

SLOVENSKI STANDARD SIST EN 1789:2000

01-julij-2000

Medicinska vozila in njihova oprema - Reševalna vozila

Medical vehicles and their equipment - Road ambulances

Rettungsdienstfahrzeuge und deren Ausrüstung - Krankenkraftwagen

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

Ta slovenski standard je istoveten z: EN 1789:1999

SIST EN 1789:2000

https://standards.iteh.ai/catalog/standards/sist/fc9306a1-fdd7-416f-9b26-f482cb75060e/sist-en-1789-2000

ICS:

11.160 Prva pomoč First aid

43.160 Vozila za posebne namene Special purpose vehicles

SIST EN 1789:2000 en

SIST EN 1789:2000

iTeh STANDARD PREVIEW (standards.iteh.ai)

SIST EN 1789:2000

EUROPEAN STANDARD NORME EUROPÉENNE EUROPÄISCHE NORM

EN 1789

October 1999

ICS 11.160; 43.160

English version

Medical vehicles and their equipment - Road ambulances

Véhicules de transport sanitaire et leurs équipements - Véhicule d'ambulances Rettungsdienstfahrzeuge und deren Ausrüstung -Krankenkraftwagen

This European Standard was approved by CEN on 5 September 1999.

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. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.



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

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

Contents

	Pa	age
Foreword		
TOICWOIG		
		4
Introduction	on	
1	Scope	
2	Normative references	4
3	Definitions	7
3.1	Patient and emergency patient	7
3.1.1	Patient	7
3.1.2	Emergency patient	7
3.2	Ambulance	7
3.3	Types of road ambulances	7
3.3.1	Type A: patient transport ambulance	7
3.3.2	Type B: emergency ambulance	7
3.3.3	Type C: mobile intensive care unit	7
3.4	Net vehicle mass; unladen mass	7
3.5	Permissible gross vehicle mass (total mass)	7
3.6	Loading capacity	7
4	Requirements	7
4.1	General requirements	7
4.1.1	General	8
4.1.2	Maximum overall dimension	8
4.1.3	Wheelarch clearance	8
4.2	Performance	8
4.2.2	Braking	8
4.3	Electrical requirements	8
4.3.1	General	8
4.3.2	Battery and generator	8
4.3.3	Electrical installation	9
4.3.4	Communication systems (radio installation)	10
4.4	Vehicle body	10
4.4.1	Fire safety	
4.4.2	Driver's seat configuration	10
4.4.3	Minimum loading capacity	12
4.4.4	Bulkhead	13
4.4.5	Emergency exits	13
4.4.6	Openings (doors, windows)	13
4.4.7	Loading area	14
4.5	Patient's compartment	
4.5.1	General	14
4.5.2	Patient's compartment dimensions	15
4.5.3	Patient's compartment dimensions Patient and attendant seating A.N.D.A.R.D.P.R.F.V.I.F.W	19
4.5.4	Ventilation and anaesthetic das scavending systems	19
4.5.5	Heating system (standards.iteh.ai)	19
4.5.6	Interior lighting	20
4.5.7	Interior noise level	20
4.5.8	Holding system for infusion	20
4.5.9	Maintain systems and fixations of the equipment in the patient's compartment Testing	20
5	Testing	20
5.1	Testing of the interior noise level	20
5.2	Testing of the acceleration	
5.3	Testing of maintain systems and fixations of the equipment in the patient's compartment	
6	Medical devices	
6.1	Provision with medical devices	
6.2	Medical devices storage	22
6.3	Requirements for medical devices	
6.3.1	General	
6.3.2	Temperature	
6.3.3	Humidity and ingress of liquids	23

SIST EN 1789:2000

	EN 1789:1999
6.3.4	Mechanical strength
6.3.5	Fixation of devices
6.3.6	Electrical safety 23
6.3.7	Electromagnetic compatibility
6.3.8	User interface
6.3.9	Gas installation
6.3.10	Marking and instructions
6.3.11	Maintenance 29
6.4	Mechanical strength - Test methods for medical devices for use in road ambulances
6.4.1	Vibration and bump test
6.4.2	Free fall
6.5	List of equipment
Annex A	(informative) Bibliography
Annex ZA	(informative) Clauses of this European Standard addressing Essential Requirements or other
	provisions of Council Directive 93/42/EEC concerning medical devices
	·

Page 3

iTeh STANDARD PREVIEW (standards.iteh.ai)

SIST EN 1789:2000

Page 4 EN 1789:1999

Foreword

This European Standard 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 April 2000, and conflicting national standards shall be withdrawn at the latest by April 2000.

