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Specifikacija za opremo za ravnanje s pacienti v reševalnih vozilih - 2. del: Nosila s pomožnim pogonom

Specification for patient handling equipment used in road ambulances - Part 2: Power assisted stretchers

Festlegungen für Krankentransportmittel im Krankenkraftwagen - Teil 2: Kraftunterstützte Krankentragen

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11.160	Prva pomoč	First aid
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Patient handling equipment used in road ambulances - Part 2: Power assisted stretcher

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

Krankentransportmittel im Krankenkraftwagen - Teil 2: Kraftunterstützte Krankentrage

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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Foreword

This document (EN 1865-2:2010) has been prepared by Technical Committee CEN/TC 239 “Rescue systems”, the secretariat of which is held by DIN.

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of an identical text or by endorsement, at the latest by February 2011, and conflicting national standards shall be withdrawn at the latest by February 2011.

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.

Together with EN 1865-1, EN 1865-3, EN 1865-4 and EN 1865-5 this document supersedes EN 1865:1999.

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(s).

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

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

— *Part 1: Specification for general stretcher systems and patient handling equipment*

— *Part 2: Power assisted stretcher*

— *Part 3: Heavy duty stretcher* (at draft stage)

— *Part 4: Mechanical assisted transfer chair* (at draft stage)

— *Part 5: Stretcher support* (at draft stage)

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

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

1 Scope

This European Standard 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 referenced documents are indispensable for the application 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, *Furniture — Assessment of the ignitability of mattresses and upholstered bed bases — Part 1: Ignition source: Smouldering cigarette*

EN 980, *Symbols for use in the labelling of medical devices*

EN 1041, *Information supplied by the manufacturer of medical devices*

EN 1789:2007+A1:2010, *Medical vehicles and their equipment — Road ambulances*

EN 1865-1, *Patient handling equipment used in road ambulances — Part 1: Specification for general stretcher systems and patient handling equipment*

EN 60601-1-2, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests (IEC 60601-1-2:2007, modified)*

EN 62366, *Medical devices — Application of usability engineering to medical devices (IEC 62366:2007)*

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

3 Terms and definition

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

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

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.

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.

4.2.2 Dimensions

Dimensions shall be measured from the outermost edges:

— length: $(1\,950\,^{+20}_{-50})$ mm;

width: (550 ± 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 total mass excluding mattress and patient restraints shall be not more than 65 kg.

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

4.2.4 Loading capacity

The loading capacity shall be a minimum of 150 kg.

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 between 150 mm and 200 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. It shall allow the fixation and use of a carrying harness.

c) The stretcher shall have a water and scratch resistant paint 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 with a minimum diameter of 100 mm 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.

NOTE There should be a facility to attach a support for infusion.

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 finish or be made of corrosive resistant material or similar surface.

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