

ARK

BRITISH STANDARD

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Incorporating
Amendment No. 1

Medical vehicles and their equipment — Road ambulances

The European Standard EN 1789:1999, with the incorporation of amendment A1:2003, has the status of a British Standard

ICS 11.160; 43.160

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National foreword

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Summary of pages

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EUROPEAN STANDARD
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English version

Medical vehicles and their equipment — Road ambulances
(includes amendment A1:2003)

Véhicules de transport sanitaire et leurs équipements —
Véhicules d'ambulances
(inclut l'amendement A1:2003)

Rettungsdienstfahrzeuge und deren Ausrüstung —
Krankenkraftwagen
(enthält Änderung A1:2003)

This European Standard was approved by CEN on 5 September 1999. Amendment A1 was approved by CEN on 28 December 2002.

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

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

Contents

Page

Foreword	4
Introduction	5
1 Scope	5
2 Normative references.....	5
3 Definitions	8
3.1 Patient and emergency patient.....	8
3.1.1 Patient	8
3.1.2 Emergency patient	8
3.2 Ambulance	8
3.3 Types of road ambulances	8
3.3.1 Type A: patient transport ambulance.....	8
3.3.2 Type B: emergency ambulance.....	8
3.3.3 Type C: mobile intensive care unit	8
3.4 Net vehicle mass; unladen mass.....	8
3.5 Permissible gross vehicle mass (total mass)	8
3.6 Loading capacity.....	9
4 Requirements.....	9
4.1 General requirements	9
4.1.1 General.....	9
4.1.2 Maximum overall dimension	9
4.1.3 Wheelarch clearance.....	9
4.2 Performance.....	9
4.2.2 Braking	9
4.3 Electrical requirements	9
4.3.1 General.....	9
4.3.2 Battery and generator	9
4.3.3 Electrical installation	10
4.3.4 Communication systems (radio installation).....	11
4.4 Vehicle body.....	11
4.4.1 Fire safety.....	11
4.4.2 Driver's seat configuration	11
4.4.4 Bulkhead	14
4.4.5 Emergency exits	14
4.4.6 Openings (doors, windows)	14
4.4.7 Loading area	15
4.5 Patient's compartment	16
4.5.1 General.....	16
4.5.2 Patient's compartment dimensions.....	16
4.5.3 Patient and attendant seating	20
4.5.4 Ventilation and anaesthetic gas scavenging systems	20

4.5.5	Heating system	20
4.5.6	Interior lighting.....	21
4.5.7	Interior noise level.....	21
4.5.8	Holding system for infusion.....	21
4.5.9	Maintain systems and fixations of the equipment in the patient's compartment	21
5	Testing.....	22
5.1	Testing of the interior noise level.....	22
5.2	Testing of the acceleration.....	22
5.3	Testing of maintain systems and fixations of the equipment in the patient's compartment	22
6	Medical devices	23
6.1	Provision with medical devices.....	23
6.2	Medical devices storage	24
6.3	Requirements for medical devices	24
6.3.1	General.....	24
6.3.2	Temperature.....	24
6.3.3	Humidity and ingress of liquids.....	24
6.3.4	Mechanical strength.....	24
6.3.5	Fixation of devices	25
6.3.6	Electrical safety.....	25
6.3.7	Electromagnetic compatibility	25
6.3.8	User interface.....	25
6.3.9	Gas installation.....	25
6.3.10	Marking and instructions.....	27
6.3.11	Maintenance.....	27
6.4	Mechanical strength – Test methods for medical devices for use in road ambulances.....	27
6.4.1	Vibration and bump test.....	27
6.4.2	Free fall	27
6.5	List of equipment.....	27
Annex A	(informative).....	34
Annex ZA	(informative).....	35

Foreword

This European Standard has been prepared by Technical Committee CEN/TC 239, Rescue systems, the Secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 2000, and conflicting national standards shall be withdrawn at the latest by April 2000.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

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

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

Foreword to amendment A1

This document (EN 1789:1999/A1:2003) has been prepared by Technical Committee CEN/TC 239, Rescue systems, the Secretariat of which is held by DIN.

This amendment to the 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 September 2003, and conflicting national standards shall be withdrawn at the latest by September 2003.

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

Introduction

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

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

^(A1) Text deleted ^(A1)

1 Scope

This European Standard specifies requirements for the design, ^(A1) testing ^(A1), performance and equipping of road ambulances used for the transport of sick or injured persons. This standard is applicable to road ambulances capable of transporting at least one person on a stretcher.

Requirements are specified for categories of road ambulances based in increasing order of the level of treatment that can be carried out. These are the patient transport ambulance (types A₁, A₂), the emergency ambulance (type B) and the mobile intensive care unit (type C).

^(A1) This standard gives general requirements for medical devices carried in road ambulances and used therein and outside hospitals and clinics in situations where the ambient conditions can differ from normal indoor conditions. ^(A1)

2 Normative references

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

EN 3-1

Portable fire extinguishers – Part 1: Description, duration of operation, class A and B fire tests

EN 344

Requirements and test methods for safety, protective and occupational footwear for professional use

EN 420

General requirements for gloves

EN 443

Helmets for firefighters

- EN 455-1
Medical gloves for single use – Part 1: Requirements and testing for freedom from holes
- EN 455-2
Medical gloves for single use – Part 2: Requirements and testing for physical properties
- EN 737-1:1998
Medical gas pipeline systems – Part 1: Terminal units for compressed medical gases and vacuum
- EN 737-2:1998
Medical gas pipeline systems – Part 2: Anaesthetic gas scavenging disposal systems – Basic requirements
- EN 737-3:1998
Medical gas pipeline systems – Part 3: Pipelines for compressed medical gases and vacuum
- EN 737-4:1998
Medical gas pipeline systems – Part 4: Terminal units for anaesthetic gas scavenging systems
- prEN 737-6:1998
Medical gas pipeline systems – Part 6: Dimensions of probes for terminal units for compressed medical gases and vacuum
- EN 738-1
Pressure regulators for use with medical gases – Part 1: Pressure regulators and pressure regulators with flow metering devices
- EN 738-3
Pressure regulators for use with medical gases – Part 3: Pressure regulators integrated with cylinder valves
- EN 739
Low-pressure hose assemblies for use with medical gases
- EN 740:1998
Anaesthetic workstations and their modules – Particular requirements
- EN 793
Particular requirements for safety of medical supply units
- EN 794-3
Lung ventilators – Part 3: Particular requirements for emergency and transport ventilators
- EN 850
Transportable gas cylinders - Pin-index, yoke-type valve outlet connections for medical use
- EN 864
Medical electrical equipment - Capnometers for use with humans – Particular requirements
- EN 865
Pulse oximeters – Particular requirements
- EN 980
Graphical symbols for use in the labelling of medical devices
- EN 1041
Information supplied by the manufacturer with medical devices
- EN 1865
Specifications for stretchers and other patient handling equipment used in ambulances

