SLOVENSKI STANDARD
SIST EN 1789:2007+A2:2015

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Medicinska vozila in pripadajoča oprema - Cestna reševalna vozila

Medical vehicles and their equipment - Road ambulances

Rettungsdienstfahrzeuge und deren Ausrüstung - Krankenkraftwagen

Véhicules de transport sanitaire et leurs équipements - Ambulances routières

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11.160	Prva pomoč	First aid
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Medical vehicles and their equipment - Road ambulances

Véhicules de transport sanitaire et leurs équipements - Ambulances routières

Rettungsdienstfahrzeuge und deren Ausrüstung - Krankenkraftwagen

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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Foreword

This document (EN 1789:2007+A2:2014) 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of an identical text or by endorsement, at the latest by March 2015, and conflicting national standards shall be withdrawn at the latest by March 2015.

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.

This document includes Amendment 1, approved by CEN on 2010-03-06 and Amendment 2, approved by CEN on 2014-07-14.

This document supersedes [A2] EN 1789:2007+A1:2010 [/A2].

The start and finish of text introduced or altered by amendment is indicated in the text by tags [A1] [/A1] and [A2] [/A2].

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.

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

Introduction

In the development of the European standard EN during the 90's, Directive 70/156/EEC has been considered.

In October 2009, CEN/TC 239 appointed an ad-hoc group to evaluate the impact of the Directive 2007/46/EC which replaces Directive 70/156/EEC, on EN 1789:2007 and to assess its application in different member countries of CEN.

Moreover the definition of ambulance of the COMMISSION REGULATION (EU) No 678/2011 (14 July 2011 replacing Annex II and amending Annexes IV, IX and XI to Directive 2007/46/EC) refers to EN 1789:2007.

The appointed ad-hoc group reported its findings as follows:

— EN 1789:2007 has not been applied consistently by notified bodies since the text for verifying compliance is open to interpretation and may cause difficulties to Technical Services (TS) as defined in Directive 2007/46/EC, EN 1789:2007 or local authorities;

— these differences can lead to declarations that the same ambulance complies or does not comply with EN 1789:2007;

— manufacturers of ambulances may have the same problems of interpretation in the design of their ambulances;

— users of ambulances may have the same problems of interpretation that affects their responsibility.

This second amendment[1)] gives an answer to questions concerning the application of EN 1789:2007 and avoids differences in interpretation between such notified bodies to check compliance of vehicles specially adapted to medical transportation (Road ambulances).

NOTE Such as the demonstration of compliance to the requirements of 4.5.9 or 4.3.

1) The first amendment published in 2010 only updates Table ZA.1 to consider the revision of Directive 93/42/EEC.

1 Scope

This European Standard specifies requirements for the design, testing, performance and equipping of road ambulances used for the transport and care of patients. It contains requirements for the patient's compartment.

This European 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.

This European 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 European 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.

[A2⟩ EN 3-7:2004+A1:2007 ⟨A2], *Portable fire extinguishers — Part 7: Characteristics, performance requirements and test methods*

[A2⟩ EN 420:2003+A1:2009 ⟨A2], *Protective gloves — General requirements and test methods*

[A2⟩ EN 455-1:2000 ⟨A2], *Medical gloves for single use — Part 1: Requirements and testing for freedom from holes*

[A2⟩ EN 455-2:2009+A2:2013 ⟨A2], *Medical gloves for single use — Part 2: Requirements and testing for physical properties*

[A2⟩ *deleted text* ⟨A2]

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

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

[A2⟩ *deleted text* ⟨A2]

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

[A2⟩ *deleted text* ⟨A2]

[A2⟩ EN 1041:2008+A1:2013, *Information supplied by the manufacturer of medical devices* ⟨A2]

[A2] EN 1865-1:2010, *Patient handling equipment used in road ambulances — Part 1: General stretcher systems and patient handling equipment* [A2]

[A2] EN 1865-2:2010, *Patient handling equipment used in road ambulances — Part 2: Power assisted 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* [A2]

[A2] EN 12470-1:2000+A1:2009 [A2], *Clinical thermometers — Part 1: Metallic liquid-in-glass thermometers with maximum device*

[A2] EN 13501-1:2007+A1:2009, *Fire classification of construction products and building elements — Part 1: Classification using test data from reaction to fire tests* [A2]

[A2] EN 13544-1:2007+A1:2009 [A2], *Respiratory therapy equipment — Part 1: Nebulizing systems and their components*

[A2] EN 14052:2012+A1:2012 [A2], *High performance industrial helmets*

[A2] EN 60068-2-6:2008, *Environmental testing — Part 2-6: Tests — Tests Fc: Vibration (sinusoidal) (IEC 60068-2-6:2007)* [A2]

[A2] EN 60068-2-29:1993 [A2], *Basic environmental testing procedures — Part 2: Tests; test Eb and guidance: bump (IEC 60068-2-29:1987)*

EN 60068-2-32, *Basic environmental testing procedures — Part 2: Tests; test Ed: free fall (IEC 60068-2-32:1975 + A1:1982 + A2:1990)*

