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Medicinska vozila in pripadajoča oprema - Cestna reševalna vozila

Medical vehicles and their equipment - Road ambulances

Rettungsdienstfahrzeuge und deren Ausrüstung - Krankenkraftwagen

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Medical vehicles and their equipment - Road ambulances

Rettungsdienstfahrzeuge und deren Ausrüstung - Krankenkraftwagen

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

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

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European foreword

This document (prEN 1789:2018) 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 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).

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

Introduction

The document was first developed in the late 1990s to define a common approach to requirements to enhance patient and crew safety. The standard has evolved and matured through several amendments and revisions.

This latest revision work of EN 1789 has had two key objectives:

The first objective was to revise the technical side of the document with more manageable verification in mind, while maintaining the high quality and strict nature of the requirements.

The second objective was to check all the references and regulations, paying special attention to EU regulations and updated standardization rules.

Testing of special purpose vehicle, such as an ambulance, is complex. Multiple functions (e.g. fixations, maintain systems, noise, illumination, heating, cooling etc.) may require numerous tests, which can be destructive. In this edition, carefully planned tests according to worst-case scenario strategies have reduced the number of destructive tests without sacrificing test qualities.

The previous edition of this standard (EN 1789+A2:2014) contained a number of direct references to EU regulations. According to CEN Internal Regulations Part 3:2017 and to avoid duplication as well as outdated references and to enable use of this standard independently of the ECE rules, EU regulations and directives, these references have now been removed from the normative section of the standard.

This standard is a reference document which can be used in support of regulations.

For the purpose of verification of an ambulance according to EU vehicle approval process, a section of EN 1789:2007+A1:2010+A2:2014 (i.e. patient's compartment) has been referenced directly in Directive 2007/46/EC (Annex XI).

1 Scope

This document specifies requirements for the design, testing, performance and equipping of road ambulances used for the transport, monitoring, treatment and care of patients. It contains requirements for the patient's compartment in terms of the working environment, ergonomic design and the safety of the crew and patients. This document does not cover the training of the crew which is the responsibility of the authority/authorities in the country where the ambulance is to be registered.

This document is applicable to road ambulances capable of transporting at least one person on a stretcher and excludes the transportation of hospital beds.

This document also specifies requirements for ambulances intended to carry transport incubator systems.

This document covers the specific requirements of each type of road ambulance which are designated according to the patient condition.

This document gives general requirements for medical devices carried in road ambulances and used therein and outside hospitals and clinics in situations where the ambient conditions can differ from normal indoor conditions.

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.

CEN/TS 16165:2016, *Determination of slip resistance of pedestrian surfaces - Methods of evaluation*

DIN 51130:2014, *Testing of floor coverings - Determination of the anti-slip property - Workrooms and fields of activities with slip danger - Walking method - Ramp test*

EN 3-7:2004+A1:2007, *Portable fire extinguishers - Part 7: Characteristics, performance requirements and test methods*

EN 420:2003+A1:2009, *Protective gloves - General requirements and test methods*

EN 443:2008, *Helmets for fire fighting in buildings and other structures*

EN 455-1:2000, *Medical gloves for single use - Part 1: Requirements and testing for freedom from holes*

EN 455-2:2015, *Medical gloves for single use - Part 2: Requirements and testing for physical properties*

EN 794-3:1998+A2:2009, *Lung ventilators - Part 3: Particular requirements for emergency and transport ventilators*

EN 1041:2008+A1:2013, *Information supplied by the manufacturer of medical devices*

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

EN 1865-2:2010+A1:2015, *Patient handling equipment used in road ambulances - Part 2: Power assisted stretcher*

EN 1865-3:2012+A1:2015, *Patient handling equipment used in road ambulances - Part 3: Heavy duty stretcher*

EN 1865-4:2012, *Patient handling equipment used in road ambulances - Part 4: Foldable patient transfer chair*

EN 1865-5:2012, *Patient handling equipment used in road ambulances - Part 5: Stretcher support*