- EN 12218
Rail systems for supporting medical equipment
- prEN 12470-1
Clinical thermometers – Part 1: Metallic liquid-in-glass thermometers with maximum device
- EN 60601-1:1990
Medical electrical equipment – Part 1: General requirements for safety (IEC 60601-1 : 1988)
- EN 60601-1-2
Medical electrical equipment – Part 1: General requirements for safety; 2. collateral standard: electromagnetic compatibility; Requirements and tests (IEC 60601-1-2:1993)
- EN ISO 10079-1
Medical suction equipment – Part 1: Electrically powered suction equipment - Safety requirements (ISO 10079-1:1991, including Technical Corrigendum 1:1992 and Technical Corrigendum 2:1993)
- EN ISO 10079-2
Medical suction equipment – Part 2: Manually powered suction equipment (ISO 10079-2:1992)
- IEC 60068-2-6
Environmental testing – Part 2: Tests; Test Fc: Vibration (sinusoidal)
- IEC 60068-2-29
Basic environmental testing procedures – Part 2: Tests; Test Eb and guidance: Bump
- IEC 60068-2-32
Basic environmental testing procedures – Part 2: Tests; Test Ed: Free fall
- IEC 60068-2-36
Basic environmental testing procedures – Part 2: Tests; Test Fdb: Random vibration wide band -- Reproducibility medium
- IEC 60364-7-708
Electrical installations for buildings – Part 7: Requirements for special installations or locations; Section 708: Electrical installations in caravan parks and caravans
- IEC 60601-2-4
Medical electrical equipment – Part 2: Particular requirements for the safety of cardiac defibrillators and cardiac defibrillator-monitors
- A1** ISO 3795
*Road vehicles, and tractors and machinery for agriculture and forestry — Determination of burning behaviour of interior materials. **A1***
- ISO 5128:1980
Acoustics - Measurement of noise inside motor vehicles
- EN ISO 8185
Humidifiers for medical use - General requirements for humidification systems (ISO 8185:1997)
- prEN ISO 15002
Flow-metering devices for connection to terminal units of medical gas pipeline systems (ISO/DIS 15002:1996)

3 Definitions

For the purposes of this standard, the following definitions apply:

3.1 Patient and emergency patient

3.1.1 Patient

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

3.1.2 Emergency patient

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

3.2 Ambulance

^(A1) Vehicle or craft intended to be crewed by a minimum of two appropriately trained staff for the provision of care and transport of at least one stretchered patient. ^(A1)

3.3 Types of road ambulances¹⁾

3.3.1 Type A: patient transport ambulance

Road ambulance designed and equipped for the transport of patients who are not expected to become emergency patients.

Two types of patient transport ambulance exist:

Type A₁: suitable for transport of single patient

Type A₂: suitable for transport of one or more patient(s) (on stretcher(s) and/or chair(s)).

3.3.2 Type B: emergency ambulance

Road ambulance designed and equipped for the transport, basic treatment and monitoring of patients.

3.3.3 Type C: mobile intensive care unit

Road ambulance designed and equipped for the transport, advanced treatment and monitoring of patients.

3.4 Net vehicle mass; unladen mass

^(A1) Net vehicle mass according to 70/156/EEC of the road ambulance including the driver taken as 75 kg and all fixed installations. ^(A1)

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

3.5 Permissible gross vehicle mass (total mass)

Permissible gross mass according to 70/156/EEC includes the net mass (see 3.4) and additionally the sanitary, medical and technical equipment and persons (75 kg per person) as well as any eventual mass reserve.

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

3.6 Loading capacity

Difference between the gross vehicle mass and the net vehicle mass.

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

4 Requirements

4.1 General requirements

(A1) The road ambulance shall comply with the relevant regulation(s) for special use vehicles (see Footnote 1 on page 8). **(A1)**

4.1.1 General

4.1.2 Maximum overall dimension

The maximum overall dimensions shall not exceed the following:

Length: 6 500 mm

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

Width: 2 200 mm (measured excluding external fold back mirrors)

4.1.3 Wheelarch clearance

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

4.2 Performance

4.2.1 Acceleration

(A1) A road ambulance loaded to permissible gross vehicle mass shall be able to accelerate from 0 km/h to 80 km/h within 35 s.

Type B and C road ambulances loaded to permissible gross vehicles mass up to 3,5 t shall be able to accelerate from 40 km/h to 80 km/h in the 3rd or 4th gear, 4th (or 5th gear where 5-speed transmission is fitted) within 27 s. **(A1)**

4.2.2 Braking

An anti-lock braking system should be fitted.

4.3 Electrical requirements

4.3.1 General

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

(A1) There shall be both an optical and audible warning system. **(A1)**

4.3.2 Battery and generator

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

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

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

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 120 Ah more than 4 seats in the compartment	80 Ah	80 Ah
	nominal voltage 24 V	—	—	63 Ah (2 × 12 V)	63 Ah (2 × 12 V)
additional battery(ies)	nominal voltage 12 V	—	—	80 Ah ¹⁾	80 Ah
	nominal voltage 24 V	—	—	63 Ah ¹⁾ (2 × 12 V)	63 Ah (2 × 12 V)
generator power		700 W	700 W	910 W	1 200 W

¹⁾ For special operational conditions.

4.3.3 Electrical installation

4.3.3.1 ^{A1} In type B and C road ambulances there shall be an externally mounted connector to enable charging and/or operation of, for example:

- a battery(ies);
- medical devices when installed;
- a patient compartment heater when installed;
- an engine preheater when installed. ^{A1}

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

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

^{A1} If the connector is located at the side of the vehicle it shall not be possible to start the engine whilst it is connected to an external 220/240 V power supply. ^{A1}

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

^{A1} Text deleted ^{A1}

4.3.3.2 The patient's compartment shall be fitted with the minimum number of ^{A1} connections ^{A1} as given in table 2.

Table 2: 12 V ^(A1) connections for medical devices in patient's compartment ^(A1)

Type of road ambulance	A ₁	A ₂	B	C
minimum number of ^(A1) connections ^(A1)	1	1	2	3

4.3.3.3 ^(A1) The electrical system in a road ambulance shall be separated from the base vehicle electrical system. All circuits in the additional system shall have separate overload protection²⁾. All circuits shall be well defined and clearly marked at the connection points and at a maximum of 1 m intervals along its length. The system shall have enough circuits and be so constructed that when/if a circuit fails, all illumination or medical technical equipment shall not be turned off. ^(A1)

4.3.3.4 ^(A1) The wiring and, where applicable conduits, shall withstand vibration. No wiring shall be located in or pass through conduit intended for medical gas installation. The wiring may not be loaded higher than stated by the wire manufacture. ^(A1)

4.3.3.5 Where there are different voltage systems, the ^(A1) connections ^(A1) shall be non-interchangeable.

4.3.3.6 The electrical generator shall be capable of delivering a constant supply of 40 % of the generator power specified in table 1 when the road ambulance is stationary.