This European Standard 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 standard.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

This European Standard specifies definitions, requirements, testing and equipment for road ambulances. Road ambulances fall under the following categories:

- Type A1: suitable for transport of single patient
- Type A2: suitable for transport of one or more patient(s) (on stretcher(s)/chair(s))
- Type B: emergency ambulance
- Type C: mobile intensive care unit

This standard specifies also the mechanical strength requirements for medical devices. This includes stretchers located in the stretcher holding assembly.

NOTE 1: "The stretcher holding assembly" is the means by which the stretcher is directly or indirectly fixed to the vehicle.

NOTE 2: Standardisation work will continue with the aim of ensuring the safe transfer of patients and equipment without compromising continuity of patient care and the safety of staff.

1 Scope

This European Standard specifies requirements for the design, test methods, 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 used in road ambulances and outside hospitals and clinics in situations where the ambient conditions can differ from normal indoor conditions.

2 Normative references

This European Standard incorporates by dated or undated reference provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to, or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to 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 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

prEN 737-6: 1998

Medical gas pipeline systems - Part 6: Dimensions 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

Particular requirements for safety of medical supply units

Lung ventilators – Part 3: Particular requirements for emergency and transport ventilators

(standards.iteh.ai)

Transportable gas cylinders - Pin-index, yoke-type valve outlet connections for medical use SIST EN 1789:2000

EN 864

https://standards.iteh.ai/catalog/standards/sist/fc9306a1-fdd7-416f-9b26-

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

Information supplied by the manufacturer with medial devices

Page 6

EN 1789:1999

EN 1865

Specifications for stretchers and other patient handling equipment used in ambulances

EN 12218

Rail systems for supporting medical equipment

prEN 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 10079-1

Medical suction equipment - Part 1: Electrically powered suction equipment - Safety requirements (ISO 10079-1: 1991, including Technical Corrigendum 1:1992 and Technical Corrigendum 2:1993)

EN ISO 10079-2

Medical suction equipment - Part 2: Manually powered suction equipment (ISO 10079-2: 1992)

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

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 60364-7-708

Electrical installations for buildings - Part 7: Requirements for special installations or locations; Section 708: Electrical installations in caravan parks and caravans

IEC 60601-2-4

Medical electrical equipment - Part 2: Particular requirements for the safety of cardiac defibrillators and cardiac defibrillator-monitors

EN ISO 3785

Steel - Designation of test piece axes (ISO 3785:1976)

PREVIEW

ISO 5128: 1980

(standards.iteh.ai)

Acoustics - Measurement of noise inside motor vehicles

https://standards.iteh.ai/catalog/standards/sist/fc9306a1-fdd7-416f-9b26-**EN ISO 8185**

Humidifiers for medical use - General requirements for humidification systems (ISO 8185:1997)

prEN ISO 15002

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

3 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 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 ambulances¹⁾

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 A₁: suitable for transport of single patient

Type A₂: 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; unladen mass

Mass 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 mass according to 70/156/EEC 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. https://standards.iteh.ai/catalog/standards/sist/tc9306a1-fdd7-416f-9b26-

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

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.

Page 8 EN 1789:1999

4 Requirements

4.1 General requirements

The road ambulance shall comply with the relevant regulation for special use vehicles (see footnote 1).

4.1.1 General

4.1.2 Maximum overall dimension

The maximum overall dimensions shall not exceed the following:

Length: 6500 mm

Height: 3000 mm (measured at net vehicle mass excluding flexible antenna)

Width: 2200 mm (measured excluding external fold back mirrors)

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 with gross vehicle mass shall be able to accelerate from 0 km/h to 80 km/h within 35 s.

