STANDARD SHQIPTAR

SSH EN 1789:2020+A1:2023

Automjetet mjekësore dhe pajisja e tyre - Autoambulancat

Medical vehicles and their equipment - Road ambulances

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Hyrje

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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

This European Standard was approved by CEN on 13 April 2020 and includes Amendment approved by CEN on 21 September 2023. This European Standard was corrected and reissued by the CEN-CENELEC Management Centre on 31 January 2024.

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

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European foreword

This document (EN 1789:2020+A1:2023) 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of an identical text or by endorsement, at the latest by June 2024, and conflicting national standards shall be withdrawn at the latest by June 2024.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

▌A1⟩ This document supersedes EN 1789:2020 ⟨A1▐.

This document includes Amendment 1, approved by CEN on 2023-09-21.

The start and finish of text introduced or altered by amendment is indicated in the text by tags ▌A1⟩ ⟨A1▐

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.

Any feedback and questions on this document should be directed to the users’ national standards body. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organisations 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, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Introduction

Road ambulances are subject to a higher risk in use. The exact circumstances of operation cannot always be planned or anticipated in detail.

Vehicles are designed so as to be safe. Design requirements can be derived from European and national occupational safety and health legislation.

Under EU law, employers are responsible for carrying out a risk assessment (89/391/EEC, OSH framework directive) and for provision of safe work equipment (89/655/EEC, use of work equipment directive) that allows employees to work without their health being at risk.

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

〚A1〉 This revision in 2020 had two key objectives: 〈A1〛

— 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.

〚A1〉 The previous edition EN 1789:2007+A2:2014 〈A1〛 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 document 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 〚A1〉 EN 1789:2020 〈A1〛 (i.e. patient's compartment) has been referenced directly in Regulation (EU) 2018/858.

〚A1〉 The energy sources for motor vehicles are in turmoil due to environmental fight against global climate warming. Alternative energies are becoming more regular in motor vehicles and electric vehicles are already common by most vehicle manufacturers.

In all standardization criteria, combustion engine characteristics have guided the requirements. Therefore, the most obvious ambulance standard requirements (EN 1789) need adjustments introduced by an Amendment to allow verification of electric engine ambulances as compliant to this document. 〈A1〛

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 patient 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.

〚A1〛 EN 16165:2021, *Determination of slip resistance of pedestrian surfaces - Methods of evaluation* 〚A1〛

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

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

〚A1〛 EN 455-1:2020+A1:2022, *Medical gloves for single use - Part 1: Requirements and testing for freedom from holes* 〚A1〛

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*

〚A1〛 EN ISO 20417:2021, *Medical devices - Information to be supplied by the manufacturer (ISO 20417:2021, Corrected version 2021-12)* 〚A1〛

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

〚A1〛 prEN 1865-2:2022[1], *Patient handling equipment used in ambulances - Part 2: Power assisted stretcher* 〚A1〛

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

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

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

[A1] EN ISO 27427:2019, *Anaesthetic and respiratory equipment - Nebulizing systems and components (ISO 27427:2013)* [A1]

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 + Cor.:2006 + Cor.:2007 + A1:2012)*

[A1] EN 60601-1-12:2015+A1:2020, *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 (IEC 60601 1 12:2014 + A1:2020)* [A1]

[A1] EN 60601-2-4:2011+A1:2019, *Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators (IEC 60601 2 4:2010 + A1:2018)* [A1]

EN 60601-2-27:2014, *Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment*

[A1] EN ISO 407:2021, *Small medical gas cylinders - Pin-index yoke-type valve connections (ISO 407:2021)* [A1]

EN ISO 5359:2014+A1:2017, *Anaesthetic and respiratory equipment - Low-pressure hose assemblies for use with medical gases (ISO 5359:2014 + Amd 1:2017)*

[A1] EN ISO 9170-1:2020, *Terminal units for medical gas pipeline systems - Part 1: Terminal units for use with compressed medical gases and vacuum (ISO 9170-1:2017)* [A1]

EN ISO 7396-1:2016+A1:2019, *Medical gas pipeline systems - Part 1: Pipeline systems for compressed medical gases and vacuum (ISO 7396-1:2016 + Amd 1:2017)*

[A1] EN ISO 10079-1:2022, *Medical suction equipment - Part 1: Electrically powered suction equipment (ISO 10079-1:2022)* [A1]

[A1] EN ISO 10079-2:2022, *Medical suction equipment - Part 2: Manually powered suction equipment (ISO 10079-2:2022)* [A1]

[A1] EN ISO 10079-3:2022, *Medical suction equipment - Part 3: Suction equipment powered from a vacuum or positive pressure gas source (ISO 10079-3:2022)* [A1]

EN ISO 10524-1:2019, *Pressure regulators for use with medical gases - Part 1: Pressure regulators and pressure regulators with flow-metering devices (ISO 10524-1:2018)*

EN ISO 10524-2:2019, *Pressure regulators for use with medical gases - Part 2: Manifold and line pressure regulators (ISO 10524-2:2018)*

EN ISO 10524-3:2019, *Pressure regulators for use with medical gases - Part 3: Pressure regulators integrated with cylinder valves (VIPRs) (ISO 10524-3:2019)*

[A1] EN ISO 11197:2019, *Medical supply units (ISO 11197:2019)* [A1]

[A1] EN ISO 14971:2019+A11:2021, *Medical devices - Application of risk management to medical devices (ISO 14971:2019)* [A1]

[A1] prEN ISO 15002:2022[1], *Flow control devices for connection to a medical gas supply system (ISO/DIS 15002:2022)* [A1]

[A1] EN ISO 15223-1:2021, *Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)* [A1]

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

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 21420:2020-06, *Protective gloves - General requirements and test methods (ISO 21420:2020)*

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)*

EN ISO 80601-2-61:2019, *Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment (ISO 80601-2-61:2017, Corrected version 2018-02)*

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

3.2
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

3.3
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

3.4
type A road ambulance
patient transport ambulance
vehicle 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)).

3.5
type B road ambulance
emergency ambulance
vehicle designed and equipped for the transport, basic treatment and monitoring of patients

3.6
type C road ambulance
mobile intensive care unit
vehicle designed and equipped for the transport, advanced treatment and monitoring of patients

3.7
net vehicle mass
<Rescue Service>
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.

3.8
road ambulance loading capacity
difference between the permissible gross vehicle mass and the net vehicle mass of the road ambulance

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.

3.9
fixation system
system or device to ensure the permanent fixation of medical devices or other equipment into the road ambulance

3.10
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

3.11
restraint system
device or combination of devices that minimize movement of the vehicle occupants during crash or major deceleration (e.g. seat belts)

3.12
patient compartment
interior section of an road ambulance for patient treatment and/or transport

4 Requirements

4.1 General requirements

Road ambulances and 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 ▌A1⟩ EN ISO 14971:2019+A11:2021 ⟨A1▌, 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 ▌A1⟩ IEC 60364-7-717:2009 ⟨A1▌ which are applicable to road ambulances. For the supply system of the medical equipment EN 60601-1:2006+A1:2013 and ▌A1⟩ EN 60601-1-12:2015+A1:2020 ⟨A1▌, Clause 11 shall apply.

4.2.2 Electromagnetic compatibility (EMC)

In order to minimize the risk to 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:

— Communication equipment (e.g. radio installation) shall comply with national and/or European regulations.

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

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 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 devices, located in the area of use and in the storage area. 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 voltage 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, subclause 4.2.3, Figure 2. In that case the nominal current needs to be assessed (minimum 23 Amp according to EN 13976-1:2018, subclause 4.1.3).

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

	Type of road ambulance							
	A_1		**A_2**		**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 identified 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 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 system and audible warning system (siren)

4.2.5.1 General

The road ambulance shall be fitted with a visual warning and audible warning system (in accordance with national regulations) to alert other road vehicles and pedestrians of its approach, in order to expedite its journey through traffic, whilst being used for emergency operation.

4.2.5.2 Visual warning system

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 systems (siren)

The vehicle shall have an audible warning system additional to the warning lights. The audible warning 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 Reversing systems

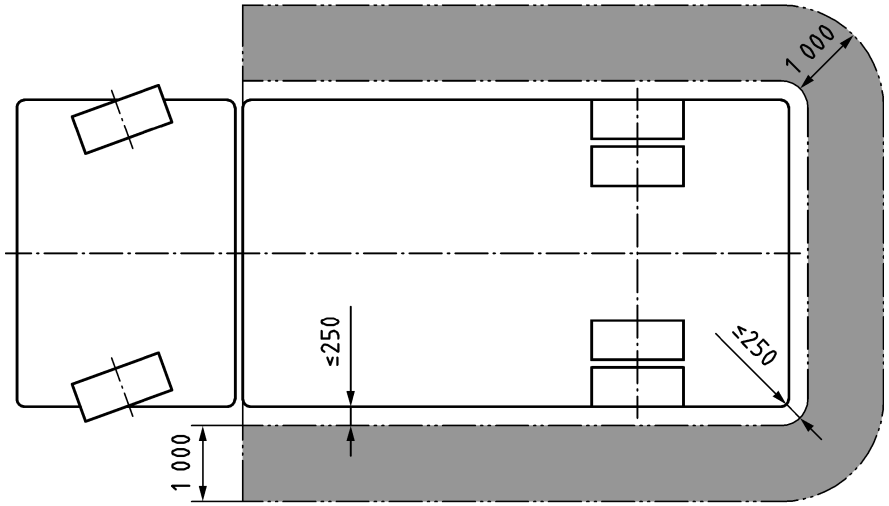
The ambulance shall be fitted with an audible reversing warning alarm, activated by the selection of the reverse gear. This function shall be possible to disable from the driver seating position, with default back to on, when reverse gear is engaged the next time.

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 on type B and type C vehicles. Illumination shall be measured at ground level.

Dimensions in millimetres



Key

Grey area Area of illumination of at least 5 lx

Figure 1 — Exterior lighting for type B and type C

4.3 Vehicle body

4.3.1 Fire safety

All interior materials shall have a burning rate of less than 100 mm/minute when tested in accordance with ISO 3795:1989.

4.3.2 Driver's seat configuration

For all types of road ambulances the ergonomic space of the driver's compartment and of the seat adjustment as approved by the base manufacturer shall not be reduced.

4.3.3 Minimum passenger capacity

The minimum passenger capacity shall be in accordance with Table 3.

NOTE Passenger includes crew, patient and accompanying persons.

Table 3 — Minimum passenger capacity

	Type of road ambulance			
	A_1	**A_2**	**B**	**C**
Number of passengers on seats and/or stretchers (in addition to the driver)	3	4	3	4 5[a]
[a] With two stretchers.				

A notice shall be displayed in the drivers' compartment stating the maximum number of seated and stretcher passengers that can be carried.

The notice shall be supplied by the manufacturer taking into account the maximum weight capacity of the vehicle.

4.3.4 Bulkhead

A full bulkhead or a bulkhead with a door shall separate the driver's compartment from the patient's compartment. Where a door is fitted, it shall not be possible to drive the vehicle with the door in the open position. This door shall be secured against opening if the road ambulance is in motion.

NOTE A bulkhead is also called a "partition wall".

One or two windows with a minimum separation of 100 mm shall be provided in the bulkhead. The windows shall allow direct visual contact with the driver. The opening area of the window shall have a maximum area of 0,2 m^2. It shall be secured against self-opening and shall have an adjustable blind or other means of preventing the driver being disturbed by the light of the patient's compartment.

4.3.5 Openings (doors, windows, emergency exits)

4.3.5.1 General

The patient compartment shall have at least two openings. One at the rear (door/tailgate) and one at the side.

All openings shall have seals to protect against the ingress of water.

All openings shall comply with the minimum dimensions according to Table 4.

Table 4 — Minimum opening dimensions in the patient's compartment

		Type of road ambulance			
		A_1 [a] mm	**A_2 [a] mm**	**B mm**	**C mm**
Side opening	Height [c] Width [c]	b	800 600	1 200 660	1 400 660
Rear opening	Height Width	900 900	900 900	1 200 1 050	1 500 1 050

a Corner radius of conversions which reduce the opening area by less than 10 % are permitted.

b The dimensions provided by the original manufacturer shall not be reduced.

c If it is a window, the height and width dimensions may be interchanged.