EN 12470-1:2000+A1:2009, *Clinical thermometers - Part 1: Metallic liquid-in-glass thermometers with maximum device*

EN 13544-1:2007+A1:2009, *Respiratory therapy equipment - Part 1: Nebulizing systems and their components*

EN 13976-1:2018, *Rescue systems - Transportation of incubators - Part 1: Interface requirements*

EN 60601-1:2006+A1:2013, *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005/A1:2012)*

EN 60601-1-12:2015, *Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment*

EN 60601-2-4:2011, *Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators (IEC 60601 2 4:2010)*

EN 60601-2-27:2014, *Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment (IEC 60601 2 27:2011 + Corrigendum May 2012)*

EN ISO 407:2004, *Small medical gas cylinders - Pin-index yoke-type valve connections (ISO 407:2004)*

EN ISO 5359:2014, *Anaesthetic and respiratory equipment - Low-pressure hose assemblies for use with medical gases (ISO 5359:2014)*

prEN ISO 9170-1:2017, *Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases and vacuum (ISO/DIS 9170-1:2017)*

EN ISO 7396-1:2016, *Medical gas pipeline systems - Part 1: Pipeline systems for compressed medical gases and vacuum (ISO 7396-1:2016)*

EN ISO 10079-1:2015, *Medical suction equipment - Part 1: Electrically powered suction equipment (ISO 10079-1:2015)*

EN ISO 10079-2:2014, *Medical suction equipment - Part 2: Manually powered suction equipment (ISO 10079-2:2014)*

EN ISO 10079-3:2014, *Medical suction equipment - Part 3: Suction equipment powered from a vacuum or positive pressure gas source (ISO 10079-3:2014)*

prEN ISO 10524-1:2017, *Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow-metering devices (ISO/FDIS 10524-1:2017)*

prEN ISO 10524-2:2017, *Pressure regulators for use with medical gases - Part 2: Manifold and line pressure regulators (ISO/FDIS 10524-2:2017)*

prEN ISO 10524-3:2017, *Pressure regulators for use with medical gases — Part 3: Pressure regulators integrated with cylinder valves (ISO/DIS 10524-3:2017)*

prEN ISO 11197:2018, *Medical supply units (ISO/DIS 11197:2018)*

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

EN ISO 15002:2008, *Flow-metering devices for connection to terminal units of medical gas pipeline systems (ISO 15002:2008)*

EN ISO 15223-1:2016, *Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)*

EN ISO 19054:2006+A1:2016, *Rail systems for supporting medical equipment (ISO 19054:2005+ Amd1:2016)*

EN ISO 20345:2011, *Personal protective equipment - Safety footwear (ISO 20345:2011)*

EN ISO 20471:2013+A1:2016, *High visibility clothing — Test methods and requirements (ISO 20471:2013, Corrected version 2013-06-01+Amd 1:2016)*

EN ISO 80601-2-55:2018, *Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors (ISO 80601-2-55:2018)*

prEN ISO 80601-2-61:2017, *Medical electrical equipment — Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment (ISO/DIS 80601-2-61:2017)*

IEC 60364-7-721:2017, *Low-voltage electrical installations — Part 7-721: Requirements for special installations or locations — Electrical installations in caravans and motor caravans*

ISO 3795:1989, *Road vehicles, and tractors and machinery for agriculture and forestry — Determination of burning behaviour of interior materials*

ISO 5128:1980, *Acoustics — Measurement of noise inside motor vehicles*

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
patient and emergency patient

3.1.1
patient
person whose condition requires appropriately trained personnel to provide medical care and/or suitable transport

3.1.2
emergency patient
patient who through sickness, injury or other circumstances is in immediate or imminent danger to life unless emergency treatment and/or monitoring and suitable transport to diagnostic facilities or medical treatment is provided

3.2
road ambulance
vehicle intended to be crewed by a minimum of two appropriately trained crew members for the provision of care and transport of at least one stretchered patient

3.3
types of road ambulances

3.3.1
type A
patient transport ambulance
road ambulance designed and equipped for the transport of patients who are not expected to become emergency patients

Note 1 to entry: Two types of patient transport ambulance exist:

— type A_1: suitable for transport of a single patient;

— type A_2: suitable for transport of one or more patient(s) (on stretcher(s) and seat(s)).