4.3.3.7 The electrical system in road ambulances shall consist of at least four separate ^(A1) systems ^(A1) as follows.

- a) Basic system in non-equipped vehicle.
- b) Supply system for specific body mounted devices.
- c) Supply system for patient compartment.
- d) Supply system for communications.

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

4.3.4 Communication systems (radio installation)

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

Transceivers for use during transportation shall be permanently installed and connected to external antenna(e). They shall be electromagnetically compatible ^(A1) with the vehicle's electronic management system and medical devices. ^(A1)

NOTE: Attention is drawn to Directive ^(A1) 99/5 EC R&TTE ^(A1) on electromagnetic compatibility.

4.4 Vehicle body

4.4.1 Fire safety

All interior materials shall have a burning rate of less than 100 mm/minute when tested in accordance with ^(A1) ISO 3795 ^(A1).

4.4.2 Driver's seat configuration

The seating dimensions shall be in accordance with table 3.

²⁾ ^(A1) Overload protection may consist of either fuses or so called Electronic Management Control systems. ^(A1)

Table 3: Driver's seat configuration

Type of road ambulance	A ₁	A ₂	B mm	C mm
Minimum width, [W]	<p>^{A1} The ergonomic space of the driver's compartment as approved by the car manufacturer shall not be reduced. ^{A1}</p>		700	700
Minimum clearance between bottom edge of the steering wheel and the top forward edge of the seat cushion, [D]			150	150
Minimum clearance between the bottom edge of the steering wheel and the seat backrest, [S]			400	400
Minimum clearance between the cab roof and the driver's seat cushion measured along a line inclined 8° rear of vertical, [H ₁]			950	950
For dimension W, D, S and H ₁ see figure 1				

The cab shall be equipped with the following:

- a windscreen defrosting system operable when the road ambulance is stationary or mobile;
- an external windscreen washer system;
- two sunblinds;
- a grab handle for an attendant situated near the lower corner of the windscreen or above the entrance doors.

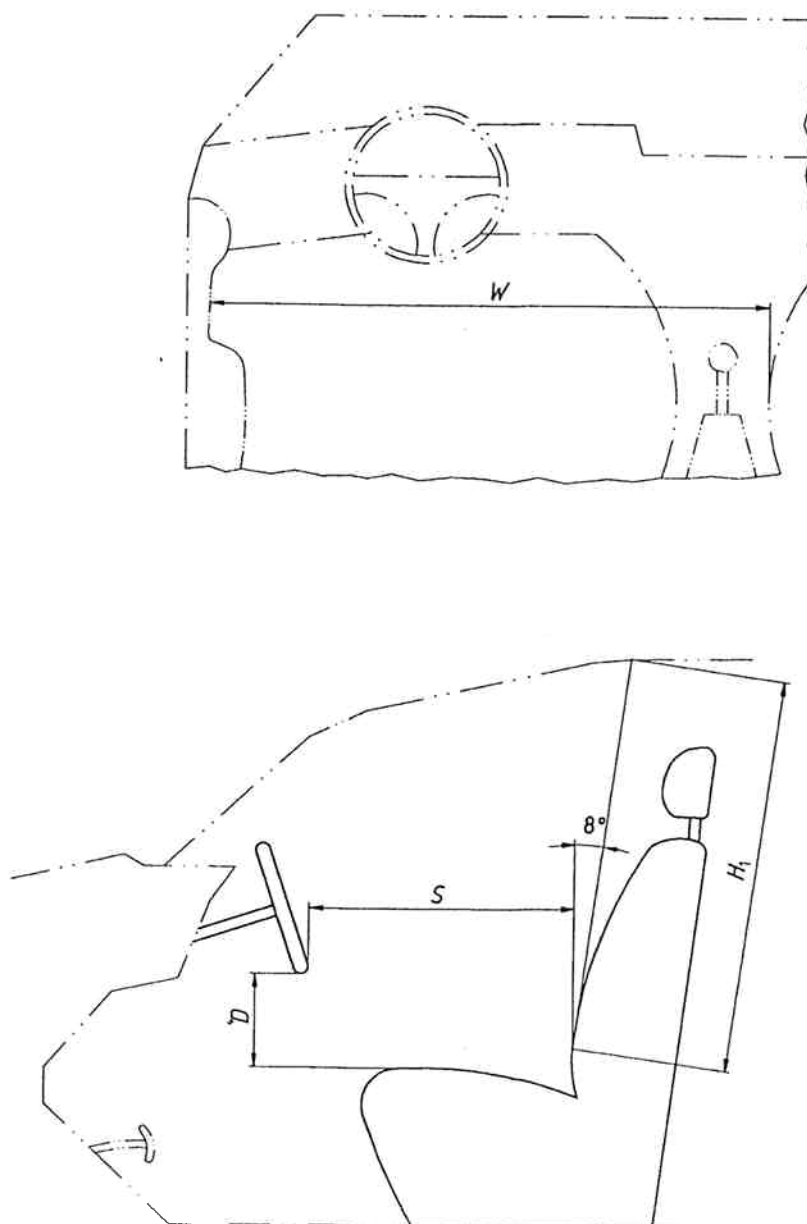


Figure 1: Driver's seat configuration

4.4.3 Minimum loading capacity

The minimum loading capacity shall be in accordance with table 4.

Table 4: Minimum loading capacity (persons)

Type of road ambulance	A ₁	A ₂	B	C
number of seats and/or stretcher facilities (without driver)	3	4	3	4
				5 ¹⁾
1) with two stretchers				

4.4.4 Bulkhead

A bulkhead³⁾ shall separate the driver's compartment from the patient's compartment. Where a door is fitted it shall be self-closing during transport and secured against self-opening.

One or two windows with a minimum separation of 100 mm shall be provided in the bulkhead made of material complying with the requirements of Directive 92/22/EEC. Each window shall have a maximum area of 0,12 m². The windows shall allow direct visual contact with the driver. 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.

A1 Text deleted A1

4.4.5 Emergency exits

In addition to the rear opening, there shall be an alternative exit from the patients compartment which permits the evacuation of patient(s) and crew.

4.4.6 Openings (doors, windows)

There shall be a minimum of two openings – one at the rear (door/tailgate) and one at the side (door/window) of the patient's compartment.

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

All openings shall comply with the minimum dimensions set out in table 5.