4.3.5.2 Emergency exits

The patient compartment shall have at least two emergency exits on different sides of the vehicle. One of the emergency exits can be on the roof. The emergency exits shall be easy to open from the inside.

The side door and rear door can be used as emergency exits. The free minimum size shall be 500 mm x 700 mm.

4.3.5.3 Doors

There shall be a central locking system which shall be possible to operate from the driver and patient compartment.

Each external door allowing direct access to the patient's compartment shall be fitted with a security system which enables the following:

a) lock and unlock from inside without use of a key;

b) lock and unlock from outside with use of a key;

c) unlock from the outside using a key when the door is locked from the inside;

NOTE 1 This security system can be integrated with an optional central locking system.

NOTE 2 The key can be a mechanical or non-mechanical device.

The patient's compartment doors shall be capable of being positively restrained in the open position.

An audible and/or visual signal shall warn the driver when any external door including those not allowing direct access to the patient's compartment, is not completely closed when the vehicle is in motion.

Handles and/or handrails of all access points shall be accessible from the outside.

4.3.5.4 Windows

In the patient's compartment, there shall be a minimum of two external windows. There shall be one on each side or one on one side and the rear.

The windows shall be positioned or designed to ensure patient's privacy when required.

4.3.6 Loading area

The loading area dimensions shall be in accordance with Table 5.

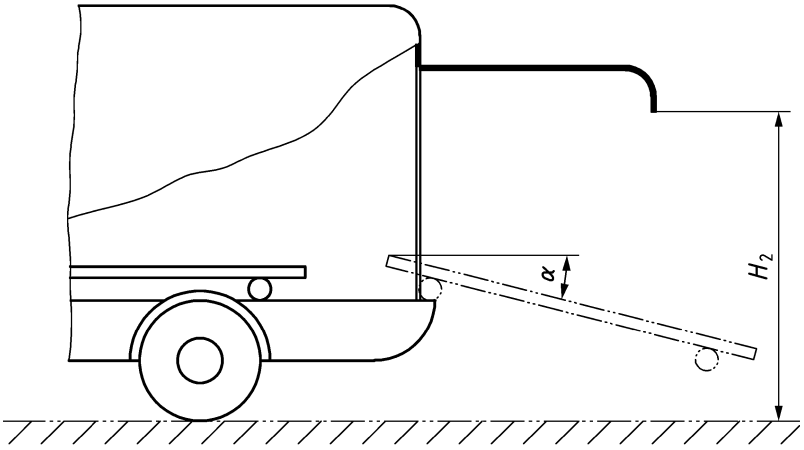
Table 5 — Loading area dimensions

	Type of road ambulance			
	A_1	**A_2**	**B**	**C**
Tailgate height (in the open H_2 minimum position) (see Figure 2)[a]	1 800 mm	1 800 mm	1 900 mm	1 900 mm
Loading angle α (stretcher) maximum	16°[b]	16° [b]	16° [b]	16° [b]
Loading height (stretcher)	When the stretcher is manually loaded or unloaded on the ambulance the maximum height of either the floor or the loading holding assembly above ground level shall not exceed 750 mm at net vehicle mass plus loose equipment.			

[a] From ground to lowest point of fully opened tailgate at gross vehicle mass.

[b] The loading angle should be kept as low as possible.

Where a ramp or lift is installed between ground level and vehicle floor level it shall be covered with an anti-slip surface and capable of taking a load of 350 kg. In the event of a power failure the loading device shall be capable of being operated manually.



Key

H_2 lowest point of the tailgate

α loading angle

Figure 2 — Tailgate height (in the open position)

4.4 Patient's compartment

4.4.1 General

The patient's compartment shall be designed and constructed to accommodate the medical devices listed in Tables 9 to 19 in accordance with the road ambulance type.

4.4.2 Safety

Exposed edges that could come into contact with the occupant's hands, legs, head etc., during normal use shall have a radius of curvature of not less than 2,5 mm except in the case of projections of less than 3,2 mm. In this case, the minimum radius of curvature shall not apply provided the height of the projection is not more than half its width and its edges are blunted.

All installations in the patient compartment above 700 mm shall not have sharp exposed edges and shall terminate in rounded edges. A sharp exposed edge is defined as an edge of a rigid material having a radius of curvature of less than 2,5 mm.

Edges that can be contacted by using the apparatus and procedure described in 5.4 shall have an edge with radius of curvature greater than or equal to 2,5 mm or shall be made from a non-rigid material. Medical equipment and their holding devices (for example stretchers, platforms, suction units etc.) are excluded.

Edges on medical equipment and their holding devices should be designed to reduce the risk of contact injury.

Cabinet drawers and doors shall be secured against self-opening and where lockers are fitted with doors that open upwards they shall be fitted with a positive hold open mechanism. Type B and C road ambulances shall be equipped with a lockable drugs compartment with security lock.

Floor coverings shall provide adequate grip including when wet and should be durable and easy to clean.

They shall as a minimum have achieved a slip resistance grading of at least R10 according to ▌A1⟩ EN 16165:2021 ⟨A1▐ using testing method as defined in ▌A1⟩ EN 16165:2021 ⟨A1▐.

Type B and C road ambulances shall be fitted with a hand-holding device positioned above the stretcher. For type C the hand-holding device shall be positioned along the longitudinal axis.

If the patient's compartment is to be equipped with a non-foldable sedan chair as defined in EN 1865-1:2010+A1:2015, space shall be provided with a width of at least 600 mm measured at elbow height and a ceiling height above the seat squab of at least 920 mm (see Table 7, footnote a).

Vehicle maintenance equipment (e.g. spare wheel and tools) shall not be accessible from within the patient's compartment. Devices, equipment and controls which may be required while the vehicle is in motion should be positioned in such a way that they can be operated with the seat belt fastened while the vehicle is in motion.

4.4.3 Hygiene

To provide a safe environment and maintain hygiene standards for both patients and crew, the equipment and interior design of an ambulance should allow for ease of cleaning to provide for infection control and prevent cross contamination. The interior of the patient compartment including the ceiling, floor, walls and doors shall be lined with a material that is non-permeable and resistant to continuous cleaning.

The edges of all surfaces shall be designed and/or sealed in such a way that no fluid can infiltrate. If the floor arrangement does not allow fluids to flow away, one or more drain with plugs shall be provided.

For further information see the informative Annex C.

4.4.4 Patient's compartment dimensions

4.4.4.1 General

The dimensions relate to the patient's compartment with lining. To achieve only structural solidity a reduction of the dimensions of up to 5 % is acceptable in limited areas; door openings excluded.

4.4.4.2 Patient's compartment dimensions for type A_1, A_2 and B road ambulances

The patient's compartment shall comply with the minimum dimensions set out in Figures 3 to 5 (without cupboards, seats, medical devices and equipment). For the Figures 3 to 5 the following key applies:

W = width measured from from side wall to side wall, except the roof curvature;

L = length measured from rear to bulkhead at height of stretcher;

H = height, measured from floor to roof;

X = height of stretcher holding assembly to roof measured in the middle of the longitudinal axis of the stretcher;

h_1 = height between centre of seat and roof;

h_2 = height between centre of seat and floor.

NOTE Full line equals interior wall and ceiling of the patient's compartment.

Dimensions in millimetres

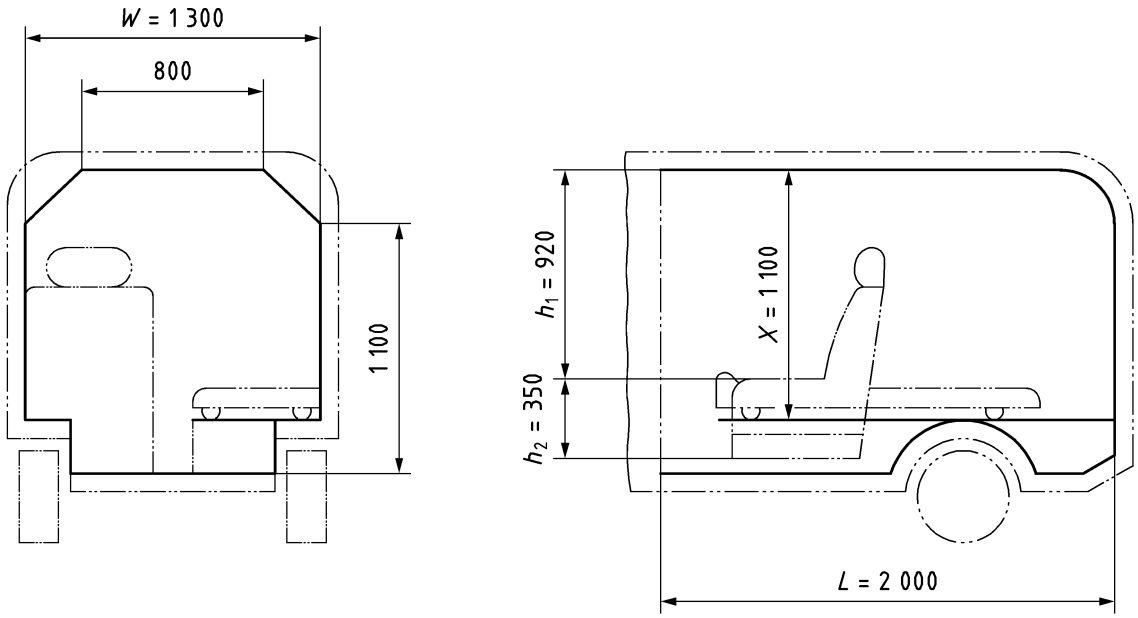
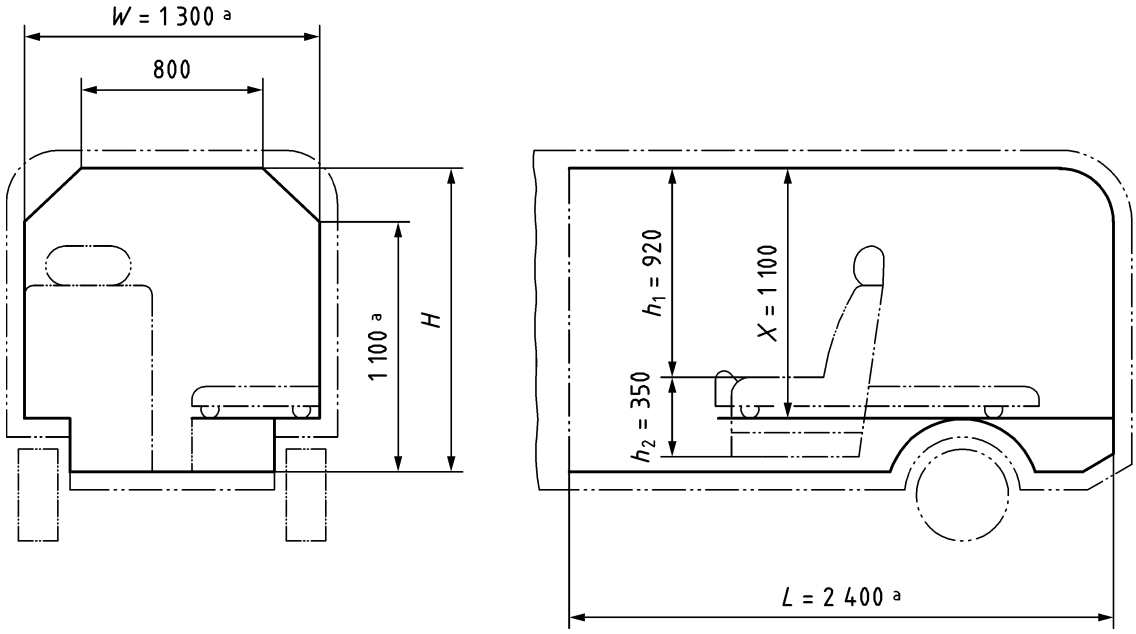


