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Medical vehicles and their equipment - Road ambulances

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Véhicules de transport sanitaire et leurs équipements - Véhicule d'ambulances

Rettungsdienstfahrzeuge und deren Ausrüstung - Krankenkraftwagen

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Foreword

This document (prEN 1789:2004) 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 1789:1999.

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 93/44/EEC.

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

Introduction

This European Standard specifies definitions, requirements, testing and equipment related to the transport and care of patients in road ambulances. It contains requirements on the patient's compartment, medical devices and_characteristics related to the staff. The standard does not cover the requirements for approval and registration of the vehicle and the training of the staff which is the responsibility of the authority/authorities in the country where the ambulance is to be registered.

Road ambulances fall under the following categories:

— Type A_1: patient transport ambulance suitable for transport of single patient

— Type A_2: patient transport ambulance suitable for transport of one or more patient(s) (on stretcher(s)/chair(s))

— Type B: emergency ambulance

— Type C: mobile intensive care unit

1 Scope

This European Standard specifies requirements for the design, testing, performance and equipping of road ambulances used for the transport of sick or injured persons. This standard is applicable to road ambulances capable of transporting at least one person on a stretcher.

Requirements are specified for categories of road ambulances based in increasing order of the level of treatment that can be carried out. These are the patient transport ambulance (types A_1 A_2), the emergency ambulance (type B) and the mobile intensive care unit (type C).

This standard 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 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 3-1, *Portable fire extinguishers — Part 1: Description, duration of operation, class A and B fire tests.*

EN 344, *Requirements and test methods for safety, protective and occupational footwear for professional use.*

EN 420, *General requirements for gloves.*

EN 443, *Helmets for firefighters.*

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

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

EN 471:1994, *High-visibility warning clothing.*

EN 737-1:1998, *Medical gas pipeline systems — Part 1: Terminal units for compressed medical gases and vacuum.*

EN 737-2:1998, *Medical gas pipeline systems — Part 2: Anaesthetic gas scavenging disposal systems — Basic requirements.*

EN 737-3:1998, *Medical gas pipeline systems — Part 3: Pipelines for compressed medical gases and vacuum.*

EN 737-4:1998, *Medical gas pipeline systems — Part 4: Terminal units for anaesthetic gas scavenging systems.*

ENV 737-6:2003, *Medical gas pipeline systems — Part 6: Dimensions and allocation of probes for terminal units for compressed medical gases and vacuum.*

EN 738-1, *Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow metering devices.*

EN 738-3, *Pressure regulators for use with medical gases — Part 3: Pressure regulators integrated with cylinder valves.*

EN 739, *Low-pressure hose assemblies for use with medical gases.*

EN 740:1998, *Anaesthetic workstations and their modules ––Particular requirements.*

EN 793:1997, *Particular requirements for safety of medical supply units.*

EN 794-3, *Lung ventilators — Part 3: Particular requirements for emergency and transport ventilators.*

EN 850, *Transportable gas cylinders — Pin-index, yoke-type valve outlet connections for medical use.*

EN 864. *Medical electrical equipment — Capnometers for use with humans — Particular requirements.*

EN 865, *Pulse oximeters — Particular requirements.*

EN 980, *Graphical symbols for use in the labelling of medical devices.*

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

EN 1865, *Specifications for stretchers and other patient handling equipment used in ambulances.*

EN 12218, *Rail systems for supporting medical equipment.*

EN 12470-1, *Clinical thermometers — Part 1: Metallic liquid-in-glass thermometers with maximum device.*

EN 60601-1:1990, *Medical electrical equipment — Part 1: General requirements for safety (IEC 60601-1: 1988).*

EN 60601-1-2, *Medical electrical equipment — Part 1: General requirements for safety; 2. collateral standard: electromagnetic compatibility; Requirements and tests (IEC 60601-1-2:1993).*

EN ISO 8185, *Humidifiers for medical use — General requirements for humidification systems (ISO 8185:1997).*

EN ISO 10079-1:1999, *Medical suction equipment — Part 1: Electrically powered suction equipment — Safety requirements (ISO 10079-1:1999).)*

EN ISO 10079-2:1999, *Medical suction equipment — Part 2: Manually powered suction equipment (ISO 10079-2:1999).*

EN ISO 10079-3:1999, *Medical suction equipment — Part 3: Suction equipment powered from a vacuum or pressure source (ISO 10079-3:1999).*

prEN ISO 15002, *Flow-metering devices for connection to terminal units of medical gas pipeline systems (ISO/DIS 15002:1996).*

IEC 60068-2-6, *Environmental testing — Part 2: Tests; Test Fc: Vibration (sinusoidal).*

IEC 60068-2-29, *Basic environmental testing procedures — Part 2: Tests; Test Eb and guidance: Bump.*

IEC 60068-2-32, *Basic environmental testing procedures — Part 2: Tests; Test Ed: Free fall.*