Table 5: Minimum opening dimensions in the patient compartment

Type of road ambulance		A ₁ ¹⁾ mm	A ₂ ¹⁾ mm	B mm	C mm
side opening	height: ³⁾	²⁾	800	1 200	1 400
	width: ³⁾		600		
rear opening	height:	750	750	1 200	1 500
	width:	900	900		
¹⁾ Corner radii which reduce the opening area by less than 10 % are permitted. ²⁾ The dimensions provided by the original manufacturer shall not be reduced. ³⁾ If it is a window, the height and width dimensions may be interchanged.					

Openings shall take into account the dimension of the stretcher, see EN 1865.

4.4.6.1 Doors

Each external door of 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 key⁴⁾;
- b) lock and unlock from outside with use of a key⁴⁾;
- c) unlock from the outside using a key⁴⁾ when the door is locked from the inside.

NOTE: This security system may be integrated with an optional central locking system.

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 door is not completely closed when the vehicle is in motion.

³⁾ Also called "partition wall".

⁴⁾ The key can be a mechanical or non-mechanical device.

4.4.6.2 Windows

(A1) 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. **(A1)**

The windows shall be positioned or screened to ensure patient's privacy when required. Windows shall be made of material complying with the requirements of Directive 92/22/EEC.

4.4.7 Loading area

The loading area dimensions shall be in accordance with table 6.

Table 6: Loading area dimensions

Type of road ambulance		A ₁	A ₂	B	C
tailgate height (in the open position) ¹⁾ (see figure 2)	H ₂ minimum	1 800 mm	1 800 mm	1 900 mm	1 900 mm
loading angle (stretcher)	maximum	16° ²⁾	16° ²⁾	16° ²⁾	16° ²⁾
loading height (stretcher)	When the patient is loaded or unloaded on the stretcher, the centre of the stretcher handles shall be no more than 825 mm above ground level. The maximum height of the floor or the loading holding assembly above ground level shall not exceed 750 mm at net vehicle mass plus loose equipment.				
¹⁾ From ground to lowest point of fully opened tailgate at gross vehicle mass.					
²⁾ The loading angle shall be kept as low as possible.					

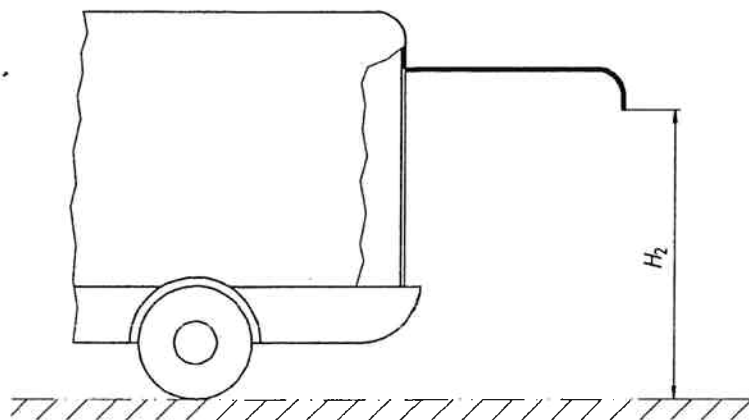


Figure 2: Tailgate height (in the open position)

4.5 Patient's compartment

4.5.1 General

The patient's compartment shall be designed and constructed to accommodate the medical devices listed in tables 10 to 20 in accordance with the vehicle type.

The ceiling, the interior side walls and the doors of the patient's compartment shall be fully lined.

The edges of 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.

Open shelves shall be constructed with rounded edges. Drawers shall be secured against self-opening. Type B and C road ambulances shall be equipped with a lockable drugs compartment with security lock.

Type B and C road ambulances shall be fitted with a hand-holding device positioned above ^(A1) each stretcher ^(A1) along the longitudinal axis.

If the patient's compartment is to be equipped with a non-foldable sedan chair as defined in EN 1865, space shall be provided with a width of at least 600 mm measured at elbow height and a vertical clearance between the roof and the seat of at least 920 mm.

Vehicle maintenance equipment (e.g. spare wheel and tools) shall not be accessible from within the patient's compartment.

^(A1) NOTE 1: Floor coverings should be chosen that will provide adequate grip for the attendant including when wet and should be durable and easy to clean.

NOTE 2: The interior design should be in accordance with the Directive 70/156/EEC. ^(A1)

4.5.2 Patient's compartment dimensions

4.5.2.1 Patient's compartment dimensions for type A₁, A₂ and B road ambulances

The patient's compartment shall comply with the minimum dimensions set out in figures 3 to 5, ^(A1) without cupboards, seats, medical devices and equipment. ^(A1)

W = Width measured from RH-side to LH-side, except the roof curvature

L = Length measured from rear to partition wall 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 seat level and roof