Figure 3 — Patient's compartment dimensions for type A1 (schematic)

Dimensions in millimetres

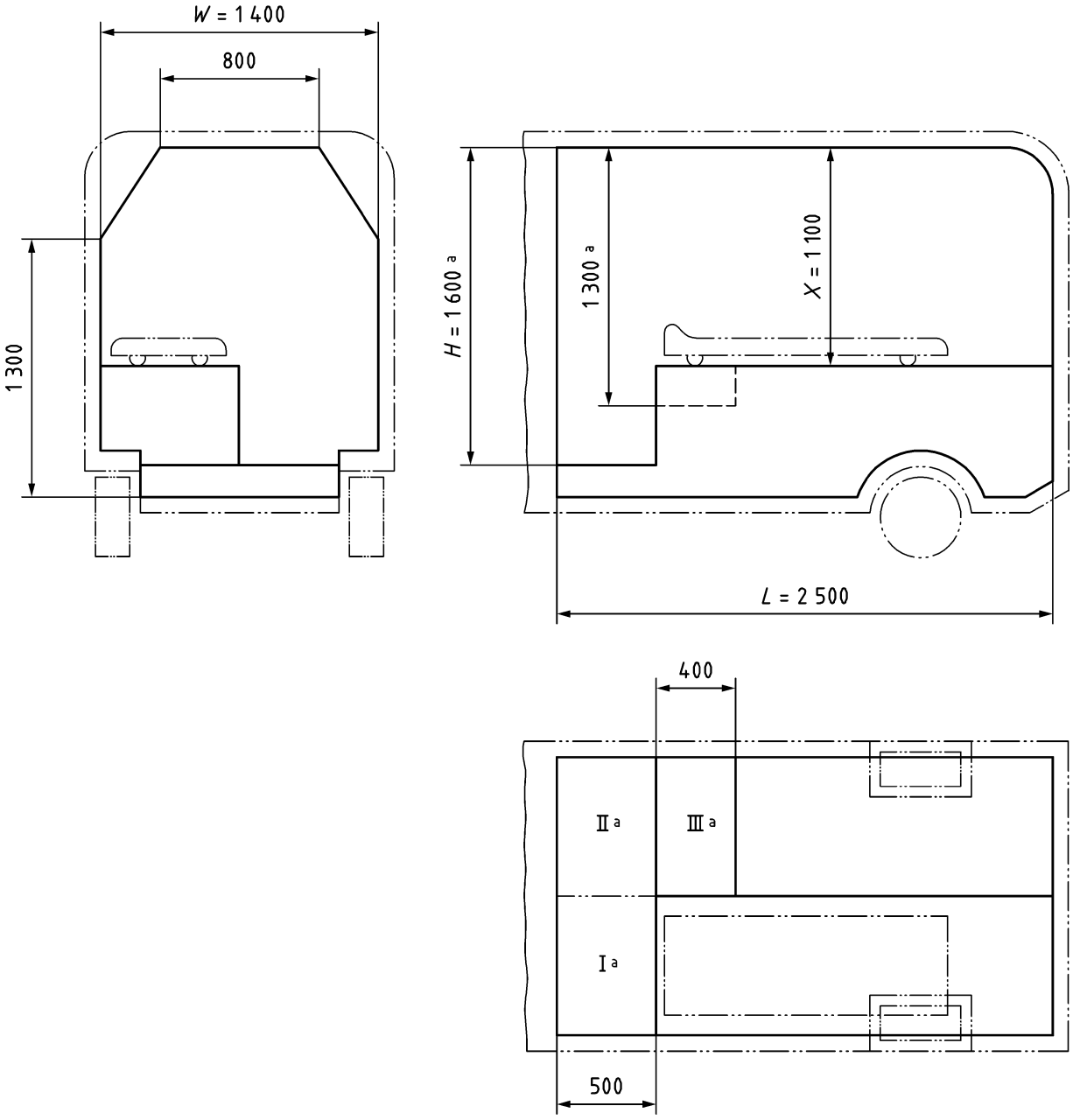


Key

a nensions for Type A2 with more than four seats in the patient's compartment. The length (L) shall be 3 100 mm, width (W) 1 500 mm. The height (H) shall be 1 750 mm. From a heights of 1 500 mm to 1 750 mm the sides shall have a radius no greater than 250 mm

Figure 4 — Patient's compartment dimensions for type A2 (schematic)

Dimensions in millimetres



Key

a **Area I**

When it is necessary to facilitate emergency treatment there shall be a minimum of 500 mm between the lining of the bulkhead and the head-end part of the stretcher frame or stretcher platform measured in the mid-axis and at the height of the stretcher. A minimum height of 1 600 mm shall be provided

Area II

A minimum height of 1 600 mm shall be provided

Area III

A flat and horizontal surface of a minimum length of 400 mm shall be provided alongside the stretcher from the head-end part of the stretcher frame. A minimum height of 1 300 mm shall be provided

Figure 5 — Patient's compartment dimensions for type B (schematic)

4.4.4.3 Patient's compartment and treatment area dimensions for type C

In type C road ambulances the patient's compartment shall be large enough to incorporate the treatment area provided with dimensions as set out in Figure 6. Any protrusions into the treatment area shall be designed and constructed to fold away to provide these minimum dimensions. A seat (in stored position) and the medical equipment operated from this seat may intrude into the treatment area as follows:

— in this case the maximum intrusion shall be 125 mm at the head end of the stretcher;

— or 125 mm on one side or a sum of 125 mm on both sides.

NOTE 1 A treatment area is also called "ergonomic space".

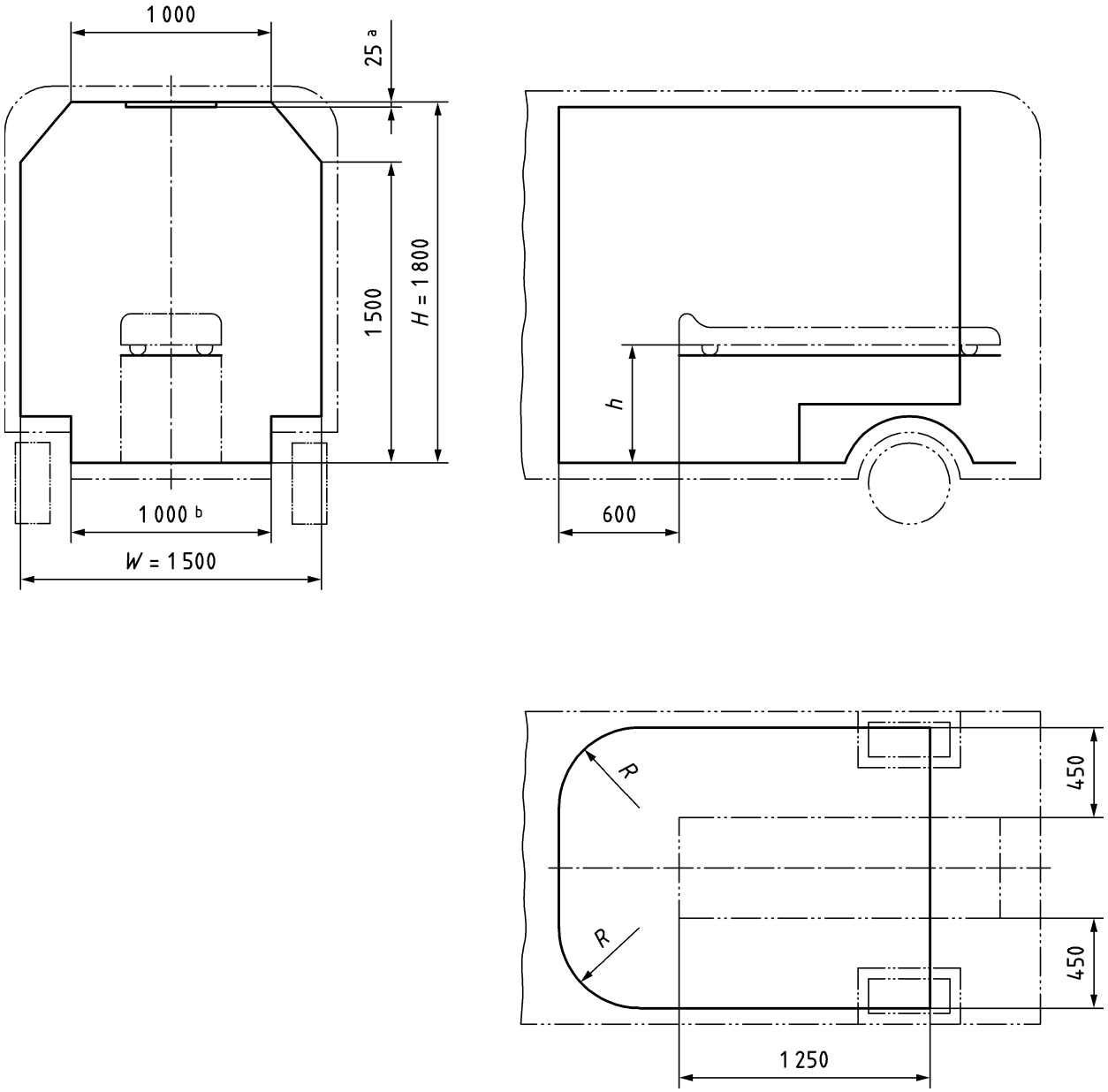
Verification of conformity of dimension of the treatment area shall be made when the stretcher is placed in the mean position of the treatment area.

h = A working height of the stretcher surface (excluding mattress and included a support platform where fitted) between 320 mm (minimum) and 650 mm (maximum) shall be ensured; measured at the head end of the stretcher.

R = 500 mm (maximum), where R is the radius.

NOTE 2 Full line represents the ergonomic space.

Dimensions in millimetres



Key

a Reduced (25 mm maximum) in the roof area over the stretcher

b Where the height of the wheel arch exceeds 400 mm, the clearance width between the wheel arches above 400 mm shall not be less than 1 250 mm

Figure 6 — Treatment area dimensions for type C

4.4.5 Patient and crew seating

The minimum number of patient and crew seats shall be as given in Table 6.

Table 6 — Number of patient and crew seats

		Type of road ambulance			
		A_1	A_2	B	C
Minimum number		1	2	2	2
Position(s)	on one side of the stretcher	1	1	–	–
	on one side of the stretcher upper $^2/_3$ end	–	–	1	1
Position(s) at head or side of the stretcher		–	1 [a]	1	1
[a] Only when fewer than four seats.					

The seats shall comply with the minimum dimensions according to Table 7.

Table 7 — Minimum dimensions for seating

	Single seat (crew/patient) mm	**Folding seat (crew)** mm
Width	450	450
Depth	330	330
Height above seat [a]	920	920
Thickness of upholstery	50	50
[a] Measured vertically above and in the middle of the 75 kg loaded seat.		

Where possible the seat height should be adjustable.

Seats fitted in accordance with Tables 6 and 7 shall be installed in either forward or rear-facing positions. Backrests shall be constructed to a minimum dimension of 300 mm × 100 mm, the upholstery of which shall be a minimum thickness of 20 mm.

All seats shall be equipped with head rests.

Seats in the patient compartment shall be fitted with a seatbelt alarm. The seatbelt alarm shall alert the driver visually or acousticly when someone is seated but not secured by the seatbelt.

4.4.6 Ventilation and anaesthetic gas scavenging systems

4.4.6.1 Ventilation system

There shall be a ventilation system which shall provide a minimum of 20 air changes per hour when the vehicle is stationary.

For safety, if a pressurized gas is stored in a storage compartment, the compartment shall be ventilated.

4.4.6.2 Anaesthetic gas scavenging system (AGSS)

If the ambulance is intended to be used with delivery systems for anaesthetic gases e.g. N_2O or anaesthetic agent vapour it shall be equipped with an AGSS to make sure that the maximum permissible level of air contamination is not exceeded. This level is found in national or regional regulations.

