SLOVENSKI STANDARD
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Oprema za ravnanje s pacienti v reševalnih vozilih - 6. del: Prenosni stol

Patient handling equipment used in ambulances - Part 6: Powered chairs

Krankentransportmittel im Krankenkraftwagen - Teil 6: Kraftunterstützte Krankenstühle

Spécifications d'équipements pour le transport de patient dans les ambulances routières - Partie 6 : Fauteuils à assistance électrique

Ta slovenski standard je istoveten z: **prEN 1865-6**

ICS:

11.160	Prva pomoč	First aid
43.160	Vozila za posebne namene	Special purpose vehicles

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This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 239.

If this draft becomes a European Standard, 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.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (prEN 1865-6:2022) has been prepared by Technical Committee CEN/TC 239 “Rescue systems”, the secretariat of which is held by DIN.

This document is currently submitted to the CEN Enquiry.

This European Standard is a part of EN 1865, *Patient handling equipment used in ambulances*, which consists of the following parts:

- Part 1: *General stretcher systems and patient handling equipment; (forseen for revision)*
- Part 2: *Power assisted stretcher; (forseen for revision)*
- Part 3: *Heavy duty stretcher; (forseen for revision)*
- Part 4: *Foldable patient transfer chair; (forseen for revision)*
- Part 5: *Stretcher support; (forseen for revision)*
- Part 6: *Powered chairs. (the present document)*

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

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

1 Scope

This document defines the minimum requirements for the design and performance of power assisted chairs, which are used for the conveyance of patients to and/or from road ambulances. It aims to ensure patient safety and to minimize the physical effort required by staff operating the equipment.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 597-1:2015, *Furniture - Assessment of the ignitability of mattresses and upholstered bed bases - Part 1: Ignition source smouldering cigarette*

EN ISO 20417:2021, *Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021, Corrected version 2021-12)*

EN 1865-1:2010+A1:2015, *Patient handling equipment used in road ambulances - Part 1: General stretcher systems and patient handling equipment*

prEN 1865-2:2022, *Patient handling equipment used in ambulances — Part 2: Power assisted stretcher*

EN 60601-1-2:2015,[1] *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances— Requirements and tests (IEC 60601-1-2:2014 and A1:2020)*

EN 62366-1:2015,[2] *Medical devices — Part 1: Application of usability engineering to medical devices (IEC 62366-1:2015 and COR1:2016 and A1:2020)*

EN ISO 14971:2019,[3] *Medical devices — Application of risk management to medical devices (ISO 14971:2019)*

EN ISO 15223-1:2021, *Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)*

[1] Document impacted by A1:2021.

[2] Document impacted by AC:2015 and A1:2020.

[3] Document impacted by A11:2021.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

3.1
power assisted chair
device designed to transfer a patient in a sitting position to the road ambulance, but not to be used to transport a patient within the road ambulance

4 Requirements

4.1 General

These power assisted chairs shall be fitted with a powered mechanism to assist the descent and/or ascent of steps in order to minimize the need for manual transportation of the patient and chair.

When power assisted chairs are operated and maintained in accordance with manufacturer instructions, they should not present any high level of risk. Any identified risk shall be reduced to an acceptable level by using risk management principles in accordance with EN ISO 14971:2019 in normal and single fault condition.

The chair shall ensure that the operators are able to use the chair on stairs whilst maintaining good ergonomics and posture (e.g. by handles, bars).

All equipment for the handling of patients shall be free of any sharp edges or deformation that could cause injury to persons or damage to other equipment. The minimum radius should be 0,5 mm.

4.2 Dimensions

The dimensions of the power assisted chair in open position shall be as follows:

— The seat:

  — minimum height of 300 mm, measured from the ground;

  — maximum height of 550 mm, measured from the ground;

  — minimum width of 330 mm;

  — minimum depth of 350 mm;

— The backrest: minimum height of 395 mm, measured from the seat;

  — minimum width of 300 mm.

4.3 Mass

The total mass (excluding patient restraint) shall be not more than 32 kg.

The mass should be as low as possible.

4.4 Loading capacity

The loading capacity shall be a minimum of 200 kg.

4.5 Frame

The frame of the power assisted chair shall be a sturdy, lightweight construction. It shall be furnished with 2 non-slip lift points on the lower frame, and 2 non-slip lift points on the top frame. It shall also have a footrest and a minimum of two wheels of a diameter 100 mm minimum at the rear. It shall be possible to store the power assisted chair in a folded position.

4.6 Power source

a) The chair travel mechanism shall have an integral safety feature to prevent the chair from uncontrolled ascent / descent. An override system shall be provided to allow the chair to be used manually in the event of power loss. The override system shall be easily accessible to the operator(s).

b) If a battery is fitted it shall be supplied with a facility to charge from both the vehicle voltage or from an external AC power supply. The system shall also indicate the battery power condition. In case of power loss a second battery combined with a charger shall be available.

c) The operating controls shall be clearly and permanently labelled, preferably with graphical symbols, indicating their positions and settings according to EN 60601-1-2:2015 and EN 62366-1:2015.

4.7 Seat and Backrest

The patient seat and backrest shall be made of a strong material which is bacteria resistant, fungi resistant, stain resistant, putrid resistant, easy to clean, washable, waterproof and petrol-oil resistant.

4.8 Restraint system

Patient restraint-systems shall secure the patient, but at the same time shall permit treatment of the patient. Carrying patients down stairs would require a system designed to avoid patient movement side-to-side and up-and-down, forward from pelvis and forward from shoulders.

All restraint systems shall have a quick-release.

4.9 Flammability — toxicity burning gases

There shall be no progressive smoldering or flaming ignition when tested in accordance with EN 597-1:2015.

4.10 Deformation of the frame

There shall be no remaining deformation of the frame when tested in accordance with prEN 1865-2:2022, 5.1.

4.11 Locking

The hinges and locks shall not open spontaneously or bend.

4.12 Deformation of the backrest lying-sitting area

There shall be no remaining deformation of the backrest and lying-sitting area when tested in accordance with EN 1865-1:2010+A1:2015, 5.1.

5 Marking

The foldable transfer chair covered by this European Standard shall be labelled in accordance with EN ISO 15223-1:2021 and EN ISO 20417:2021.

Annex ZA
(informative)

Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered

This European standard has been prepared under M/575 to provide one voluntary means of conforming to the General Safety and Performance Requirements of Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up.

Once this standard is cited in the Official Journal of the European Union under that Regulation, compliance with the normative 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 General Safety and Performance Requirements of that Regulation, and associated EFTA Regulations.

Where a definition in this standard differs from a definition of the same term set out in Regulation (EU) 2017/745, the differences shall be indicated in this Annex Z. For the purpose of using this standard in support of the requirements set out in Regulation (EU) 2017/745, the definitions set out in this Regulation prevail.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Regulation (EU) 2017/745. This means that risks have to be 'reduced as far as possible', 'reduced to the lowest possible level', 'reduced as far as possible and appropriate', 'removed or reduced as far as possible', 'eliminated or reduced as far as possible', 'removed or minimized as far as possible', or 'minimized', according to the wording of the corresponding General Safety and Performance Requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with General Safety and Performance Requirements 1, 2, 3, 4, 5, 8, 9, 10, 11, 14, 16, 17, 18, 19, 20, 21 and 22 of the Regulation.

NOTE 3 When a General Safety and Performance Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.