h_2 = Height between seat level and floor

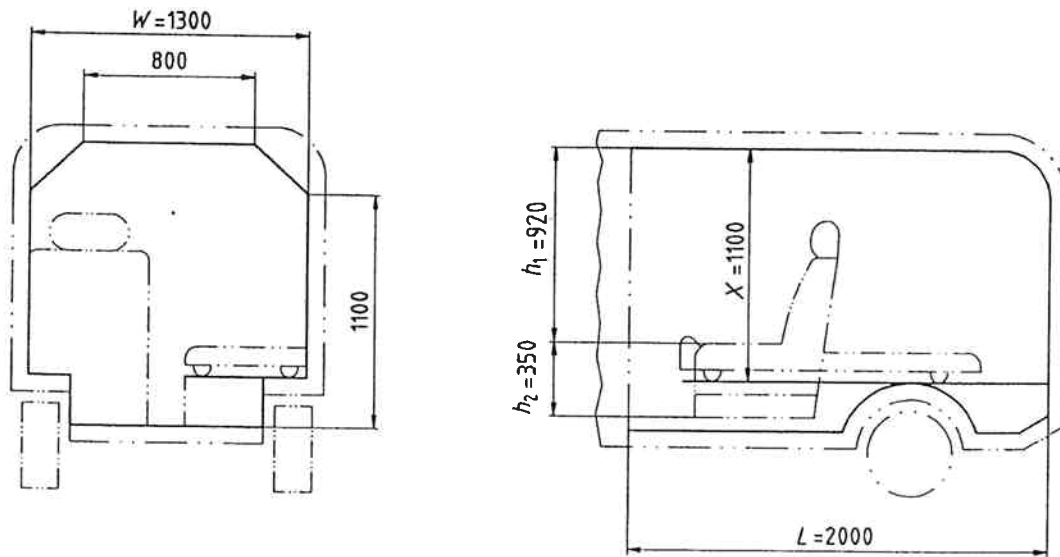
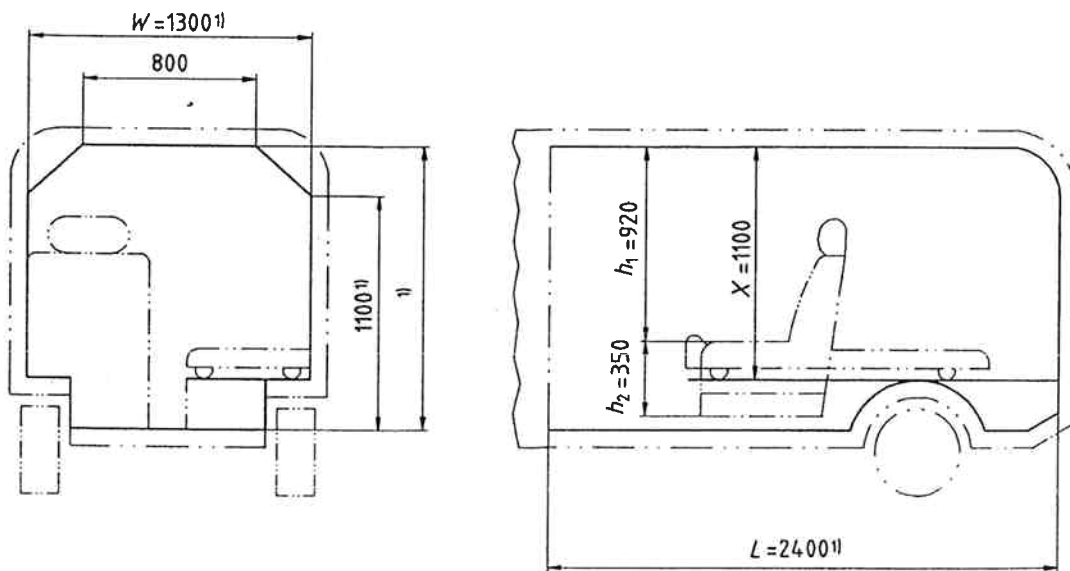
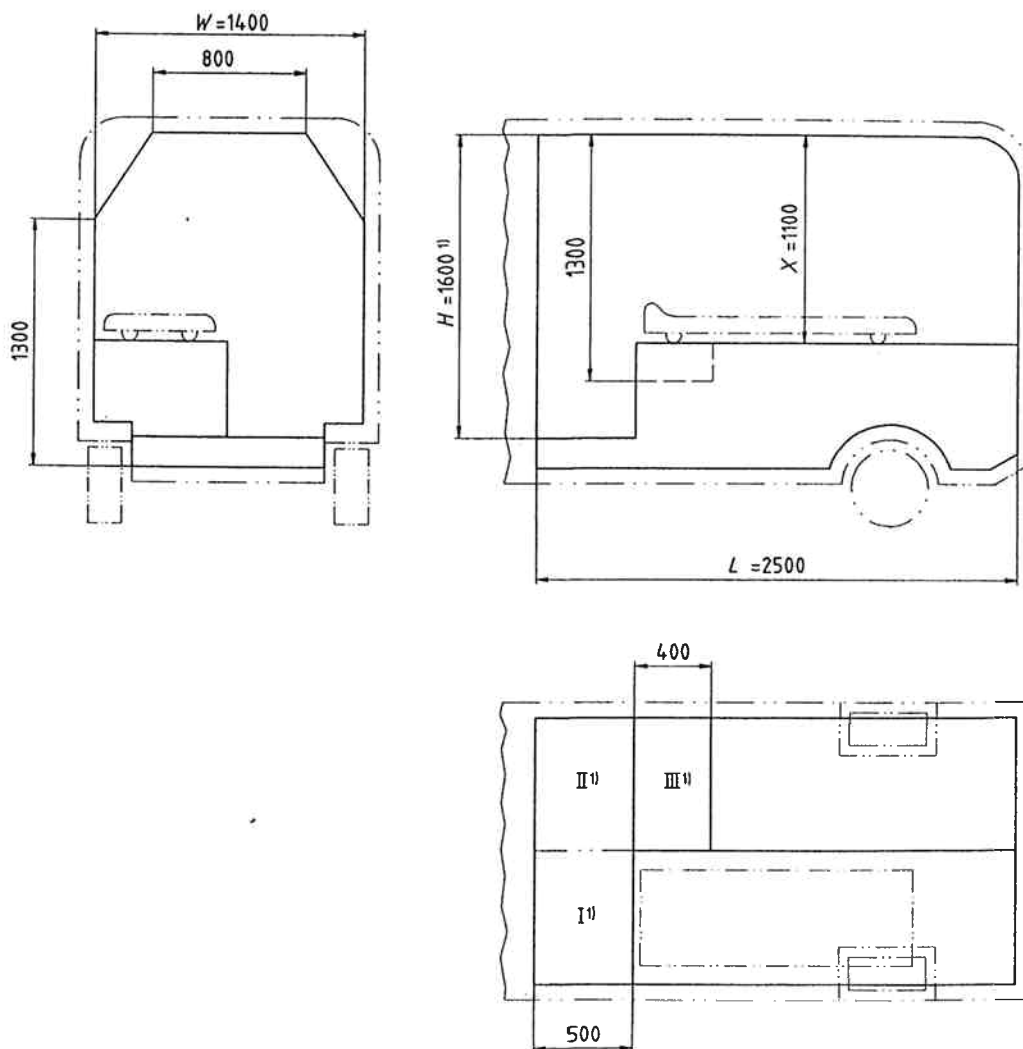


Figure 3: Patient's compartment dimensions for type A₁ (schematic)



- ¹⁾ Dimensions for Type A₂ with more than four seats in the patient's compartment: The length (L) shall be 3100 mm, width (W) 1500 mm. From a height of 1500 mm to 1750 mm the sides shall have a radius no greater than 250 mm. The height (H) shall be 1750 mm.

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



1) Area I

There shall be a minimum of 500 mm between the lining of the bulkhead and the head-end part of the stretcher frame measured in the mid-axis and at the height of the stretcher in its most forward position when an attendant is seated at the head of the stretcher. A minimum height of 1 600 mm shall be provided.