NOTE Examples of an AGSS system can be found in EN ISO 9170-2:2008 and EN ISO 7396-2:2007.

4.4.7 Temperature control system

4.4.7.1 General

Heating and cooling systems in the patient compartment shall be independently controlled from the driver's compartment system. Heating/cooling in the patient compartment can be provided in a combined system.

4.4.7.2 Heating

In addition to the heating of the driver's compartment there shall be an independent adjustable system as follows:

— heating for type A and B road ambulance;

— fresh air heating for type C road ambulances.

This system shall be such that given an outside and inside temperature of 5 °C, the heating up to at least 22 °C shall not take longer than 15 min when measured in the centre of the stretcher(s) and at the mid-point from the heater outlets (if several outlets are available).

The heating shall be controlled by an adjustable thermostat or by an electronic climate control system. The actual temperature shall not vary from the set temperature by more than 5 °C.

The heating system shall be capable of meeting the performance criteria with the ventilation system switched off and the heating system set to re-circulate the air in the patient's compartment.

The installation of the system shall not encourage exhaust gases entering the patient's compartment.

4.4.7.3 Cooling

At an inside temperature of 32 °C, the cooling system shall reduce the temperature in the patient's compartment to 27 °C or less within 15 min and reduce to 25 °C or less within 30 min. The temperature shall be measured in the centre of the stretcher(s) and at the midpoint from the cooling outlets (if several outlets are available).

The cooling system shall be able to meet the requirements if the air conditioning system is set to the air recirculation of the patient compartment.

The installation of the system shall not encourage exhaust gases entering the patient's compartment.

4.4.8 Interior lighting

Natural colour balance lighting shall be provided as set out in Table 8.

NOTE The colour temperature of the light will change the appearance of skin and organs. Therefore it is important that the interior lighting is suitable for patient care during transportation. It is believed that it is not necessary in road ambulance use to define "daylight" or "natural colour balance" in a more exact way other than the colour temperature. Regarding the colour temperature a comparison can be that examining lights in hospitals are normally between 3 800 K to 4 300 K (see EN 12464-1:2011).

In type C road ambulances there shall be an additional light within the treatment area with a minimum of 1 650 lx. It shall be measured at the stretcher surface in its lowest position. The minimum distance of the measurement shall be 750 mm below the light and in an area with a minimum diameter of 200 mm.

Table 8 — Patient's compartment illumination

		Type of road ambulance			
		A_1	A_2	B	C
Patient (task) area	minimum:	200 Ix	200 Ix	500 Ix [a]	500 Ix [a,c]
Immediate surrounding area	minimum:	50 Ix	50 Ix	300 Ix [a]	300 Ix [a]
Colour temperature		≥ 3500 K ≤ 5 000 K [b]	≥ 3500 K ≤ 5 000 K [b]	≥ 3500 K ≤ 5 000 K [b]	≥ 3500 K ≤ 5 000 K [b]
Ra (colour rendering)	minimum:	80	80	90	90

[a] Additionally there shall be a facility for switching the lighting level down to 150 lx in the patient's compartment.

[b] Recommended between 3 800 K and 4 300 K as the optimum range.

[c] With an additional 1 650 lx for the treatment area.

Light levels shall be measured along the central longitudinal axis of the stretcher at the head, mid-point and foot position with the stretcher in its normal position for transportation in the ambulance.

4.4.9 Interior noise level

The noise level in the patient and drivers compartment shall be kept as low as possible across the vehicle speed range. Maximum sound pressure level shall not exceed 77 dB(A) at 120 km/h or the vehicle maximum speed if it is lower than 120 km/h.

Noise measurements shall be made using the most appropriate gear for the speed being examined as determine by the base vehicle manufacturer.

4.4.10 Holding system for infusion

A holding system shall be provided to support two vertically fixed infusions in such a way as to use the maximum available height above the stretcher holding assembly. It shall be possible to position the infusions for use at either end of the stretcher holding assembly. The infusion mounting shall have a minimum capacity of 5 kg and be able to hold two bags of fluids independent of each other and shall be designed to minimize oscillation.

4.4.11 Retention, fixation and restraint systems

All persons and items e.g. medical devices, equipment and objects carried in the road ambulance shall be restrained, installed or stowed to prevent them becoming a projectile when subjected to accelerations/decelerations of 10 g in the forward, rearward, left, right and vertical directions. When subjected to these accelerations/decelerations, the distance travelled by a person or item shall not endanger the safety of persons in the road ambulance.

After being subjected to these accelerations/decelerations:

a) no items shall have sharp edges or endanger the safety of persons in the road ambulance;

b) the maximum distance the stretcher and any item attached to either the holding assembly or stretcher may travel shall be no more than 150 mm. The displacement of the patient during the test may exceed 150 mm.

All lockers, rails and non-dedicated storage locations or storage devices shall be labelled to show the total maximum permissible weight allowed.

If the road ambulance is intended to carry a transport incubator system and the incubator is to be interchangeable between road ambulances and other vehicles or craft, then to ensure interoperability and interchangeability an interface as specified in EN 13976-1:2018, Clause 4.1 shall be used.

4.4.12 Mass reserve

The minimum mass reserve required for the listed sanitary, medical and technical devices in Tables 9 to 19 shall be as follows:

— road ambulance type A_1: 100 kg;

— road ambulance type A_2: 115 kg;

— road ambulance type B: 225 kg;

— road ambulance type C: 260 kg.

5 Testing

5.1 General

Equipment in the road ambulance shall be in place during testing according to 5.2 and 5.3.

Stretcher(s) shall be loaded according to this standard and be tested in the normal position for use.

NOTE Surrogate stretcher(s) can be used.

5.2 Testing of the interior noise level

5.2.1 Specific measurement conditions

The measurements of the interior noise level in the patient's compartment shall be taken under the conditions given in ISO 5128:1980 with the following exceptions:

— the road ambulance shall be provided with the permanently installed equipment specified in this document;

NOTE 1 Permanently installed equipment means stretcher(s), their mattresses and accessories that cannot be removed without using tools.

— contrary to the minimum tyre wear of 300 km specified in ISO 5128:1980, 8.1, new tyres without wear may be used;

— apart from the requirements in ISO 5128:1980, 8.3, the stretcher trays shall be in the normal position according to the manufacturer's recommendations;

— the measurement shall be made at a constant speed in accordance with ISO 5128:1980, 8.4.1 b);

— the measurements in accordance with ISO 5128:1980, 8.4.2 and 8.4.3, are not necessary;

— measurements shall only be taken in the patient's compartment and are required on all seats of the patient's compartment (including lying/carrying chair) according to ISO 5128:1980, 9.1, (but only in the longitudinal median plane of the seat) and on all stretchers according to ISO 5128:1980, 9.3;

— determination of octave and terz spectrums, according to ISO 5128:1980, 10.6, is not necessary;

— during the measurements, the audible warning and communication system shall be switched off.

NOTE 2 Values are to Leq (average).

5.2.2 Measurements

The noise level of the vehicle at the speed according to 4.4.9 is determined by measuring the interior noise level in the patient's compartment at a speed of 120 km/h, or at the vehicle maximum speed if it is lower than 120 km/h

Two measurements are carried out. The test result is the average of these two measurements.

5.3 Testing of retention systems and fixation of the equipment in the patient's compartment

5.3.1 General

The requirements of 4.4.11 should be verified by a third party.

NOTE 1 To verify compliance with 4.4.11, Regulation (EU) 2018/858 states that verification is required to be carried out by a Technical Service.

For verification of the requirements of 4.4.11 a dynamic test under 5 axis, ± x'x, ± y'y and for + z'z axis shall be performed (see Figure 7).

The test body or shell is determined depending on the ambulance construction:

— For a panelled van, the body shell of the base vehicle shall be used.

— A box body requiring structural support of the base chassis shall be tested jointly.

— A box body not requiring structural support of the base chassis is tested without base chassis, or on request of the manufacturer, with the base chassis.

It is permissible to perform the test in each direction on a fresh sample body at the request of the manufacturer.

Each direction in the test is an independent test. Use of fresh sample body is therefore allowed.

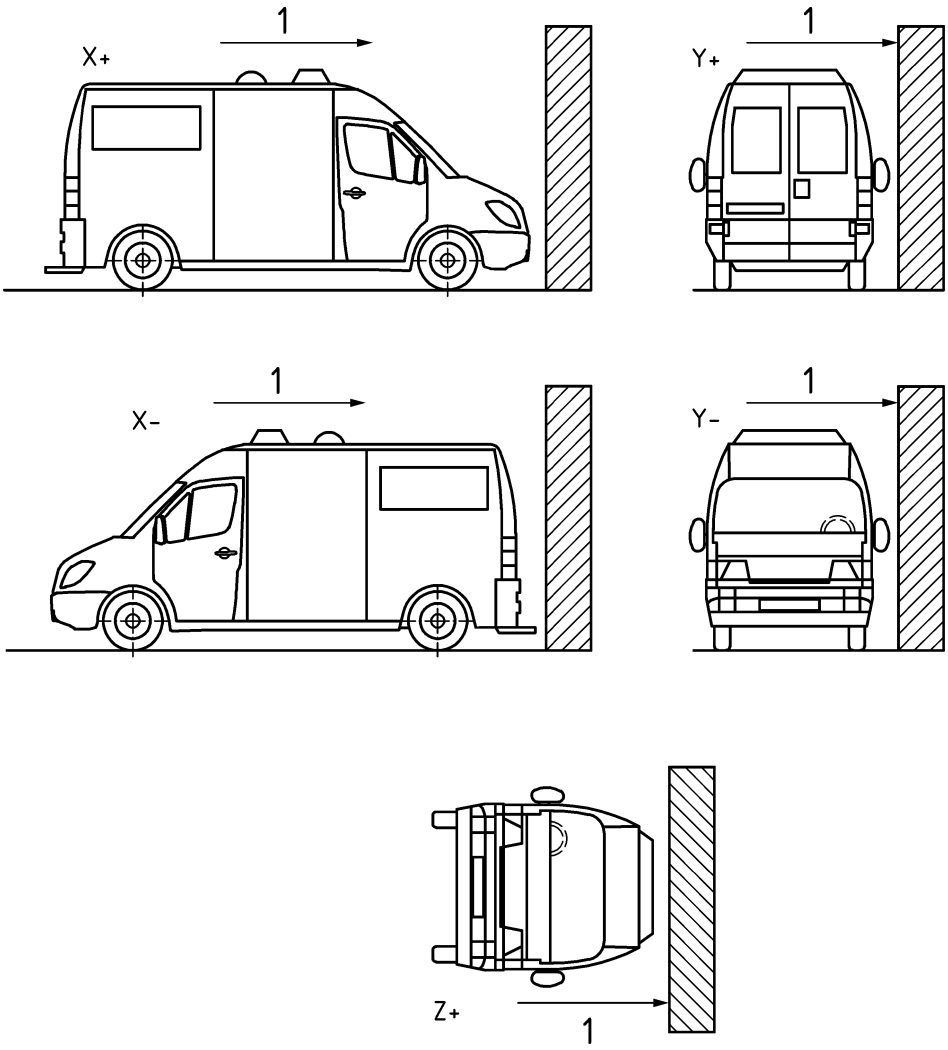
If the patient's compartment or base chassis is changed in a way that it cannot be covered by the original worst case scenario, a full or partial test shall be performed as deemed necessary.

Test configuration is defined on the principle of the worst-case scenario to limit the number of tests. The test sample does not have to be the actual product rather than as worst case scenario.

NOTE 2 Test configuration is defined on the principle of the worst case scenario to limit the number of tests.

NOTE 3 Bodies in white or chassis cab in white plus box bodies can be used for test purposes.

NOTE 4 Body in white (BIW) variants of base chassis cab with the box body or base vehicle, can be used for test purposes.



Key

1 test direction

Figure 7 — Test directions for dynamic test

The maximum test mass for which the devices are qualified shall be indicated by a label.

The method used to secure the vehicle during the test shall not be such as to strengthen the body or the arrangement of the patient's compartment or to lessen the normal deformation of the structure.

