

Nederlandse norm

NEN-EN 1789+A2

(en)

Medische voertuigen en hun uitrusting -
Ambulances

Medical vehicles and their equipment - Road
ambulances

Vervangt NEN-EN 1789:2007+A1:2010;
NEN-EN 1789:2007+A1:2010/Ontw. A2:2014

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Krankenkraftwagen

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Contents

Page

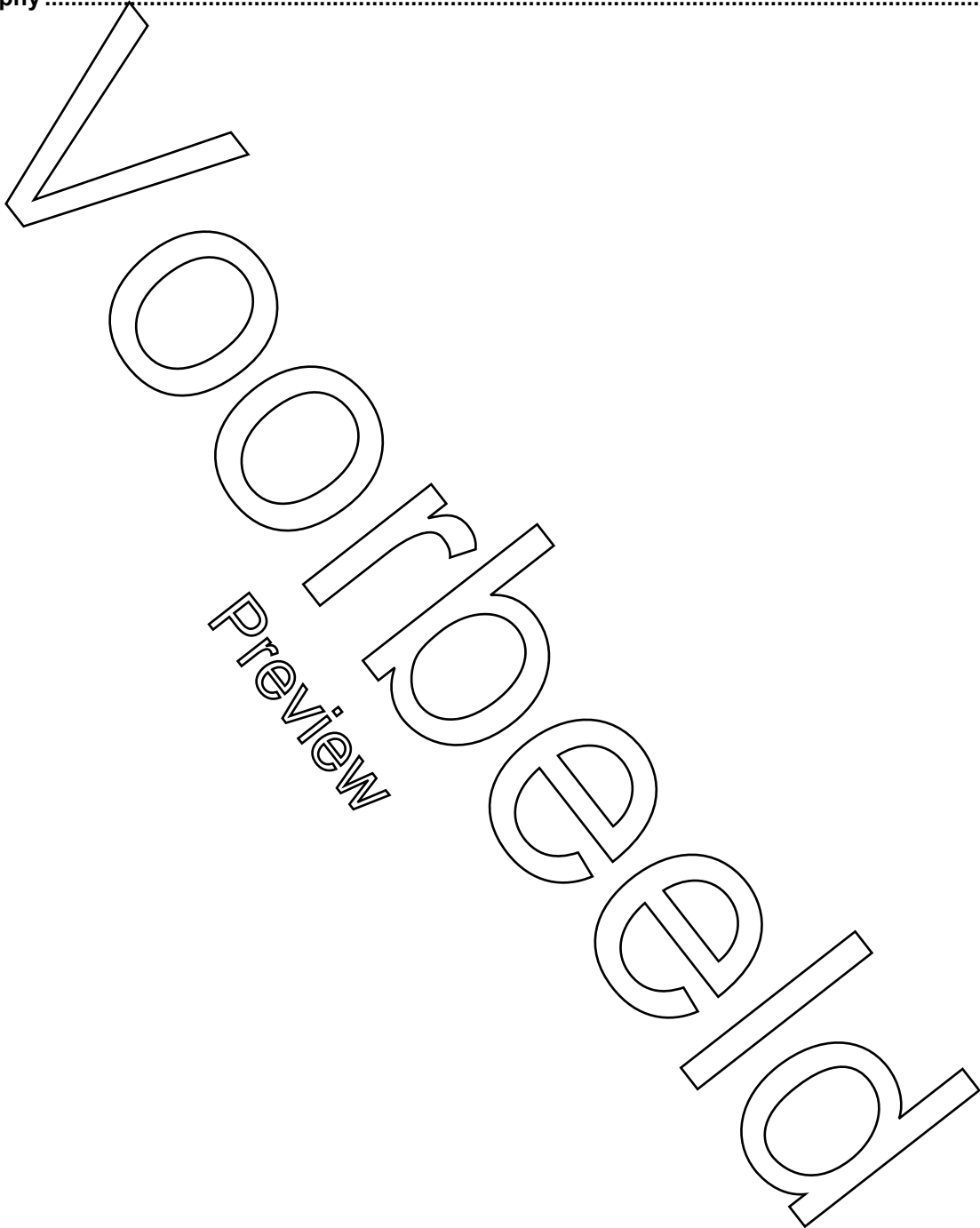
Foreword.....	5
A2 Introduction A2	6
1 Scope.....	7
2 Normative references.....	7
3 Terms and definitions.....	9
4 Requirements.....	11
4.1 General requirements.....	11
4.1.1 General.....	11
4.1.2 Maximum overall dimensions.....	11
4.1.3 Wheel arch clearance.....	11
4.2 A2 Performance-braking and acceleration A2	11
4.2.1 Acceleration.....	11
4.2.2 Braking.....	12
4.2.3 Safety system.....	12
4.3 Electrical requirements.....	12
4.3.1 General.....	12
4.3.2 Electromagnetic compatibility (EMC) – Communication equipment.....	12
4.3.3 Battery and alternator.....	12
4.3.4 Electrical installation.....	13
4.3.5 Visual and audible warning system.....	14
4.4 Vehicle body.....	14
4.4.1 Fire safety.....	14
4.4.2 Driver's seat configuration.....	14
4.4.3 Minimum loading capacity.....	14
4.4.4 Bulkhead.....	15
4.4.5 Openings (doors, windows, emergency exits).....	16
4.4.6 Loading area.....	17
4.5 Patient's compartment.....	18
4.5.1 General.....	18
4.5.2 Patient's compartment dimensions.....	19
4.5.3 Patient and attendant seating.....	23
4.5.4 Ventilation and anaesthetic gas scavenging systems.....	24
4.5.5 Temperature system.....	25
4.5.6 Interior lighting.....	25
4.5.7 Interior noise level.....	26
4.5.8 Holding system for infusion.....	26
4.5.9 Mounting systems.....	26
4.5.10 Mass reserve.....	27
5 Testing.....	27
5.1 General.....	27
5.2 Testing of the interior noise level.....	27
5.2.1 A2 Specific measurement conditions A2	27
5.2.2 Measurements.....	28
5.2.3 Establishment of compliance.....	29
5.3 Testing of the acceleration.....	30
5.4 Testing of maintain systems and fixations of the equipment in the patient's compartment.....	30
5.4.1 General.....	30