Area II

A minimum height of 1600 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)

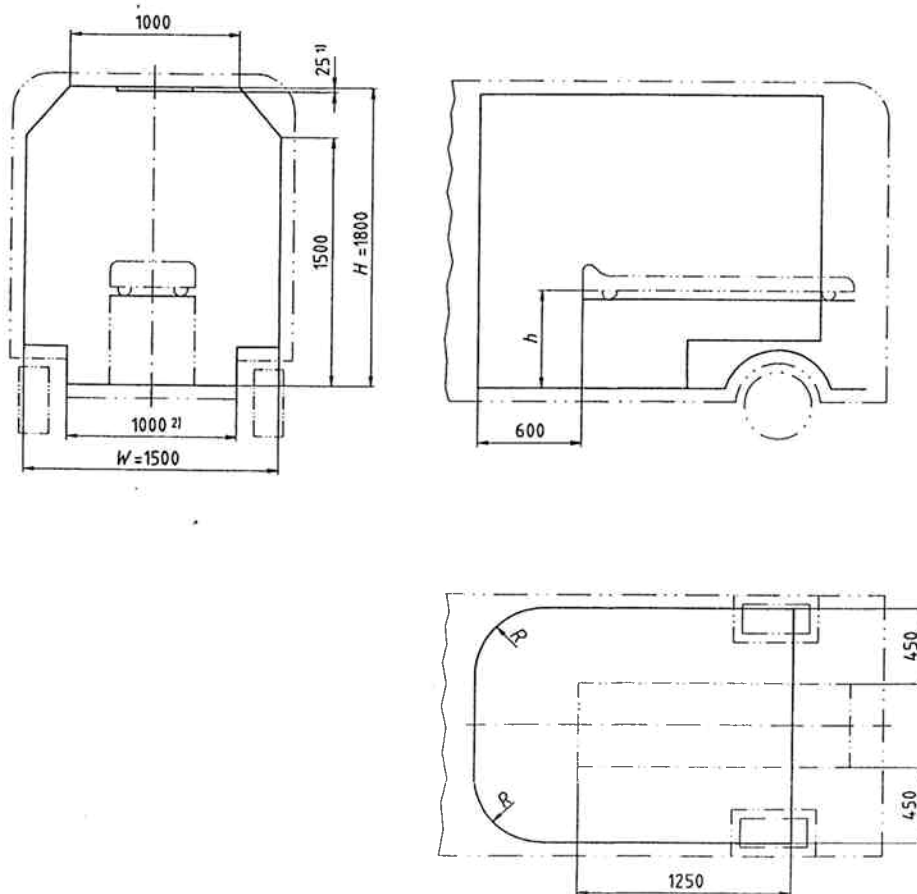
4.5.2.2 Patient's compartment and treatment area dimensions for type C

In type C road ambulances the patient's compartment shall be large enough to incorporate the treatment area⁵⁾ 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 technical 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 headend of the stretcher
- or 125 mm on one side or a sum of 125 mm on both sides

h = A working height of the stretcher surface (excluding mattress) between 400 mm (minimum) and 650 mm (maximum) shall be ensured.

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



- ¹⁾ Reduced (25 mm maximum) in the roof area over the stretcher.
- ²⁾ Where the height of the wheelarch exceeds 400 mm, the clearance width between the wheelarches above 400 mm shall not be less than 1250 mm.

Figure 6: Treatment area dimensions for type C

⁵⁾ Also called "ergonomic space".

4.5.3 Patient and attendant seating

The minimum number of patient and attendant seats shall be as given in table 7.

Table 7: Number of patient and attendant 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	–	–
	on one side of the stretcher upper $\frac{2}{3}$ end	–	–	1
position(s) at head of stretcher	–	1 ¹⁾	1	1
¹⁾ only when fewer than four seats				

The seats shall comply with the minimum dimensions set out in table 8.

Table 8: Minimum dimensions for seating

	single seat (patient) mm	single seat (attendant) mm	folding seat (attendant) mm
width	450	450	450
depth	400	330	330
height above seat ¹⁾	920	920	920
thickness of upholstery	50	50	50
¹⁾ Measured vertically above and in the middle of the 75 kg loaded seat.			

Seats fitted in accordance with tables 7 and 8 shall be installed in either forward or rear-facing positions. Restraint systems and head restraints shall be fitted. 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.

A1) Seats for patients and attendants shall not be installed as side-facing. **A1)**

4.5.4 Ventilation and anaesthetic gas scavenging systems

4.5.4.1 Ventilation system

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

4.5.4.2 Anaesthetic gas scavenging system (AGSS)

If the road ambulance is intended to be used with delivery systems for anaesthetic gases and vapours, e. g. N₂O, anaesthetic agent vapours, it shall be equipped with an AGSS in compliance with EN 740:1998, EN 737-2:1998 and EN 737-4:1998.

4.5.5 Heating system

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 - 10 °C or in extremely cold zones, a temperature of - 20 °C the heating up to at least 5 °C shall not take longer than 15 minutes. After 30 minutes a temperature of at least 22 °C shall be reached in the patient's compartment. The inside temperature shall be measured in the centre of the stretcher(s) and at the mid point from the heater outlets (if several outlets are available).

A1) The heating shall be controlled by an adjustable thermostat. The actual temperature shall not vary from the set temperature by more than 5 °C. **A1)**

The installation shall prevent exhaust gases entering the patient's compartment.

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.

4.5.6 Interior lighting

Natural colour balance lighting shall be provided as set out in table 9.

In type C there shall be an additional light with 1 650 lx measured in a distance of 750 mm and in an area with a diameter of 200 mm.

Table 9: Patient's compartment lighting

Type of road ambulance		A ₁ lx	A ₂ lx	B lx	C lx
patient area	minimum:	100	100	300 ¹⁾	300 ¹⁾
surrounding area	minimum:	30	30	50	50

¹⁾ **A1)** Additionally there shall be a facility for switching the lighting level down to 150 lx. **A1)**

4.5.7 Interior noise level

The interior noise level across the vehicle speed range shall be such that when tested in accordance with 5.1 it shall not exceed the maximum graphical line resulting from coordinates 70 dB(A) at 60 km/h or 40 % of the maximum speed, whichever is lower, to 78 dB(A) at 120 km/h or 60 % of the maximum speed, whichever is lower. A deviation of up to 3 dB(A) of the measured sound pressure level is permissible, within any vehicle type.

4.5.8 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.

4.5.9 Maintain systems and fixations of the equipment in the patient's compartment

A1) All persons and items e.g., medical devices, equipment and objects normally carried on the road ambulance shall be "maintained" to prevent them becoming a projectile when subjected to a force of 10 g in the forward, rearward, transverse and vertical direction. **A1)**

When subjected to these forces the distance travelled by a person or item shall not endanger the safety of persons on the road ambulance.

After being subjected to these forces:

- a) no items shall have sharp edges or endanger the safety of persons in the road ambulance;
- b) **A1)** 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; **A1)**
- c) it shall be possible to release all persons in the road ambulance without the use of equipment not carried on the road ambulance.

A1) NOTE: The restraint systems and seats for patient and attendants as well as the restraint systems for patient in chairs can be tested according to the EU Directives 76/115/EEC and 77/541/EEC as an alternative to the test according to 5.3. **A1)**

5 Testing

5.1 Testing of the interior noise level

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 standard;
- contrary to the minimum tyre wear of 300 km specified in 8.1 of ISO 5128:1980, new tyres without wear may be used;
- apart from the requirements of 8.3 of ISO 5128:1980, 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 8.4.1 b) of ISO 5128:1980;
- the measurements in accordance with 8.4.2 and 8.4.3 of ISO 5128:1980 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 9.1 of ISO 5128:1980 (but only in the longitudinal median plane of the seat) and on all stretchers according to 9.3 of ISO 5128:1980;
- determination of octave and terz spectrums, according to 10.6 of ISO 5128:1980 is not necessary;
- during the measurements, the audible warning and communication system shall be switched off.