The only reinforcements allowed are:

— a sub frame under the original van shell; or

— chassis longitudinal box sections; or

— chassis rails to fix the body/shell to the test facility.

For a box body, a sub frame representing the chassis can be used in conjunction with the original attachment points under the box designated for fixing to the vehicle chassis.

In the case of a fully independent box body, it is possible to test it alone.

To check 4.4.11 on a new vehicle, a dynamic test in the five directions shall be carried out. Dynamic test is the reference method.

Manufacturer shall present documentation of the fixation and retention system.

For a modification on a previously dynamically tested and approved ambulance body or shell, a dynamic test or a static test of the modified components or a computer simulation can be presented depending on the nature of the change. The appropriate method shall be agreed with the approval authority.

Documentation of all modifications shall be added to the original tests documentation.

For racks, rails and non-dedicated storage devices or storage, the test report shall state the maximum approved load. The test mass shall remain fixed to the attachment point. Cracks and tears of metal sheet are acceptable.

An example of a test summary can be found in Annex A.

5.3.2 Testing of the stretcher fixation on the vehicle floor

For all types, the test shall be performed with a stretcher support or floor mounted locks and an equivalent mass simulating the stretcher and the dummy whose characteristics are:

— stretcher and dummy test mass: 126 kg according to EN 1865-5:2012;

— table stretcher support as defined by the ambulance manufacturer, with maximum weight and height of the centre of gravity defined by the ambulance manufacturer.

Manufacturer shall present documentation of the fixation and retention system. In addition, the stretcher support fixed in the ambulance shall comply to EN 1865-5:2012.

5.3.3 Testing of the medical devices fixation

Fixation points shall be tested with a test mass corresponding to the permissible load declared by the manufacturer of the ambulance for each point.

NOTE For the medical equipment fixed in the road ambulance, the manufacturer of the ambulance defines the type of fixation to use, the admissible mass and the location of the fixation points. The manufacturer provides recommendations to the users.

5.3.4 Testing of furniture

For the same vehicle type or a specific box body, the patient's compartment furniture shall be validated utilizing the worst case condition.

The test is carried out according to 5.3.5.

The test shall be performed with simulation mass easily removable from the furniture without tools.

The maximum allowed load, expressed in kg, shall be visible to the users.

5.3.5 Test procedure

For test purposes a surrogate stretcher can be used and shall be fixed to its locking devices in the same way as the original product, and surrogate masses representing medical devices can be used.

Verification of conformity to 4.4.11 shall be made when the stretcher(s)/medical device(s) is/are placed in the mean position of all possible positions available.

Appropriate verification shall be carried out by static or dynamic testing depending on the individual technical problem.

The sample submitted for test shall be identical to or have the same characteristics and behaviour during test as the production item or vehicle.

Care should be taken that no internal/external additional reinforcement through the rig modifies the behaviour during the test.

The surrogate of the stretcher shall be fixed on the stretcher's holding assembly. The non-foldable carrying chair, when provided, shall also be fixed in its holder. Representative test mass can be used.

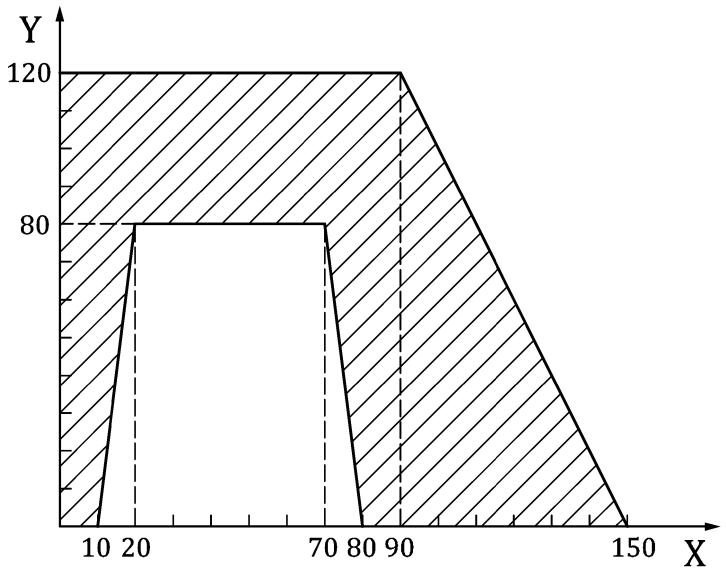
The impact tests can be carried out with medical device(s) installed or stowed in the holding system(s) or with weights having the mass distribution and dimensions corresponding to the mass and dimensions of the stretcher(s) and device(s) intended to be installed on or stowed in the holding system.

In case of dynamic testing, the dynamic test shall be carried out using a patient's compartment assembly and the following test method. When a modification to an approved ambulance patient's compartment requires testing, a relevant part of the construction may be used

The test assembly shall be accelerated/decelerated in the longitudinal, transverse and vertical directions in accordance with Figure 8. The impact speed shall be between 30 km/h and 32 km/h.

The deceleration curve is verified according to the inertia mass method.

Test weights for use in lockers should be sand bags with masses in kg increments, with a tolerance of 0 % to +10 % maximum of the maximum of each individual compartment load.



Key

X time in ms

Y acceleration/deceleration in m/s²

Figure 8 — Acceleration impulse

5.4 Testing of rounded edges and radius inside the patient's compartment

5.4.1 Testing of rounded edges

Conduct the test with a protrusion test ball shown in Figure 9 having a diameter of 165 mm.

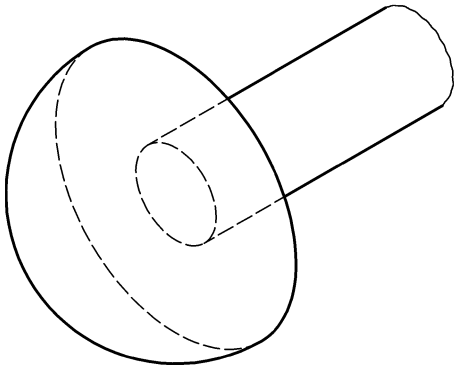
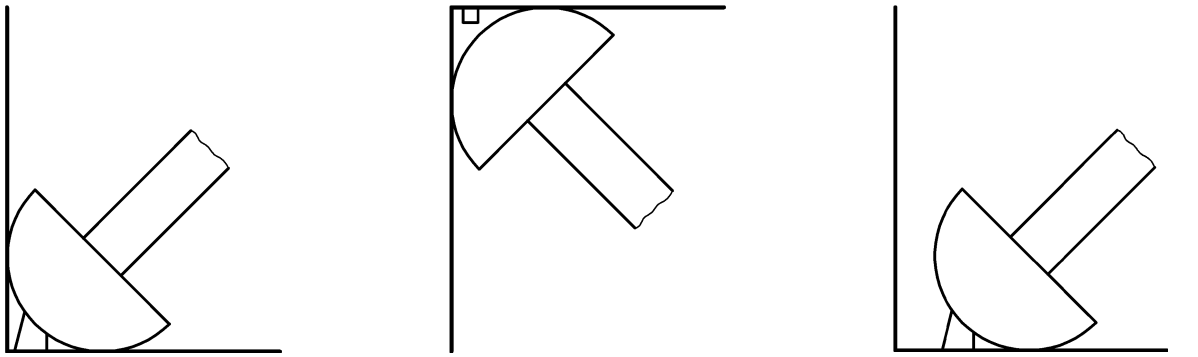


Figure 9 — Protrusion test ball

All doors in the patient's compartment and drawers shall be in closed position. Manoeuvre the protrusion test ball in all possible attitudes towards any rigid protrusion on the furniture above the plan. The plan is the horizontal plan located at 700 mm from the lowest point of the floor excluding steps or wells.

If the protrusion test ball contacts the protrusion (see Figure 10), that protrusion shall be considered to be an exposed edge and shall comply with 4.4.2.

NOTE This test uses the principle described in 2008/ECE21/EG.

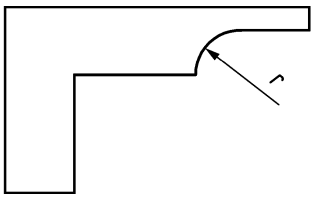


a) protrusion shall comply b) protrusion need not comply c) protrusion shall comply

Figure 10 — Examples of protrusions

5.4.2 Testing of radius inside the patient's compartment

Conduct the test with a radius test tool shown in Figure 11.



Key

r radius, r = 2,5 mm

Figure 11 — Radius test tool (example)

5.5 Procedure to verify the patient's compartment specifications

Vehicle converter shall provide the technical specification of the flooring material and confirmation of anti-slip properties.

The manufacturer shall demonstrate that surface joints of the floor, ceiling, walls and doors are designed and/or sealed in such a way that no fluid can infiltrate.

5.6 Procedure to verify the loading area specifications

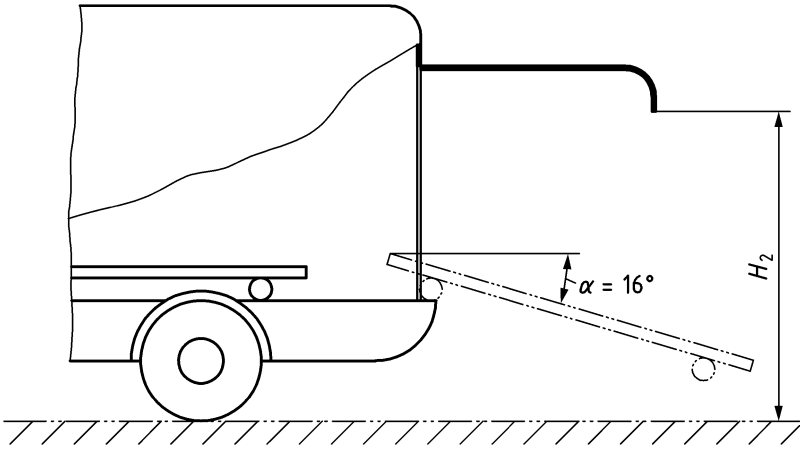
5.6.1 General

The presented vehicle shall be equipped with a stretcher complying to EN 1865-1:2010+A1:2015 or ▌A1⟩ prEN 1865-2:2023 ⟨A1▐ provided by the ambulance manufacturer and when appropriate with its stretcher support.

The test shall be conducted on a flat and horizontal surface.

5.6.2 Procedure to verify the loading angle of 16°

For verification of the loading angle see Figure 12.



Key

H_2 lowest point of the tailgate

α loading angle

Figure 12 — Verification of the loading angle

Check the loading angle and loading height with one of the stretcher specified by the manufacturer of the ambulance.

If the vehicle is fitted with lowering rear suspension, it should be fully lowered. Where it is fitted, the vehicle shall be tested with a mass of 150 kg within the patient's compartment in addition to the stretcher and its locks, mountings and loading platform where appropriate.

Where a loading ramp is provided this should be fully deployed.

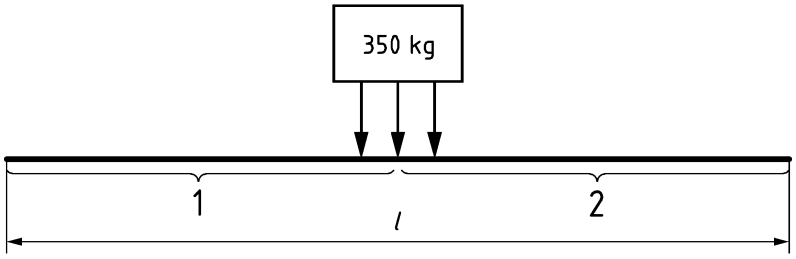
For vehicles equipped with a stretcher support (lift table), position it in the loading position according to the instructions for use. In the absence of instructions, the top tray shall be positioned such that the surface to its rear end on which the attack wheels of the stretcher engage are at the same height as the tread of the stretcher attack wheels (or the top of the undercarriage if so equipped).

Loading angle α is measured as being the incline of the ramp from ground to vehicle floor or slope of the loading platform where used.