Type B and C road ambulances with gross vehicle mass up to 3,5 t shall be able to accelerate from 40 km/h to 80 km/h (in the 3rd or 4th gear, 4th or 5th gear where 5-speed transmission is fitted) within 27 s.

4.2.2 Braking

An anti-lock braking system should be fitted.

4.3 Electrical requirements

4.3.1 General

The electrical installation shall be constructed to operate safely as specified in 4.3.2 to 4.3.4. 220/240 V installations shall conform to IEC 60364-7-708.

There shall be both an optical and acoustical warning system according to relevant national regulations to alert others of the presence of the vehicle.

4.3.2 Battery and generator

Batteries shall be positioned to allow the electrolyte level and the relative density to be checked 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.

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

(standards.iteh.ai)

SIST EN 1789:2000

Table 1: Minimum capacity/power

Type of road ambulance		A ₁	A_2	В	С
starter battery(ies)	nominal voltage 12 V	54 Ah	54 Ah up to 4 seats and 120 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	nominal voltage	-	-	80 Ah²)	80 Ah
battery(ies)	nominal voltage	-	-	63 Ah² (2 × 12 V)	63 Ah (2 × 12 V)
generator power		700 W	700 W	910 W	960 W 1200 W''

[&]quot; recommended for extreme climatic zones

4.3.3 Electrical installation

4.3.3.1 In type B and C road ambulances there shall be an externally mounted connector to enable charging of the battery(ies) and other equipment, e. g. medical devices, to preheat the engine (if this equipment is installed) while stationary and to heat the patient compartment.

Where the connector is for 220/240 V, the male connector shall be fitted towards the front of the road ambulance

- a) on the driver's side,
- b) or allow automatic disconnection provided it does not interfere with the electrical and mechanical safety.

The 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."

It shall not be possible to start the vehicle whilst it is connected to an external 220/240 V (if the connector is located at the side of the vehicle) power supply.

SIST EN 1789:2000

4.3.3.2 The patient's compartment shall be fitted with the minimum number of sockets as given in table 2.

f482cb75060e/sist-en-1789-2000

²⁾ recommended for special operational conditions

Page 10 EN 1789:1999

Table 2: 12 V sockets for medical device in patient's compartment

Type of road ambulance	A ₁	A_2	В	С
minimum number of sockets	1	1	2	3

- 4.3.3.3 All circuits within the patient's compartment shall have separate fuses or circuit-breakers readily available. The fuses or circuit-breakers shall be clearly marked and the function of each circuit clearly identified. There shall be at least two circuits so that failure in one circuit does not cut off all lights or connected medical devices. The wiring shall withstand more than the full load of the fuse or circuit-breaker.
- 4.3.3.4 The wiring and where applicable conduits shall withstand vibration. No wiring shall be located in or pass through compartment intended for medical gas installation.
- 4.3.3.5 Where there are different voltage systems, the outlets shall be non-interchangeable.
- The electrical generator shall be capable of delivering a constant supply of 40 % of the generator power 4.3.3.6 specified in table 1 when the road ambulance is stationary.
- 4.3.3.7 The electrical system in road ambulances shall consist of at least four separate sub-systems as follows:
 - a) Basic system in non-equipped vehicle
 - b) Supply system for specific body mounted devices
 - c) Supply system for patient compartment
 - d) Supply system for communications

Apart from the basic system, the road ambulance body shall not be used as part of any of the supply systems.

Communication systems (radio installation)

Road ambulances shall be equipped with a communication system which conforms to relevant current national regulations.

Transceivers for use during transportation shall be permanently installed and connected to external antenna(e). They shall be electromagnetically compatible.

NOTE: Attention is drawn to Directive 89/336/EEC on electromagnetic compatibility.

4.4 Vehicle body

4.4.1 Fire safety

All interior materials shall have a burning rate of less than 100 mm/minute when tested in accordance with EN ISO 3785. iTeh STANDARD PREVIEW

Driver's seat configuration standards.iteh.ai) 4.4.2

The seating dimensions shall be in accordance with table 3.

SIST EN 1789:2000