5.2 Testing of the acceleration

The road surface of the test track shall be dry and level to within a longitudinal slope of 1 %.

The atmospheric pressure shall be between 99,1 kPa and 101,7 kPa, outdoor temperature between 0 °C and 30 °C and the maximum wind velocity of 3 m/s.

The acceleration time shall be measured twice in each direction and the test runs completed in close succession. The result shall be the average of the four readings. On vehicles fitted with manual transmission, the recommended maximum engine speed shall not be exceeded. On vehicles fitted with automatic transmission, gears may be selected manually.

5.3 Testing of maintain systems and fixations of the equipment in the patient's compartment

Verification of conformity to 4.5.9 shall be made when the stretcher and holding assembly is placed in the mean position of all possible positions available.

Appropriate verification shall be carried out. It may be done by calculation, static or dynamic testing depending on the individual technical problem. The method of verification shall be approved by a notified body.

A) NOTE: The notified body who has to confirm the compliance with 4.5.9 according to 5.3 fo EN 1789 should:

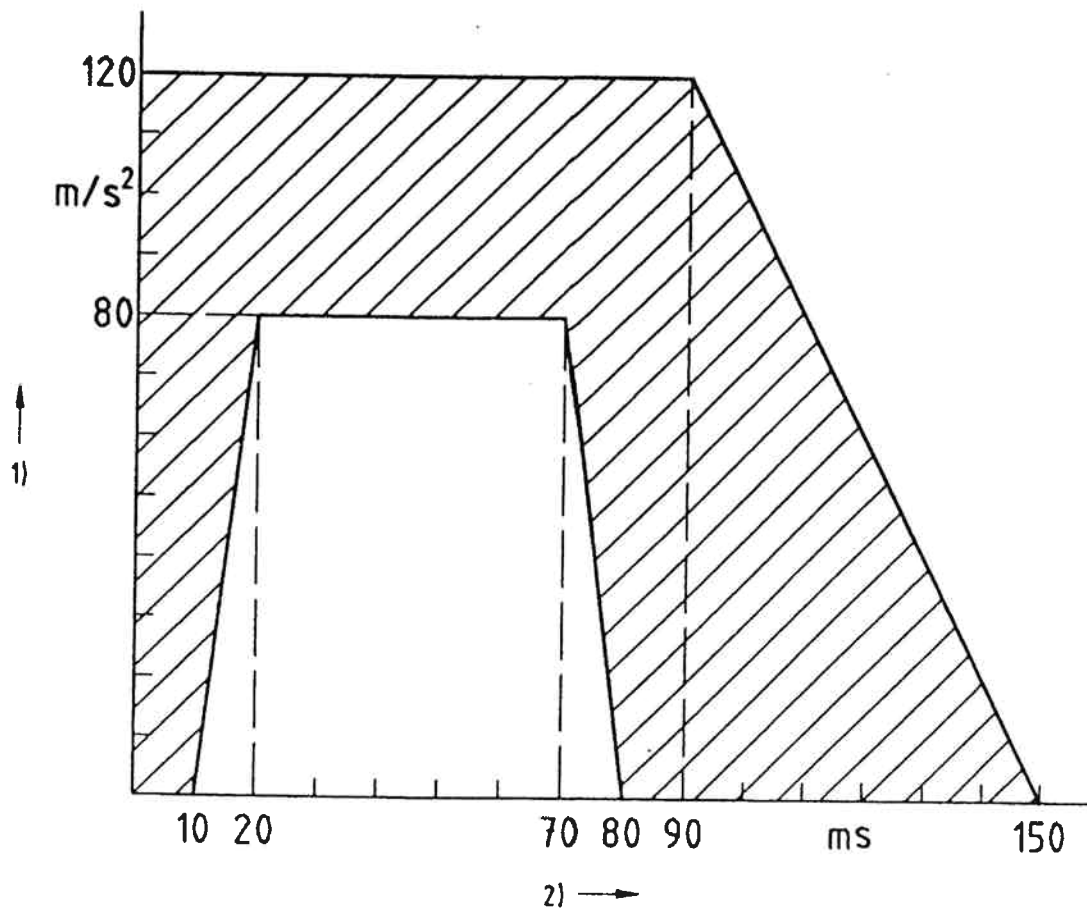
- a) be acknowledged by government authorities according to article 14 of the directives 70/156/EEC and should be competent in the three fields of static testing, dynamic testing and calculation in order to judge which method is appropriate for the verification of the individual technical problem;
- b) have an acknowledgement for the Directives 77/541/EEC and 74/408/EEC, in case of impact test also for Directives 96/79/EEC. **A)**

In case of dynamic testing, the dynamic test shall be carried out using a patient's compartment assembly and the following test method:

The stretcher shall be fixed on the stretcher's holding assembly. The sedan chair when provided shall also be fixed in its holder.

The stretchers and chairs shall be loaded with a dummy (according to ECE R16 Annex 7) which is then secured with the restraint system. The head end of the stretcher shall be fixed in a position of 15° measured from the horizontal. The lying area of the stretcher tray assembly (holding assembly) shall be in a horizontal position.

The test assembly shall be accelerated in accordance with figure 7. This corresponds to a change in speed of 30 km/h to 32 km/h.



- 1) Acceleration
- 2) Time

Figure 7: Acceleration impulse

6 Medical devices

6.1 Provision with medical devices

The road ambulance shall be designed and constructed to accommodate the items listed in the tables 10 to 20 and provide the following levels of care:

- the patient transport ambulance (types A₁ and A₂) 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 prehospital care;
- the mobile intensive care unit (type C) shall have equipment for advanced treatment and monitoring of patients with the current methods of prehospital intensive care.

6.2 Medical devices storage

All equipment required for a set procedure shall be stowed in a specified location. Essential equipment for airway management and ventilation in types B and C road ambulances shall be within reach of a seated attendant. 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).

6.3 Requirements for medical devices

6.3.1 General

The device shall be designed for use in mobile situations and in field applications⁶⁾.

If a medical device is designated as "portable" (except patient handling equipment according to table 10) it shall be in accordance with EN 60601-1:1990 and

- it shall be possible to be carried by one person⁷⁾;
- it shall have its own built in power supply (where relevant);
- it shall be capable of use outside the vehicle.

6.3.2 Temperature

6.3.2.1 Unless otherwise marked on the device, the device shall function as described in 6.3.2.2 and 6.3.2.3 when brought back to room temperature (20 °C) after storage in temperatures ranging from - 30 °C to 70 °C.