If a ramp is fitted to the vehicle:

— verify the presence of non-slip coating on the vehicle;

— Verify the strength of the ramp by placing it in a horizontal position and by placing a load of 350 kg uniformly distributed over an area of 200 mm x 200 mm at the centre of the ramp (see Figure 13) for 60 s. Support shall be placed at 300 mm of each end. After removing the load, no deformation is permitted.



Key

l length

1 part 1

2 part 2

Figure 13 — Ramp strength test - application of the load

Check dimension H_2, with the suspension of the vehicle in same position as that recommended to check the loading angle α.

5.7 Procedure to verify the dimensions of the patient's compartment

5.7.1 Type A and B road ambulances

Dimensions shall be checked in an ambulance fully fitted with all interior, sides and ceiling lining panels. Other interior fittings and medical devices (with the exception of the stretcher, loading platform where used and permanent seats) are to be ignored for this test.

5.7.2 Type C road ambulances

The dimensions of the patient's compartment are checked without medical devices fitted.

To check the dimensions of the ergonomic space in the vehicle, use a main stretcher to the nominal dimensions of EN 1865-1:2010+A1:2015 in the position corresponding to the main settings as defined by the ambulance manufacturer.

NOTE 1 The area corresponding to the head of the stretcher stops at the articulation point of the head of the stretcher.

NOTE 2 The patient’s compartment dimensions in Figure 6 are minimum dimensions except where specific figures and/or tolerances are mentioned in this standard.

Dimensions are checked on the stretcher lying surface excluding the mattress.

If the dimensions of the stretcher support are higher than those of the stretcher, check the ergonomic space dimensions around the stretcher support.

Ergonomic space is checked at the level of the horizontal plan tangent to the top tray of the stretcher support.

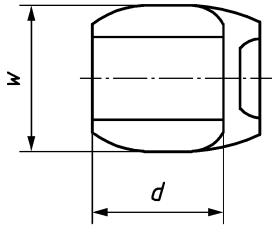
Consider the possible authorized maximum intrusion at the head end of the stretcher or on one side (see 4.4.4.3).

Oxygen cylinders, which can be operated from a seat and the flexible part of their support, can enter the ergonomic space under the conditions of 4.4.4.3.

The intrusion of seats is checked in the stretcher plan.

5.8 Procedure to verify the seats dimensions of the patient's compartment

Check the dimensions of the seats in Table 7 as shown in Figure 14. The dimensions of the seats shall be checked physically or by reference to drawings. Rounded corners are to be ignored.



Key

w width

d depth

Figure 14 — Checking of the seat dimensions

The width of the carrying chair at the elbow level, including width of the chair, shall be measured at a height between 250 mm to 300 mm above the seat (conventional elbow height).

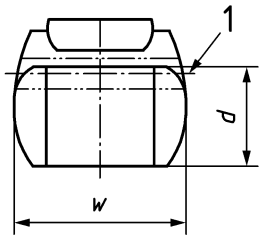
Check that swivel seats can be locked, in predetermined position, front or rear facing.

Seats not intended for use when the vehicle is travelling are not included in this section. They are not necessarily equipped with seat belt and headrest.

In the event that the seat's design implies a reduction of the seat at the height of H point due to rotating axis allow a significant reduction in the width at −30 mm of H point (dotted line on Figure 15).

Seats designed with tip up seat bases may have the 450 mm width dimension reduced adjacent to the back rest. See dotted area in Figure 15.

Ensure that the dimension of the seat is not less than a 300 mm by 450 mm rectangle taken 30 mm from H point.



Key

w width

d depth

1 H point

Figure 15 — Measurement of 450 mm width

5.9 Testing of the ventilation system

It shall be verified by:

— checking the technical documentation of the product;

— checking the calculation that the choice of the product allows at least 20 changes per hour of the air volume of the patient's compartment (without interior arrangement).

5.10 Testing of the heating system

This procedure shall be used for all types of ambulance (A, B, C).

There shall be no external power supply connected.

If necessary install a coolant temperature sensor at the T connection of the heater (engine side).

a) open the doors of the patient's compartment;

b) condition the vehicle for at least 6 h at the temperature specified in 4.4.7.1;

c) check that the patient's compartment heating system is turned off;

d) start the engine;

e) start the heater of the driver's compartment in the most favourable position;

f) operate the engine until it reaches its normal operating temperature (the engine is considered hot after two openings of the thermostat);

g) close the doors of the patient's compartment, start the heating system of the patient's compartment (control in maximum position), with the engine at idle speed or accelerated idle speed if it comes into operation during the test without manual action.

The test report shall indicate if the accelerated idle came into action during the test.

Start of test: t_0

— record the temperature over time.

End of the test: t_0 + 20 min

— Validation of the test: the temperature sensors shall reach the values indicated in 4.4.7.1 at t_0 + 15 min.

The measurements recorded on one sensor at the centre of the stretcher shall meet the criteria.

Given the varying conditions of use of ambulances, check the set temperature only by comparing the displayed temperature (22°C) after 15 min temperature rise. The measured temperature shall not differ by more than 5°C.

5.11 Testing of the cooling system

5.11.1 Test procedure

a) open the doors of the patient's compartment;

b) condition the vehicle for at least 6 h at the temperature specified in 4.4.7.2;

c) start the engine;

d) start the air conditioning of the driver's compartment;

e) wait for 10 min;

f) close the doors of the patient's compartment, start the air conditioning system of the patient's compartment (control in maximum position), with the engine at idle speed or accelerated idle speed if it comes into operation during the test without manual action.

Start of test: t_0

— record the temperature over time.

End of the test: t_0 + 35 min

— Validation of the test: the temperature sensors shall reach the values indicated in 4.4.7.2 at t_0 + 15 min and t_0 + 30 min.

5.11.2 Testing of independent air conditioning system

a) open the doors of the patient's compartment;

b) condition the vehicle for at least 6 h at the temperature specified in 4.4.7.2;

c) close the doors of the patient's compartment, start the air conditioning system of the patient's compartment (control in maximum position).

Start of test: t_0

— record the temperature over time.

End of the test: t_0 + 35 min

— Validation of the test: the temperature sensors shall reach the values indicated in 4.4.7.2 at t_0 + 15 min and t_0 + 30 min.

The measurements recorded on one sensor at the centre of the stretcher shall meet the criteria.

Given the varying conditions of use of ambulances, check the set temperature only by comparing the displayed temperature (22°C) after 30 min temperature rise. The measured temperature shall not differ by more than 5 °C.

NOTE It is not necessary to verify the criteria about the absence of entering vehicle or heating system exhaust gases.

5.12 Testing of interior lighting

The test shall be performed in a darkroom or with the exterior surface of all saloon windows covered in non-light transmitting material to avoid light entering.

For types B and C ambulances take the lowest possible position of the stretcher into account.

The measurements shall be taken with the mattress in place.

Before starting the measurement wait a minimum of 10 min after switching the light on.

5.13 Testing of infusion holding system

Each infusion holding system shall be loaded with a mass of 5 kg for a dynamic test and 7,5 kg for a static test. In the case of an adjustable/mobile holder, position the mass in the longitudinal axle of the stretcher at the middle.

6 Equipment and medical devices

6.1 Provision of medical devices

The road ambulance shall be designed and constructed to accommodate the items listed in Tables 9 to 19 and provide the following levels of care:

— the patient transport ambulance (types A_1 and A_2) shall have basic professional equipment for first aid and nursing care;

— the emergency ambulance (type B) shall have equipment for basic treatment and monitoring of patients with the current methods of pre-hospital care;

— the mobile intensive care unit (type C) shall have equipment for advanced treatment and monitoring of patients with the current methods of pre-hospital intensive care.

6.2 Medical devices storage

All equipment required for a set procedure shall be stowed in a specified location. Essential equipment required for use outside the vehicle shall be easily accessible via normally used doors. All equipment shall be securely and safely stowed to prevent damage or injury whilst the vehicle is in motion (see 6.3.5). Devices, equipment and controls which may be required while the vehicle is in motion should be positioned in such a way that they can be operated with the seat belt fastened while the vehicle is in motion.

6.3 Requirements for medical devices

6.3.1 General

For all electrical and non electrical medical devices the relevant clauses of ⟦A1⟩ EN 60601-1-12:2015+A1:2020 ⟨A1⟧ apply.

If a medical device is designated as “portable” (except patient handling equipment according to Table 9 it shall

— be possible to be carried by one person;

— have its own built in power supply (where relevant);

— be capable of use outside the vehicle.

6.3.2 Temperature

Medical devices shall comply with 4.2 of ⟦A1⟩ EN 60601-1-12:2015+A1:2020 ⟨A1⟧ and with requirements related to environmental conditions in relevant particular medical device standards as listed in Tables 9 to 16 as applicable.

6.3.3 Humidity and ingress of liquids

Medical devices shall comply with 4.2 of ⟦A1⟩ EN 60601-1-12:2015+A1:2020 ⟨A1⟧ and with requirements related to environmental conditions in relevant particular medical device standards as listed in Tables 9 to 16 as applicable.

6.3.4 Mechanical strength

Medical devices shall comply with ⟦A1⟩ EN 60601-1-12:2015+A1:2020 ⟨A1⟧, Clause 10.1 and with requirements related to mechanical strength in relevant particular medical device standards as listed in Tables 9 to 16 as applicable.

6.3.5 Fixation of devices

Medical devices shall be restrained by means of a fixation system, retention or storage system, as appropriate.

If a charging device in the fixation system is present it shall automatically connect when fixed in the fixation system.

The fixation system(s), retention system(s) or storage system(s) shall hold the device to withstand accelerations or decelerations of 10 g longitudinal (forward, backward), 10 g transverse (left, right) and 10 g vertical. This is to be tested as described in subclause 5.3.

Terminal units and electrical socket outlets shall not be used as part of the fixation system.

If rails systems are used, they shall comply with EN ISO 19054:2006+A1:2016.

NOTE Rail systems consist of e.g. rail supports, rails, rail clamps, equipment mount holders, equipment mounts, equipment pin holders and equipment pins.

6.3.6 Electrical safety

All medical devices shall be selected and mounted so that no harmful influences to the electrical supply results.

6.3.7 User interface

Buttons, switches, indicators and controls shall be easily accessible and visible from the attendant's seat. SI units (except for blood pressure and airway pressure) and standardized graphical symbols shall be used where applicable.

6.3.8 Gas installation

6.3.8.1 Source of supply

The source of supply shall consist of one or more of the following:

a) medical gas in cylinders, e.g. oxygen, air;

b) non-cryogenic liquid in cylinders, e.g. N_2O, CO_2;

c) cryogenic liquid in cylinders, e.g. oxygen;

d) cryogenic liquid in stationary vessels, e.g. oxygen;

e) non-cryogenic liquid in stationary vessels, e.g. N_2O, CO_2;

f) air compressor system;

g) proportioning system, e.g. oxygen and nitrogen;

h) vacuum system;

i) oxygen 93 %.

NOTE EN ISO 7396-1:2016+A1:2019 can be used as guidance for designing the source of supply.

6.3.8.2 Medical gas piping

All ducts for medical gas installations or medical gas piping shall be vented.

If the road ambulance is intended to carry a transport incubator system there shall be an adapter for medical gases cross-border transportation meeting the requirements of EN 13976-1:2018 subclause 4.3.3.

6.3.8.3 Flexible hoses for connecting devices

Flexible hoses for connecting medical devices to outlet connectors (i.e. terminal units or a gas-specific connection points) shall comply with EN ISO 5359:2014+A1:2017.

6.3.8.4 Flexible hoses for medical gas supply

If flexible hoses are used for medical gas supply between the pressure regulators and the terminal units, the requirements of ▌A1⟩ EN ISO 11197:2019 apply ⟨A1▐.

6.3.8.5 Stationary oxygen supply

The stationary oxygen supply shall comprise a source in accordance with Table 11 (under normal temperature and pressure) pressure regulators and terminal units or pressure regulators with flow metering devices.

