SLOVENSKI STANDARD
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Oprema za ravnanje s pacienti v reševalnih vozilih - 2. del: Nosila z zložljivim podvozjem

Patient handling equipment used in ambulances - Part 2: Power assisted stretcher

Krankentransportmittel im Krankenkraftwagen - Teil 2: Kraftunterstützte Krankentrage

Spécifications d'équipements pour le transport de patient dans les ambulances routières - Partie 2: Brancard motorisé

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11.160	Prva pomoč	First aid
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English Version

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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 1865-2:2022) 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 document will supersede EN 1865-2:2010+A1:2015.

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 (the present document)*
- 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. (under new development)*

Compared to EN 1865-2:2010+A1:2015 the following main technical changes were made:

a) Title changed from ” *Patient handling equipment used in road ambulances*” to ” *Patient handling equipment used in ambulances*”;

b) Normative reference up-dated;

c) Annex ZA revised to show relationship to Medical Device Regulations (MDR) instead of Medical Device Directive (MDD);

d) new definition for loading system (3.2) included;

e) requirements for mass (4.2.3), power source (4.2.6) and restraint system (4.2.8) revised;

f) loading capacity (4.2.4) from 150 kg to 200 kg increased;

g) new Clause 5 for testing included.

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.

Introduction

In this document, reference is made to EN 1789:2020 which specifies design requirements and test methods for road ambulances, which are relevant for checking requirements for such handling equipment.

1 Scope

This document defines minimum requirements for the design and performance of power assisted stretchers used in road ambulances for the treatment and transportation of patients. It aims to ensure patient safety and 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 1789:2020, *Medical vehicles and their equipment - Road ambulances*

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 — 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)*

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 stretcher
device designed for the conveyance of sick and/or injured persons or those in labour in transit in a recumbent position in safety and in comfort whilst facilitating treatment and providing powered movements in the operation of the stretcher to reduce the physical effort required by operatives

[1] Document impacted by A1:2021.
[2] Document impacted by AC:2015 and A1:2020.
[3] Document impacted by A11:2021.

3.2
loading system
system installed on the vehicle and/or on the stretcher to assist loading or unloading the stretcher

4 Requirements

4.1 General

When operated and maintained in accordance with the manufacturer's instructions, power assisted stretchers shall 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.

Power assisted stretchers shall also:

- allow patients to be secured so that any movement during ambulance transport is minimized;
- be free of sharp edges that could cause injury to persons or damage to other equipment on board. The minimum radius should be 0,5 mm.

For all patients transported in the patient compartment, patient restraint-systems shall be available. All patient restraint-systems shall have quick release systems.

Patient restraint-systems for all patient handling equipment shall secure the patient, but at the same time shall permit treatment of the patient.

The lying-sitting part shall be made of a strong material which is bacterial resistant, fungal resistant, stain resistant, putrid resistant, easy to clean, washable, waterproof and petrol-oil resistant.

4.2 Main stretcher

4.2.1 General

The main stretcher shall consist of a stretcher part that can be used either alone or in combination with an integrated or detachable undercarriage.

The power assisted stretcher and ambulance loading system shall be compatible. The loading system shall support the crew, so no manual lifting should be done to load the stretcher under normal daily use.

NOTE To minimize manual loading under normal use.

4.2.2 Dimensions

Dimensions shall be measured from the outermost edges:

length: $(1\,950\ ^{+120}_{-50})$ mm;

width: $(550 \pm\ ^{+60}_{-20})$ mm ;

height: maximum 300 mm from loading holding assembly to unloaded lying part. This height dimension does not apply to stretchers with monoblock undercarriages. If a monoblock is not available, the stretcher shall be constructed such that it is detachable from the undercarriage. Where a stretcher support is used the measurement shall be taken from the top surface of the stretcher support to the lying part of the stretcher.

— Undercarriage: length and width of the frame of the undercarriage when located in the ambulance shall not exceed length and width of the stretcher.

4.2.3 Mass

The complete mass of a stretcher with integrated undercarriage system (monoblock), excluding the mattress and patient restraints, shall not be more than 75 kg.

The complete mass of a detachable stretcher and undercarriage system combined, excluding the mattress and patient restraints, shall not be more than 81 kg.