3.3.2
type B
emergency ambulance
road ambulance designed and equipped for the transport, basic treatment and monitoring of patients

3.3.3
type C
mobile intensive care unit
road ambulance designed and equipped for the transport, advanced treatment and monitoring of patients

3.4
net vehicle mass
net mass of the road ambulance including the driver taken as 75 kg, 90% fuel tank and all fixed installations

Note 1 to entry: Loose portable patient handling, sanitary, medical and technical equipment are not included in net vehicle mass.

3.5
road ambulance loading capacity
difference between the permissible gross vehicle mass and the net vehicle mass of the road ambulance including the driver taken as 75 kg and all fixed installations, mass reserve and all passengers

Note 1 to entry: This represents the mass that may be distributed on the road ambulance such that the permissible axle loads are not exceeded.

3.6
fixation system
system or device to ensure the permanent fixation of medical devices or other equipment into the road ambulance

3.7
retention system
bracket or other interface device used to secure a mobile or transportable item of equipment or medical device in the road ambulance without the use of tools

3.8
patient compartment
interior section of an road ambulance for patient treatment and/or transport

4 Requirements

4.1 General requirements

Road ambulances equipment shall, when operated in normal use and maintained according to the instructions of the manufacturer, cause no safety hazard which could reasonably be foreseen using risk management procedures, e.g. in accordance with EN ISO 14971:2012, and which is connected with their intended application, in normal condition and in single fault condition.

4.2 Electrical requirements

4.2.1 General

Electrical installations added to the base vehicle shall comply with those clauses of IEC 60364-7-721:2017 which are applicable to road ambulances. For the supply system of the medical equipment EN 60601-1:2006+A1:2013 and EN 60601-1-12:2015 Clause 11 shall apply.

4.2.2 Electromagnetic compatibility (EMC)

Communication equipment (e.g. radio installation) shall comply with national regulations.

To minimize any risk of the safe operation of the complete road ambulance and any of the equipment operated on or in the vehicle from the effects of electromagnetic influences created by the vehicle or its equipment, the complete operational vehicle should consist of components, equipment or sub systems that comply or are certified as conforming to the respective industry EMC regulations.

NOTE A road ambulance as supplied and certified may not be fully equipped and therefore some responsibility for added equipment after conversion rests with the customer/user.

4.2.3 Battery and alternator

Batteries shall be positioned to allow maintenance without removing the battery from its securing device. The construction of the battery and all connections to it shall be such as to prevent any possibility of an inadvertent short circuit.

For types A2, B and C road ambulances the electrical system shall be capable of holding a reserve of electrical power for restarting the engine.

The characteristics of the alternator, the starter batteries as well as additional batteries, if fitted, shall comply with Table 1.

Additional batteries may be required to power the medical devices carried on board and the intended use of the road ambulance.

Table 1 — Minimum capacity/power

		Type of road ambulance			
		A_1	A_2	B	C
Starter battery(ies)	Nominal voltage 12 V	54 Ah	54 Ah up to 4 seats and 80 Ah for more than 4 seats in the patient compartment	80 Ah	80 Ah
	Nominal voltage 24 V	–	–	63 Ah (2 × 12 V)	63 Ah (2 × 12 V)
Additional battery(ies)[b]	Nominal voltage 12 V	–	–	80 Ah[a]	80 Ah
	Nominal voltage 24 V	–	–	63 Ah[a] (2 × 12 V)	63 Ah (2 × 12 V)
Alternator power		700 W	700 W	1 200 W	1 200 W

[a] Recommended for special operational conditions.

[b] Additional batteries shall have high cyclic stability (e.g. gel batteries) and shall be be of a sealed type.

When the engine is idling electrical stability should be maintained between electrical load and alternator output. In order to achieve this it may be necessary to fit an electrical load prioritization device to the vehicle.

