test methods. Annexes A–D give further guidance concerning design, performance etc.
Full or partial conformity with all clauses/subclauses. In particular: **8**	2	EN 1441 (risk analysis) is generally valid. Information, labelling, warnings etc.
Full or partial conformity with all clauses/subclauses	3	Each device needs to be considered against its intended use. EN 1441 (risk analysis) is generally valid.
Full or partial conformity with all clauses/subclauses.	4	The test methods are designed with respect to stresses which can occur during the lifetime of the device under normal conditions of use.
Full or partial conformity with all clauses/subclauses. In particular: **6.5**	5	Requirement for wheelchairs intended for use in motor vehicles.
Full or partial conformity with all clauses/subclauses	6	EN 1441 (risk analysis) is generally valid.

Table Z.1 — Correspondence between this European Standard and EU Directives *(continued)*		
Clauses/subclauses of this European Standard	**Corresponding annexes/paragraphs of Directive 93/42/EEC concerning medical devices — annex I, Essential requirements**	**Comments**
5 **7.3**	7.1	Toxicity and biocompatibility. Reference to prEN 12182:1999. Ignition/flammability. Reference to ISO 7176-16. prEN 12182:1999 applies.
5	7.2	Contaminants and residues. Reference to prEN 12182:1999.
—	7.3	Not normally applicable. Manufacturers should be aware that in some circumstances their products may be exposed to unusual risks, and provide appropriate advice, information etc. Example: oxygen cylinders carried on a wheelchair.
5	7.5, 7.6	Overflow, spillage, leakage, ingress of liquids. Reference to prEN 12182:1999.
5	8.1	Biocompatibility, toxicity, contaminants, residues, infection. Reference to prEN 12182:1999
5	8.2	Not normally applicable. Some guidance is given in prEN 12182:1999.
7.7	9.1	Not normally applicable. Manufacturers should be aware that in some circumstances their products may be used in combination with other equipment, and provide appropriate advice, information etc. Example: oxygen cylinders attached to a wheelchair. Electrically powered ancillary equipment. EN 12184:1999 (electrically powered wheelchairs) applies.
5, 6, 7 Annexes A–C	9.2	Dimension/ergonomics. prEN 12182:1999 gives additional guidance. Guidance on dimensions, ergonomics etc. Not covered: volume/pressure ratio; ageing of material; accuracy of measuring and control mechanisms. The other aspects of MDD, annex I, **9.2** are not applicable.

Table Z.1 — Correspondence between this European Standard and EU Directives *(continued)*		
Clauses/subclauses of this European Standard	**Corresponding annexes/paragraphs of Directive 93/42/EEC concerning medical devices — annex I, Essential requirements**	**Comments**
7.7	12.6	Normally not applicable. Electrically powered ancillary equipment. EN 12184:1999 (electrically powered wheelchairs) applies.
5, 6, 7 **6.1** **6.8, 7.2, 7.6, 8.2**	12.7.1	Moving parts, traps, adjusting mechanisms, surfaces, corners, edges. Reference to prEN 12182:1999. Footrests, legrests. Stability, anti-tip devices, parking brakes, tracking, user manual. Further guidance is given in annexes A–C.
7.7	12.7.4	Normally not applicable. Electrically powered ancillary equipment. EN 12184:1999 (electrically powered wheelchairs) applies.
8.2	12.7.5	Surface temperature, information.
8	13	Information supplied by the manufacturer.
5	14	Clinical evaluation. Reference to prEN 12182:1999 (which refers to EN 540, generally valid).