- The detachable stretcher part shall not be more than 23 kg.
- The detachable stretcher part may exceed 23 kg, if its main intention is not to be used for manual lifting or manual carrying purposes.

Where the stretcher is a combined stretcher and loading system, therefore requiring no additional lifting devices or manual lifting to load it into the ambulance, then the maximum mass of the stretcher excluding the mattress and patient restraint, may be increased to 95 kg.

In all cases the mass should be as low as possible.

4.2.4 Loading capacity

The loading capacity shall be a minimum of 200 kg. A label on the stretcher should indicate the maximum loading capacity.

4.2.5 Frame

4.2.5.1 General

The frame shall be in sturdy lightweight non twisting construction enabling use of cardiopulmonary resuscitation. All corners of the frame shall be radiused for greater safety.

It shall be possible to lock and secure the stretcher and undercarriage against lateral, longitudinal, vertical movements.

All mechanisms shall be constructed to prevent damage to the user and the patient.

4.2.5.2 Stretcher parts

a) If side rails are fitted, they shall have a minimum length of 500 mm and a minimum height of 150 mm measured from the top of the stretcher frame to the top of the side rail.

b) If longitudinal handles are incorporated they shall be fitted to the ends of the longitudinal frame such that they lock and do not twist when they are stowed or in use. They shall be designed to minimize the risk of injuries to the hands and wrists when being operated or the stretcher is carried at angles.

c) The stretcher shall have a water and scratch resistant surface finish or be manufactured of corrosion resistant material. Both shall be unaffected by disinfectants.

d) If intended to be used without undercarriage there shall be four wheels suitably placed to ensure stability.

e) If intended to be used with undercarriage the stretcher shall be able to be fixed to the undercarriage without using supplementary means. A safe handling and lowering of the undercarriage shall be ensured.

f) The fixed stretcher shall be easy to release from the stretcher fastener.

g) Stretcher should be equipped with an infusion holder.

4.2.5.3 Undercarriage

a) The undercarriage shall be fitted with four wheels with a diameter of at least 100 mm. There shall be a minimum of two 360° swivel wheels at the foot end and at least two wheels shall be fitted with a brake.

b) The undercarriage shall have variable height between the lowest and upper position and be able to hold the rated load capacity in any position.

c) All the functions of the stretcher shall remain completely unimpaired when it is connected to the undercarriage.

d) The undercarriage shall either be provided with a waterproof and scratch resistant surface or be made of corrosive resistant material or similar surface.

If the undercarriage is used with a removable top part it shall be possible both to connect the undercarriage to the top part and to separate them easily. The top part shall be secured to the undercarriage in such a manner that unintentional separation of the undercarriage and top part cannot occur. It shall be possible to load and unload the undercarriage and top part so as to ensure the safety and comfort of the patient and the user.

4.2.6 Power source

a) The undercarriage height adjustment mechanism shall have an integral safety feature to prevent the stretcher collapsing in the event of failure (stretcher to lower at a controlled rate). If a battery is required to power the lifting mechanism then an override system shall be provided to allow the stretcher to be used manually.

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.

4.2.7 Lying part of the stretcher

a) The lying area shall be flat over the complete surface and shall be made of sturdy lightweight construction. The thorax area shall be manufactured of sturdy lightweight material which allows cardiopulmonary resuscitation without acting as a spring or giving way. The materials shall be unaffected by disinfectants.

b) The lying area shall be non-slip and shall be covered with a transfer mattress, or a mattress that shall provide for patient comfort and also be firm enough to enable cardiopulmonary resuscitation to be undertaken. The mattress shall be able to conform to the various treatment configuration provided by the stretcher. The mattress shall be constructed in such a way that prevents ingress of patient fluids and facilitate infectious control cleaning. In addition, the materials shall be unaffected by disinfectants. The mattress on the lying part of the stretcher shall be fixed securely.

c) The lying area shall have an adjustable head-end/backrest with a minimum length of 600 mm. It shall be possible to raise the backrest at least 75° and there shall be at least five fixing positions within this range. It shall be possible to maintain the angle of adjustment under all normal cases of loading and unloading.