6.3.2.2 Unless otherwise marked on the device, the device shall function throughout the temperature range from 0 °C to 40 °C.

6.3.2.3 Unless otherwise marked on the device, the device shall function for at least 20 minutes when placed in an environment at - 5 °C after storage at room temperature (20 °C).

6.3.3 Humidity and ingress of liquids

Devices shall comply with clauses 10 and 44 of EN 60601-1:1990 and of particular device standards of the series EN 60601-2 where applicable.

6.3.4 Mechanical strength

6.3.4.1 General

Where no stronger requirements for mechanical strength in particular devices standards exists, then the following mechanical strength requirements shall apply for medical devices for use in road ambulances.

6.3.4.2 Vibration and bump

After vibration tests and bump test according to 6.4.1 the device shall function within the tolerances specified by the manufacturer.



6.3.4.3 Free fall

If the medical device is fixed, as defined in 2.2.12 of EN 60601-1:1990, it is exempted from the free fall test.

Medical devices which are taken out of holders and/or carried by hand shall be submitted to the free fall test according to 6.4.2 and shall then function within the tolerances specified by the manufacturer.

NOTE: A medical device may consist of fixed and loose components, the free fall test applies to the loose components only.

⁶⁾ The Directive 93/42/EEC concerning medical devices  refers .

⁷⁾ The Directive 90/269/EEC concerning the manual handling of loads  refers .

6.3.5 Fixation of devices

The device shall be restrained within the vehicle ^(A) by means of a fixation system. ^(A)

The fixation system shall hold the device to withstand accelerations or decelerations of 10 g longitudinal, 10 g transverse and 10 g vertical.

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 12218.

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

6.3.7 Electromagnetic compatibility

The requirements of EN 60601-1-2 apply for both the road ambulance and the equipment in full operation.

NOTE: The Directives ^(A) 95/54/EEC ^(A) concerning the suppression of radio interference and 89/336/EEC concerning electromagnetic compatibility are to be taken into account.

6.3.8 User interface

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

6.3.9 Gas installation

6.3.9.1 Source of supply

The source of supply shall consist of one or more of the following (see also 5.1.3 of EN 737-3:1998):

- a) gas in cylinders e. g. oxygen, air;
- b) non-cryogenic liquid in cylinders e. g. N₂O, CO₂;
- 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. N₂O, CO₂;
- f) an air compressor system;
- g) a proportioning system for e. g. oxygen and nitrogen;
- h) a vacuum system.

NOTE: EN 737-3:1998 may be used as guidance for designing the source of supply. See also 4.3.3.3 of this standard.

6.3.9.2 Compartments or ducts for gas installations or gas piping shall be vented.

6.3.9.3 Stationary oxygen supply

The stationary oxygen supply shall comprise a source with a capacity of at least 2 000 l (under normal temperature and pressure) pressure regulators and terminal units or pressure regulators with flowmetering devices.

6.3.9.4 Portable oxygen supply

The portable oxygen supply shall comprise a source with a capacity of at least 400 l (under normal temperature and pressure) and a pressure regulator with flowmetering device.

6.3.9.5 Pressure regulators and flowmetering devices

Pressure regulators and pressure regulators with flowmetering devices shall comply with EN 738-1 or EN 738-3. The pressure regulators shall be directly connected to the source of supply.

Flowmetering devices for connection to terminal units shall comply with prEN ISO 15002.

6.3.9.6 Terminal units

Terminal units shall comply with EN 737-1:1998 and prEN 737-6:1998.

6.3.9.7 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 kPa
- for vacuum ≤ 40 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/minute
- for vacuum 20 % at a flow of 25 l/minute

6.3.9.8 Additional outlet connectors

For road ambulances complying with 6.3.9.7, one additional outlet connector (i.e., a terminal unit or a gas-specific connection point) complying with EN 737-1:1998 and prEN 737-6:1998 shall be fitted in addition to the outlet connectors necessary for the devices intended to be normally used.

6.3.9.9 Test pressure

The gas piping shall withstand a pressure of 1 000 kPa, i.e., twice the maximum operating pressure of 500 kPa (see 6.3.9.7).

NOTE: This pressure is also the maximum pressure supplied by pressure regulators complying with EN 738-1 and EN 738-3 in single fault condition.

6.3.9.10 Pin-index cylinder valves

Pin-index outlet connections of cylinder valves shall comply with EN 850.

6.3.9.11 Flexible hoses

Flexible hoses for connecting medical devices to outlet connectors (i.e. terminal units or a gas-specific connection points) shall comply with EN 739. If flexible hoses are used between the pressure regulators and the terminal units, the requirements of 59.5.1 b) of EN 793 apply.

6.3.9.12 Alarms

If alarms are provided as part of the gas installation, they shall comply with clause 6 of EN 737-3:1998.

6.3.10 Marking and instructions

Marking and instructions for use shall comply with EN 980 and EN 1041.

Operating and maintenance instructions shall accompany the product, along with a service record in standardized symbols or be written in the native language of the area where the equipment is to be used, if there are no other regulations available.

6.3.11 Maintenance

The manufacturer shall supply instructions for carrying out preventive maintenance.

6.4 Mechanical strength – Test methods for medical devices for use in road ambulances

6.4.1 Vibration and bump test

The medical device shall be submitted to the following tests:

Vibration (sinusoidal) according to IEC 60068-2-6, Test Fc

Frequency range: 10 to 150 Hz

Amplitude/acceleration: $\pm 0,15 \text{ mm/2 g}$

Sweep rate: 1 octave/minute

Number of sweep cycles: 4 in each axis

Random vibration wide band - Reproducibility Medium according to IEC 60068-2-36, Test Fdb

ASD⁸⁾ 10 to 20 Hz: $0,05 \text{ g}^2/\text{Hz}$, -3 dB/Octave

ASD 20 to 150 Hz: $0,05 \text{ g}^2/\text{Hz}$, -3 dB/Octave

Total rms acceleration $1,6 \text{ g}_{\text{rms}}$

Duration/axis/mounting: 30 min

Bump according to IEC 60068-2-29, Test Eb

Peak acceleration: 15 g

Pulse duration: 6 ms

Number of bumps: 1000

Direction: Vertical, with the medical device in its normal operating position(s).

6.4.2 Free fall

The medical device shall, while functioning, be submitted to the following test:

Free fall according to IEC 60068-2-32, Procedure 1

Height of fall: 0,75 m

Number of falls: 1 on each of the six surfaces

6.5 List of equipment

The tables 10 to 20 designate the minimum equipment carried by the road ambulances according to their type.

Where national regulations for equipment are in conflict with tables 10 to 20 the national regulations shall 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 10 to 20 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 an item is not applicable this is indicated by "-"

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

⁸⁾ Acceleration Spectral Density