6.3.8.6 Portable oxygen supply

The portable oxygen supply shall comprise a source in accordance with Table 11 (under normal temperature and pressure) and a pressure regulator with flow metering device.

6.3.8.7 Pressure regulators and flow metering devices

Pressure regulators and pressure regulators with flow metering devices shall conform to EN ISO 10524-1:2019 or EN ISO 10524-2:2019 or EN ISO 10524-3:2019. The pressure regulators shall be directly connected to the source of supply.

Flow metering devices for connection to terminal units and for connection to flow-rate control units shall conform to ▌A1⟩ prEN ISO 15002:2022 ⟨A1▐.

6.3.8.8 Terminal units

Terminal units shall comply with ▌A1⟩ EN ISO 9170-1:2020 ⟨A1▐.

6.3.8.9 Pneumatic power supply

If the road ambulance is equipped with terminal units, the range of operating pressure shall be

— for compressed medical gases $400 kPa_{0}^{+100} kPa$; for tolerances see EN ISO 7396-1:2016+A1:2019, Table 2.

— for vacuum ≤ 60 kPa absolute pressure

and the maximum allowable pressure change between the source of supply and the terminal units shall be

— for compressed medical gases 10 % at a flow of 40 l/min;

— for vacuum 20 % at a flow of 25 l/min.

6.3.8.10 Additional outlet connectors

For road ambulances complying with 6.3.8.9, one additional outlet connector (i.e. a terminal unit or a gas-specific connection point) complying with ▌A1⟩ EN ISO 9170-1:2020 ⟨A1▐ shall be fitted in addition to the outlet connectors necessary for the devices intended to be normally used.

6.3.8.11 Pin-index cylinder values

Pin-index outlet connections of cylinder values shall comply with ▌A1⟩ EN ISO 407:2021 ⟨A1▐.

6.3.8.12 Alarms

If alarms are provided as part of the gas installation, they shall comply with EN ISO 7396-1:2016+A1:2019, Clause 6.

6.3.8.13 Test pressure for mechanical integrity

The gas piping and flexible hoses used for medical gas supply shall withstand a pressure of 1 000 kPa +20 % for at least 5 min.

NOTE The pressure of 1000 kPa is the maximum pressure supplied by pressure regulators complying with EN ISO 10524-1:2019, EN ISO 10524-2:2019 and EN ISO 10524-3:2019 in single fault condition.

6.3.8.14 Test pressure for leakage

After a test period of 2 h to 24 h at nominal distribution pressure, the pressure drop in the gas piping of the distribution system shall not exceed 0,4 %/h of the test pressure.

After a test period of 2 h to 24 h at nominal distribution pressure, the pressure drop in flexible hoses for medical gas supply of the distribution system shall not exceed 0,6 %/h of the test pressure.

6.3.9 Marking and instructions

Marking and instructions for use shall comply with ▌A1⟩ EN ISO 15223-1:2021 ⟨A1▐ and ▌A1⟩ EN ISO 20417:2021 ⟨A1▐.

Operating and maintenance instructions, service records and any other appropriate requirements shall accompany the product. Standardized symbols should be used or it should be written in the native language of the area where the equipment is to be used.

6.3.10 Maintenance

The manufacturer shall supply instructions for carrying out preventive maintenance.

6.4 List of equipment

Road ambulance according to their type A_1, A_2, B or C shall carry the minimum equipment listed in Tables 9 to 19.

Where national regulations for equipment are in conflict with Tables 9 to 19 the national regulations apply. Supplementary devices may be introduced depending on local requirements.

However, if it is common practice for the road ambulances to cross national borders, equipment according to Tables 9 to 19 shall be carried in accordance with the vehicle type.

For most items a specific quantity is given. “X” in the column indicates that quantity may be varied in accordance with the local needs of the country/district.

Where applicable the equipment shall be available across the full age range of patients.

Table 9 — Type of patient handling equipment

No	Device	Standard	Type of road ambulances			
			A_1	A_2	B	C
1	Main stretcher/undercarriage	EN 1865-1:2010+A1:2015 or 〚A1〛 prEN 1865-2:2023 〚A1〛	1	1	1	1
2	Pick up stretcher	EN 1865-1:2010+A1:2015	–	–	1	1
3	Vacuum mattress	EN 1865-1:2010+A1:2015	–	–	1	1
4	Device for conveying a seated patient [a]	EN 1865-1:2010+A1:2015 and EN 1865-4:2012	1	1	1	X
5	Carrying sheet or transfer mattress	EN 1865-1:2010+A1:2015	1	1	1	1
6	Long spinal board complete with head immobilizer and securing straps	EN 1865-1:2010+A1:2015	–	–	X	X
7	powered climbing stair chair[b]		X	X	X	X

[a] Unless the main stretcher has the function of these devices.

[b] Alternative for No 4.

Table 10 — Type of immobilization equipment

No	Device	Standard	Type of road ambulance			
			A_1	A_2	B	C
1	Traction device	–	–	–	X	X
2	Immobilization, set for fractures including pelvic	–	–	–	1	1
3	Cervical upper spinal immobilization devices Cervical collar-set	–	–	–	1	1
4	Extrication devices or short spinal board with immobilisation capacity	–	–	–	1	1

Table 11— Type of ventilation/respiration equipment

No	Device		Standard	Type of road ambulance			
				A_1	A_2	B	C
1	Stationary oxygen [a] Minimum 2 000 l, (under normal temperature and pressure), flowmeter/flowgauge with maximum capacity of at least 15 l/min and regulating valve		⟩A1⟨ EN ISO 9170-1:2020 ⟩A1⟨	X	X	1	1
		quick connection	⟩A1⟨ EN ISO 9170-1:2020 ⟩A1⟨	–	–	1	1
2	Portable oxygen [b] Minimum 400 l, (under normal temperature and pressure), flowmeter/flowgauge with maximum capacity of at least 15 l/min and regulating valve		⟩A1⟨ EN ISO 9170-1:2020 ⟩A1⟨	1	1	1	1
		quick connection	⟩A1⟨ EN ISO 9170-1:2020 ⟩A1⟨	–	–	1	1
3	Resuscitator with oxygen inlet and masks and airways for all ages and oxygen reservoir		–	X	X	1	1
4	Mouth to mask ventilator with oxygen inlet		–	X	X	–	–
5	Permenantly installed or portable suction device with a minimum pressure of – 65 kPa with a minimum capacity of 1 l		EN 60601-1:2006+A1:2013 ⟩A1⟨ EN ISO 10079-1:2022 ⟩A1⟨ ⟩A1⟨ EN ISO 10079-3:2022 ⟩A1⟨	–	–	1	1
6	Portable suction device		⟩A1⟨ EN ISO 10079-2:2022 ⟩A1⟨	1	1	1	1
7	Demand valve		–	–	–	X	X

[a] A reduced capacity of 1 000 l may be fitted in type A_1 and A_2 road ambulances.

[b] A reduced capacity of 200 l may be fitted in type A_1 and A_2 road ambulances.

Table 12 — Type of diagnostics equipment

No	Device	Standard	Type of road ambulance			
			A_1	A_2	B	C
1	Manual Blood Pressure Monitor, Cuff size 10 cm – 55 cm	–	–	–	1	1
2	Automatic B P Monitor [a], Cuff size 10 cm – 55 cm for types B and C, cuff size 35 cm – 55 cm for type A A doppler type shall operate accurately in the conditions of electrical interference and vibration specified in 4.2 and 6.3.4	–	–	–	1	1
3	Oximeter [a]	EN ISO 80601-2–61:2019	X	X	1	1
4	Stethoscope	–	–	–	1	1
5	Thermometer	EN 12470-1:2000+A1:2009	–	–	1	1
6	Device for blood sugar determination	–	–	–	1	1
7	Diagnostic light	–	–	–	1	1
8	12-lead-ECG [a]	–	–	–	x	1
a If desired two or more of these functions can be combined within one device.						

Table 13 — Type of drug

No	Type of drug	Standard	Type of road ambulance			
			A_1	A_2	B	C
1	Medication according to national regulation	–	–	–	X	X

Table 14 — Type of infusion material or equipment

No	Device	Standard	Type of road ambulance			
			A_1	A_2	B	C
1	Infusion solutions, litre	–	–	–	2	2
2	Equipment for injections and infusions, set	–	–	–	2	2
3	Infusion system which is designed to allow the administration of fluid warmed to (37 ± 2) °C. This system is not required to be portable	–	–	–	1	1
4	Infusion mounting	–	1	1	2	2
5	Pressure infusion device	–	–	–	1	1
6	Cooled compartment for storage of infusion solutions and drugs with a total volume of minimum 5 l and a fixed temperature range of 5 °C to 7 °C	–	–	–	x	x

Table 15 — Type of equipment for managing of life-threatening problems

No	Device [a]	Standard	Type of road ambulance			
			A_1	A_2	B	C
1	Defibrillator with rhythm and patient data recording	▌A1⟩ EN 60601-2-4:2011+A1:2019 ⟨A1▐	1	1	1	1
2	Cardiac monitor	EN 60601-2–27:2014	–	–	1	1
3	External cardiac pacing	▌A1⟩ EN 60601-2-4:2011+A1:2019 ⟨A1▐	–	–	X	X
4	Portable airways care system (p.a.c.s.) Manual resuscitator Mouth to mask ventilator with oxygen inlet Airways oro- or nasopharyngeal airway Aspirator Suction catheter	–	–	–	1	–

No	Device [a]	Standard	Type of road ambulance			
			A_1	A_2	B	C
5	Portable advanced resuscitation system (p.a.r.s.) Contents of portable airways care system (p.a.c.s.) Infusion equipment – to include suitable venous indwelling cannulae Infusion administration sets Infusion solutions Adhesive fixing materials Intubation equipment – to include laryngoscope handle(s) with suitable blades Magill forceps Insertion stylets Endotracheal tubes with connectors Inflation tube clamp Inflation syringe Tube fixing material Stethoscope Drug administration equipment	–	–	–	–	1

No	Device [a]	Standard	Type of road ambulance			
			A_1	A_2	B	C
6	Nebulization apparatus	⟨A1⟩ EN ISO 27427:2019 ⟨A1⟩	–	–	1	1
7	Thorax drainage kit	–	–	–	–	1
8	Volumetric infusing device	–	–	–	–	1
9	intraosseous access (for all age groups)	–	–	–	–	1
10	Emergency and Transport Ventilators	EN 794-3:1998+A2:2009	–	–	–	1
11	PEEP-valve, adjustable or set	–	–	–	–	1
12	Capnometer or capnography	EN ISO 8060 1-2–55:2018	–	–	X	1
13	Cardioversion	–	–	–	X	1
14	Portable device for non-invasive CPAP application with pressure monitoring	–	–	–	X	1
15	Chest compression devices		–	–	X	X

[a] If desired two or more of these functions can be combined within one device.

Table 16 — Bandaging and nursing

No	Device	Standard	Type of road ambulance			
			A_1	A_2	B	C
1	Bedding equipment	–	1	2	1	1
2	Blankets	–	2	4	2	2
3	Material for treatment of wounds	–	1	1	1	1
4	Material for treatment of burns and corrosives	–	–	–	1	1
5	Re-plantation container to maintain the internal temperature at (4 ± 2) °C for at least 2 h	–	–	–	X	X
6	Kidney bowl	–	1	2	1	1
7	Vomiting bag	–	1	2	1	1
8	Bed-pan	–	X	X	X	X
9	Non-glass urine bottle	–	1	2	1	1
10	Sharps container	–	1	1	1	1

No	Device	Standard	Type of road ambulance			
			A_1	A_2	B	C
11	Sterile surgical gloves, pairs	▌A1⟩ EN 455-1:2020+A1:2022 ⟨A1▌, EN 455-2:2015	X	X	5	5
12	Non-sterile gloves	▌A1⟩ EN 455-1:2020+A1:2022 ⟨A1▌, EN 455-2:2015	100	100	100	100
13	Emergency delivery kit	–	X	X	1	1
14	Waste bag	–	1	1	1	1
15	Clinical waste bag	–	X	X	X	X
16	Non-wovens stretcher sheet	–	1	1	1	1
17	Supply set for special applications, consisting of: - Sifting materials - hemostyptics - tourniquets - Pneumothorax relief needles - prefabricated dressings - Thoracic occlusive dressings	–	X	X	X	X

Table 17 — Storage for personal protection equipment (for each member of the crew for protection and to identify the crew as road ambulance personnel)[1]

No	Device	Standard	Type of road ambulance			
			A_1 [a]	A_2 [a]	B [a]	C [a]
1	Basic protective clothing including high visibility reflective jacket or tabard	EN ISO 20471:2013+A1 :2016	1	1	1	1
2	Advanced protection wear	–	–	–	X	X
3	Safety/debris gloves, pairs	EN ISO 21420:2020–06	1	1	1	1
4	Safety helmet	EN 443:2008	–	–	1	1
5	Personal protection equipment against infection	–	X	X	1	1
6	CO gas detectors		X	X	X	X
[a] Numbers are quoted per crew member.						