4.2.4 Electrical installation

4.2.4.1 In type B and C road ambulances there shall be a recessed externally mounted power connector to enable external power to be provided for operations such as the following:

— charging battery(ies);

— operating medical devices, when installed;

— operating a patient compartment heater, when installed;

— operating an engine preheater, when installed.

The connector for 110 V or 220/240 V shall be a male connector and not interfere with the electrical and mechanical safety.

It shall not be possible to start the engine whilst it is connected to an external power supply unless an automatic mechanical disconnection is fitted.

If no automatic mechanical disconnection is fitted, the connector shall be on the driver's side.

The 110 V or 220/240 V circuit shall be protected either by an "earth leakage device" with a maximum setting of 30 mA or by a separate transformer. If the protection is given only by an "earth leakage device" there shall be a label near the plug that reads as follows: "CAUTION! CONNECT ONLY TO AN AUTHORISED SOCKET."

4.2.4.2 A minimum number of separately protected 12 V DC outlets shall be available according to Table 2. The outlets shall be available for medical equipment and located in the area of storage and/or used by the medical device. The nominal voltage shall be 13,8 V. Voltage fluctuations shall not exceed the range of 12,4 V and 15,1 V.

The power supply shall continuously supply the medical devices with electrical power with the engine running. The outlets for the medical devices shall be labelled with the nominal voltage and current rating. The outlets shall have a visible indication under intended operational conditions in order to show if there is power on the outlet.

If the road ambulance is intended to carry a transport incubator system it shall have a four-pole connector as specified in EN 13976-1:2018, Clause 4.2.3, Figure 3.

Table 2 — 12 V connections for medical devices in patient's compartment

	Type of road ambulance							
	A1		A2		B		C	
Minimum number of connections	1	1	1	1	3	1	3	1
Minimum capacity in Ampere	10	15	10	15	10	15	10	15

4.2.4.3 Any additional electrical systems fitted to the base vehicle shall be separate from the base vehicle electrical system and the body or chassis shall not be used as an earth return for additional circuits.

All circuits in the additional system(s) shall have separate overload protection. All circuits shall be well defined and cables clearly marked at the connection points and at a maximum of 1 m intervals along its length.

NOTE Overload protection can consist of either fuses or so called Electronic Management Control systems.

The system shall have enough circuits and be so constructed that when/if a circuit fails the patient treatment area shall remain illuminated and at least one power supply source for medical technical equipment shall still work.

Every power socket in the patient compartment shall be fitted with a permanently visible indicator light to confirm that there is power to the socket.

4.2.4.4 The wiring and, where applicable conduits, shall withstand vibrations. No wiring shall be located in or pass through conduit intended for medical gas installation. The wiring shall not be loaded higher than that stated by the wire manufacturer.

4.2.4.5 Where there are different voltage systems, the connections shall be non-interchangeable.

4.2.5 Visual warning light and audible siren warning system

4.2.5.1 General

The vehicle shall be fitted with a visual warning and audible warning system to assist emergency passage.

4.2.5.2 Warning lights

The vehicle shall have 360-degree visibility of warning lights around the vehicle.

Recommended additional warning lights for type B and type C road ambulances are:

— additional warning lights facing forward, sideways of the vehicle (front and rear corner) and facing backwards to ensure traffic safety and high visibility in heavy traffic.

4.2.5.3 Audible warning siren systems

The vehicle shall have an audible warning siren system additional to the warning lights. The audible warning siren system shall activate the visual warning light.

The audible alarm can only be in function if the visible alarm is in operation.

4.2.6 Audible reversing alarm

The ambulance shall be fitted with an audible reversing warning alarm, activated by the selection of the reverse gear. This function shall be possible to disable from the driver seating position.

There shall be a system enabling the driver to detect obstacles behind.

4.2.7 Exterior illumination lights

Exterior lighting with a minimum of 5 lx illuminating the surrounding the patient compartment area according to Figure 1 shall be provided. It shall be measured at the surface of the floor.