IEC 60068-2-36, *Basic environmental testing procedures — Part 2: Tests; Test Fdb: Random vibration wide band — Reproducibility medium.*

IEC 60601-2-4, *Medical electrical equipment — Part 2: Particular requirements for the safety of cardiac defibrillators and cardiac defibrillator-monitors.*

ISO 3795, *Vehicles, 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 standard, the following definitions apply:

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
Ambulance
Vehicle or craft intended to be crewed by a minimum of two appropriately trained staff for the provision of care and transport of at least one stretchered patient

3.3
Types of road ambulances[1)]

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

Two types of patient transport ambulance exist:

Type A_1: suitable for transport of single patient

Type A_2: suitable for transport of one or more patient(s) (on stretcher(s) and/or chair(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

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1) Road ambulances are road vehicles which comply with type approval for special use vehicles according to Directive 70/156/EEC in the last applicable amended version.

3.4
Net vehicle mass; unladen mass
Net vehicle mass according to 70/156/EEC of the road ambulance including the driver taken as 75 kg and all fixed installations

NOTE Loose portable patient handling, sanitary, medical and technical equipment is not included in net vehicle mass.

3.5
Permissible gross vehicle mass (total mass)
Permissible gross vehicle mass is the technically permissible maximum laden mass as defined in Directive 70/156/EEC should be defined by the chassis manufacturer. Permissible gross mass includes the net mass (see 3.4) and additionally the sanitary, medical and technical equipment and persons (75 kg per person) as well as any eventual mass reserve

3.6
Loading capacity
Difference between the gross vehicle mass and the net vehicle mass.

NOTE This represents the mass that may be distributed on the road ambulance such that the permissible wheel loads are not exceeded.

3.7
Fixation system
An item of equipment or medical device permanently secured direct or by use of a fixation kit to the vehicle.

3.8
Maintain system
A bracket or other interface device used to secure a mobile or transportable item of equipment or medical device of the vehicle. The item of equipment or medical device is removable without the use of tools from the bracket or interface.

4 Requirements

4.1 General requirements

The road ambulance shall comply with the requirements of Directive 70/156/EEC, and separate directives, for ambulances or corresponding national requirements for approval of vehicles.

4.1.1 General

4.1.2 Maximum overall dimension

The maximum overall dimensions shall be in accordance with the following:

Length: according to Directive 70/156/EEC

Height: 3 000 mm (measured at net vehicle mass excluding flexible antenna)

Width: according to Directive 70/156/EEC

4.1.3 Wheelarch clearance

Vehicle converters shall maintain the minimum wheelarch clearance recommended by the chassis manufacturer.

4.2 Performance

4.2.1 Acceleration

A road ambulance loaded to permissible gross vehicle mass shall be able to accelerate from 0 km/h to 80 km/h within 35 s.

4.2.2 Braking

An original equipment manufacturer's anti-lock braking system shall be fitted.

4.2.3 Safety System

The vehicle should be fitted with a control system for stabilisation and a passive safety system.

4.3 Electrical requirements

4.3.1 General

To minimise any risk to the safe operation of the complete ambulance and any of the equipment operated on or in the vehicle from the effects of electromagnetic influences created by the vehicle or it's equipment, each item shall comply with the appropiate EMC regulation(s).

The complete operational vehicle shall consist of components, equipment or sub systems that are certified as conforming to the respective industry EMC regulations.

Additionally for the supply system of the medical equipment the EN 60601 series shall apply.

There shall be both an optical and acoustical warning system.

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

4.3.1.2 The vehicle's electric/electronic system, components, sub systems and all permanently fixed equipments shall be e-marked in accordance with directive 95/54/EC.

NOTE It is recommended that the elctrical medical equipment can withstand the exposure of radiated RF field strenght of 20 V/m, measured according to IEC 60601-1-2, be considered as minimum acceptable limit.

4.3.2 Battery and alternator

Batteries shall be positioned to allow service and maintance 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 A_2, B and C road ambulances the electrical system shall be capable of holding a reserve of electrical power for restarting the engine.

Minimum battery and alternator ratings shall be in accordance with table 1.

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 more than 4 seats in the compartment	80 Ah	80 Ah
	nominal voltage 24 V	–	–	63 Ah (2×12 V)	63 Ah (2×12 V)
additional [b] battery(ies)	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	1200 W	1200 W

[a] recommended for special operational conditions.

[b] additional batteries shall have high cyclic stability (e.g. gel batteries).

NOTE 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 prioritisation device to the vehicle.

4.3.3 Electrical installation

4.3.3.1 In type B and C road ambulances there shall be a recessed externally mounted connector to enable and/or operate, for example:

— a battery(ies)

— medical devices when installed;

— a patient compartment heater when installed;

— an engine preheater when installed.

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

It shall be not possible to start the engine whilst it is connected to an external 220/240 V 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 110V 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 AUTHORIZED SOCKET."

4.3.3.2 The patient's compartment shall be fitted with the minimum number of connections as given in table 2. For these connections a permanent power supply shall exist.