1 Table servesas a checklist to ensure that storage facilities at least for the listed equipment are available. It does not constitute any requirement regarding the number, selection and use of personal protective equipment.

Table 18 — Rescue and protection material

No	Device	Standard	Type of road ambulance			
			A_1	A_2	B	C
1	Cleaning and disinfection material	–	1	1	1	1
2	Light rescue tools, set	–	–	–	X	X
3	Seat belt cutter	–	1	1	1	1
4	Warning triangle/lights	–	2	2	2	2
5	Spotlight	–	1	1	1	1
6	Fire extinguisher	EN 3-7:2004+A1:2007	1	1	1	1

Table 19 — Communication

No	Device	Standard	Type of road ambulance			
			A_1	A_2	B	C
1	Mobile radio transceiver	–	1	1	1	1
2	Portable radio transceiver	–	–	–	1	1
3	Access to the public telephone network e.g. via the normal radio-transmitter or by mobile (cellular) telephone	–	–	–	1	1
4	Portable alerting system, per person Can be included in portable radio receiver	–	–	–	1	1
5	Intercom system between driver and patient compartment	–	1	1	1	1

Annex A
(informative)

Test summary[2]

This is to certify that ambulance compartment produced by……

on the chassis……..

equipped as a ..... (type A B or C) ambulance complies with ▌A1⟩ EN 1789:2020+A1:2023 ⟨A1▌, 4.4.11 and 5.3 static and/or

dynamic tests have been carried from…….. to

…..…….(dates)

Detailed data are to be found in test report number .....

Authorized designated official ..... (name)

Signed .....

Date.....

2 To be prepared by the manufacturer company for each vehicle/vehicle series.

Annex B
(informative)

Recognition

B.1 Recognition and visibility of ambulances

To enhance the recognition and visibility of the vehicle in daylight the base body colour should be yellow (RAL 1016) or white.

Where the white body option is selected additional fluorescent yellow or yellow (RAL 1016) or fluorescent red (RAL 3024) should be used on the external surface of the vehicles.

NOTE RAL colour space system, maintained by Deutsches Institut für Gütesicherung und Kennzeichnung e.V

For night time visibility micro-prismatic reflective material tested and approved in accordance with ECR-R 104 should be applied.

With the exception of Red Cross societies or where the “Star of life” is locally registered, a blue reflective “Star of life” emblem (minimum size 500 mm) together with reflective letters, numerals or a symbol identifying the organization and the vehicle, should be applied to the roof of the ambulance.

With the exception of Red Cross societies or where the “Star of life” is locally registered, a blue reflective “Star of life” emblem should be applied to the sides and rear of the ambulance. The word “ambulance” or equivalent national translation should be applied in reflective upper case letters, a minimum of 100 mm high, in a colour contrasting with the background, to the side and rear of the ambulance and if possible on the front.

B.2 Recognition of crew

Safety garments should conform to at least class 2 of EN ISO 20471:2013+A1:2016.

With the exception of Red Cross societies or where the “Star of life” is locally registered, a blue reflective “Star of Life” emblem should be fixed to the garments. The garments should identify the designation of the wearer.

Annex C
(informative)

Hygiene

Hygiene in a road ambulance should ensure safe environment to both patient/-s and crew.

Hygiene addresses patient's compartment, patient's compartment interior and fixed installations, stretcher and patient handling equipment, immobilization equipment, medical devices, medical equipment etc..

Patient's compartment interior should be lined with material that is non-permeable, easily cleaned and non-porous. Ceilings and joints should be constructed for easy cleaning and to prevent infiltration.

Body fluids and contamination can be easily and safely removed with simple cleaning equipment. The cleaned area can post cleaning be safely disinfected.

Areas where airborne particles that might be contagious can be present should be cleaned and disinfected easily and safely for both patient and crew.

Equipment and devices carrying CE mark should be cleaned and disinfected with products carrying CE mark.

All other equipment, devices and surfaces should be cleaned with products suitable for medical environment to ensure the safety for both patient and crew.

Hand hygiene equipment should be placed to enable the crew to use them easily in all phases of the ambulance mission.

Cleaning and disinfection material should be carried in the ambulance to respond to biological spills during duty and for ensure appropriate hygiene level between calls.

Annex D
(informative)

A–deviations

A- deviation: National deviation due to regulations, the alteration of which is for the time being outside the competence of the CEN/ CENELEC member.

This European Standard falls under Directive Directive 93/42/EEC

NOTE (from CEN-CENELEC IR Part 2:2015, 2.16) Where standards fall under EU Directives or Regulations, it is the view of the Commission of the European Communities (OJ No C 59; 1982–03–09) that the effect of the decision of the Court of Justice in case 815/79 Cremonini/Vrankovich (European Court Reports 1980, p. 3583) is that compliance with A-deviations is no longer mandatory and that the free movement of products complying with such a standard should not be restricted except under the safeguard procedure provided for in the relevant Directive or Regulation.

A-deviations in an EFTA-country are valid instead of the relevant provisions of the European Standard in that country until they have been removed.

D.1 Deviation in Spain

Clause	Deviation
3.3	According to the Spanish Law RD836/2012 of 25th May 2012, article 3, section 2, paragraph 4: In type A2 road ambulances layout, the stretcher will be optional. NOTE This regulation is available on web: https://www.boe.es/eli/es/rd/2012/05/25/836 https://www.boe.es/buscar/pdf/2012/BOE-A-2012-7655-consolidado.pdf

A1 Annex E
(normative)
Electric propelled vehicles

Due to energy storing characteristic, electric motors still have limitations in service over combustion engine vehicles.

Therefore, points included in this annex are only a temporary measure to allow the use of chassis with other than combustion engines. Standardization will be carefully following alternative energies development in motor vehicle design and thereafter consider adaptation of these changes to standard requirements.

Although this annex now verifies that electrically propelled vehicles can be compliant with the document, particular attention shall be paid to possible limitations in the intended use of these vehicles (e.g. range, charging time).

Statement for 4.2.3 "Battery and alternator" of this document:

In the title and the text "*alternator*" may be intended as "*recharging system*" and the term "*idling*" does not apply to electrically propelled vehicles.

Statement for 4.2.4.2 of this document:

The term "*engine running*" does not apply to electrically powered vehicles.

Statement for 5.10 "Testing of the heating system" of this document:

Item "*c) start the engine*" should be understood as "*put the vehicle in running condition*".

In item f) and G) the term "*idling*" does not apply to electrically propelled vehicles.

Statement for 5.11 "Testing of the cooling system" of this document:

Item "*c) start the engine*" should be understood as "*put the vehicle in running condition*".

In item f) the term "*idling*" does not apply to electrically propelled vehicles. A1

Annex ZA
(informative)

Relationship between this European Standard and the essential requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered

This European Standard has been prepared under a Commission's standardization request [M/023 concerning the development of European Standards related to medical devices] to provide one voluntary means of conforming to essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [OJ L 169].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding essential requirements of that Directive and associated EFTA regulations.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC as amended by 2007/47/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with Essential Requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this European Standard and Annex I of Directive 93/42/EEC [OJ L 169]

Essential Requirements of Directive 93/42/EEC	Clause(s)/subclause(s) of this EN	Remarks/Notes
9.1, first sentence only	6.3.8	Covered as far as the gas installation is concerned
9.2, second indent	6.3.2, 6.3.3, 6.3.4, 6.3.5, 6.3.6, 6.3.8	To fully cover this ER, risks connected with reasonably foreseeable environmental conditions shall be removed or minimized as far as possible
9.3	4.1.1, 6.3.8	Covered with the respect to the gas installation only. To fully cover this ER, risks connected with fire or explosion shall be minimized
12.7.1	6.3.4, 6.3.5	Covered with respect to the fixation system, retention system and storage system to hold a medical device.

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the products falling within the scope of this standard.

Bibliography

[1] Council Directive 70/156/EEC of 6 February 1970 on the approximation of the laws of the Members States relating to the type-approval of motor vehicles and their trailers

[2] Council Directive 72/245/EEC of 20 June 1972 on the approximation of the laws of the Members States relating to the suppression of radio interference produced by spark-ignition engines fitted to motor vehicles

[3] Council Directive 74/408/EEC of 22 July 1974 on the approximation of the laws of the Member States relating to the interior fittings of motor vehicles (strength of seats and of their anchorages)

[4] Council Directive 76/115/EEC of 18 December 1975 on the approximation of the laws of the Member States relating to anchorages for motor-vehicle safety belts

[5] Council Directive 77/541/EEC of 28 June 1977 on the approximation of the laws of the Member States relating to safety belts and restraint systems of motor vehicles

[6] Council Directive 78/932/EEC of 16 October 1978 on the approximation of the laws of the Member States relating to head restraints of seats of motor vehicles

[7] Council Directive 90/269/EEC of 29 May 1990 on the minimum health and safety requirements for the manual handling of loads where there is a risk particularly of back injury to workers (fourth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC)

[8] Council Directive 92/21/EEC of 31 March 1992 on the masses and dimensions of motor vehicles of category M1

[9] Council Directive 92/22/EEC of 31 March 1992 on safety glazing and glazing materials on motor vehicles and their trailers

[10] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

[11] Directive 96/79/EC of the European Parliament and of the Council of 16 December 1996 on the protection of occupants of motor vehicles in the event of a frontal impact and amending Directive 70/156/EEC

[12] Commission Directive 2004/104/EC of 14 October 2004 adapting to technical progress Council Directive 72/245/EEC relating to the radio interference (electromagnetic compatibility) of vehicles and amending Directive 70/156/EEC on the approximation of the laws of the Member States relating to the type-approval of motor vehicles and their trailers

[13] Regulation (EU) 2018/858 of the European Parliament and of the Council of 30 May 2018 on the approval and market surveillance of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles, amending Regulations (EC) No 715/2007 and (EC) No 595/2009 and repealing Directive 2007/46/EC (Text with EEA relevance.)

[14] Commission Regulation (EU) No 214/2014 of 25 February 2014 amending Annexes II, IV, XI, XII and XVIII to Directive 2007/46/EC of the European Parliament and of the Council establishing a

framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles

[15] ECE-Regulation No. 16; revision 3; uniform provisions concerning the approval of safety-belts and restraint systems for adult occupants of power- driven vehicles

[16] EN 12464-1:2011, *Light and lighting - Lighting of work places - Part 1: Indoor work places*

[17] EN ISO 7396-2:2007, *Medical gas pipeline systems - Part 2: Anaesthetic gas scavenging disposal systems (ISO 7396-2:2007)*

[18] EN ISO 9170-2:2008, *Terminal units for medical gas pipeline systems - Part 2: Terminal units for anaesthetic gas scavenging systems (ISO 9170-2:2008)*

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

[20] *2008/ECE21/EG, Regulation No 21 of the Economic Commission for Europe of the United Nations (UN/ECE) - Uniform provisions concerning the approval of vehicles with regard to their interior fittings*

[21] prEN 60601-2-2:2016, *Medical Electrical Equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*

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