[A2] EN 60068-2-64:2008, *Environmental testing — Part 2-64: Tests — Test Fh: Vibration, broadband random and guidance (IEC 60068-2-64:2008)* [A2]

EN 60601-1, *Medical electrical equipment*

EN 60601-2, *Medical electrical equipment*

[A2] 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)* [A2]

[A2] EN ISO 407:2004 [A2], *Small medical gas cylinders - Pin-index yoke-type valve connections (ISO 407:2004)*

[A2] *deleted text* [A2]

[A2] EN ISO 5359:2008, *Low-pressure hose assemblies for use with medical gases (ISO 5359:2008)* [A2]

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)*

[A2] EN ISO 10524-1:2006 [A2], *Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow-metering devices (ISO 10524-1:2006)*

EN ISO 10524-3:2006, *Pressure regulators for use with medical gases — Part 3: Pressure regulators integrated with cylinder valves (ISO 10524-3:2005)*

EN ISO 11197:2004, *Medical supply units (ISO 11197:2004)*

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 15223-1:2012, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements (ISO 15223-1:2012)*

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

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

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

deleted text

EN ISO 80601-2-55:2011, *Medical electrical equipment — Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors (ISO 80601-2-55:2011)*

EN ISO 80601-2-61:2011, *Medical electrical equipment — Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment (ISO 80601-2-61:2011)*

EN IEC 60364-7-721:2007, *Low-voltage electrical installations — Part 7-721: Requirements for special installations or locations — Electrical installations in caravans and motor caravans (IEC 60364-7-721:2007-04)*

deleted text

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.

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[2)]
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 a 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

3.4
net vehicle mass
〚A2〛 *deleted text* 〚A2〛
〚A2〛 *deleted text* 〚A2〛 mass according to 92/21/EEC modified 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 are not included in net vehicle mass.

〚A2〛 **3.5**
ambulance loading capacity
difference between the permissible gross vehicle mass and the mass according to 92/21/EEC modified of the road ambulance including the driver taken as 75 kg and all fixed installations, mass reserve according to 4.5.10 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. 〚A2〛

〚A2〛 *deleted text* 〚A2〛

〚A2〛 **3.6** 〚A2〛
fixation system
system or device to ensure the permanent fixation of medical devices or other equipment into the ambulance

〚A2〛 **3.7** 〚A2〛
maintain system
bracket or other interface device used to secure a mobile or transportable item of equipment or medical device of the vehicle without the use of tools

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2) Road ambulances are road vehicles which comply with type approval for special use vehicles according to 〚A2〛 Directive 2007/46/EEC 〚A2〛 in the last applicable amended version.

3.8
Technical Service (TS)
body authorized according to directive 2007/46/EEC to decide the conformity of the ambulance as a road vehicle

3.9
means of verification (MoV)
deliverables or tests to be performed to allow the technical service to establish the compliance of the ambulance to EN 1789:2007 in the context of the vehicle type approval

3.10
non equipped ambulance
ambulance without any equipment as listed in Table 9 to Table 19

Note 1 to entry: Stretcher support as defined in EN 1865-5:2012 is included in the non-equipped ambulance.

4 Requirements

4.1 General requirements

4.1.1 General

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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 in accordance with EN ISO 14971:2012 and which is connected with their intended application, in normal condition and in single fault condition.

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4.1.2 Maximum overall dimensions

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

— length in accordance with Directive 92/21/EEC modified;

— height 3 000 mm (measured at net vehicle mass excluding flexible antenna);

— width in accordance with Directive 92/21/EEC modified.

4.1.3 Wheel arch clearance

Vehicle converters shall maintain the minimum wheel arch clearance specified by the chassis manufacturer.

4.2 Performance-braking and acceleration

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.

NOTE Examples of a control system for stabilisation are an electronic brake distribution system and traction control. Examples of a passive safety system could be an air bag, a collapsible steering column and an energy absorbing body structure.'

4.3 Electrical requirements

4.3.1 General

[A2⟩ Electrical installations added to the one of the base vehicle shall comply with those clauses of IEC 60364-7-721:2007 which are applicable to ambulances. ⟨A2]

[A2⟩

4.3.2 Electromagnetic compatibility (EMC) – Communication equipment

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

For the supply system of the medical equipment the EN 60601-1 and EN 60601-2 series shall apply.

To minimize 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 its equipment, the complete operational vehicle should consists of components, equipment or sub systems that complies or are certified as conforming to the respective industry EMC regulations.

NOTE An ambulance as supplied and certified may not be fully equipped and therefore some responsibility for added equipment after conversion rests with the customer/user. ⟨A2]

4.3.3 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 A_2, 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 starter batteries shall comply with Table 1. The characteristics of additional batteries, if fitted, shall comply with Table 1.

NOTE 1 Additional batteries may be required to power the medical devices carried on board and the intended use of the ambulance.

The characteristics of the alternator shall comply 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	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 of a sealed type.

NOTE 2 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 [A2] prioritization [A2] device to the vehicle.

4.3.4 Electrical installation

4.3.4.1 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 be not possible to start the engine whilst it is connected to an external [A2] *deleted text* [A2] 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."

4.3.4.2 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.