5.4.2	Testing of the stretcher fixations on the vehicle floor	32
5.4.3	Testing of the medical devices fixations	33
5.4.4	Testing of furniture.....	33
5.4.5	Test procedure.....	33
5.5	A2 Testing of rounded edges and radius inside the patient's compartment A2	34
5.5.1	A2 Testing of rounded edges A2	34
5.5.2	Testing of rounded edges and radius inside the patient's compartment.....	35
5.6	Procedure to verify the patient's compartment specifications	35
5.7	Procedure to verify the loading area specifications	36
5.7.1	General	36
5.7.2	Procedure to verify the loading angle of 16°	36
5.8	Procedure to verify the dimensions of the patient's compartment.....	37
5.8.1	Type A and B road ambulances	37
5.8.2	Type C road ambulances	37
5.9	Procedure to verify the seats dimensions of the patient's compartment	38
5.10	Testing of the ventilation system	39
5.11	Testing of the heating system.....	39
5.12	Testing of the cooling system.....	40
5.12.1	Test procedure.....	40
5.12.2	Testing of independent air conditioning system	40
5.13	Testing of interior lighting	41
5.14	Testing of infusion holding system	41
6	Medical devices	41
6.1	Provision of medical devices	41
6.2	Medical devices storage	41
6.3	Requirements for medical devices	42
6.3.1	General	42
6.3.2	Temperature	42
6.3.3	Humidity and ingress of liquids	42
6.3.4	Mechanical strength	42
6.3.5	Fixation of devices	43
6.3.6	Electrical safety	43
6.3.7	User interface	43
6.3.8	Gas installation	43
6.3.9	Marking and instructions	45
6.3.10	Maintenance	45
6.4	Mechanical strength – Test methods for medical devices for use in road ambulances	45
6.4.1	Vibration and bump test	45
6.4.2	Free fall	46
6.5	List of equipment.....	46
7	Conformity assessment.....	53
8	Requirements to be met for a Certificate of Compliance	53
Annex A	(informative) A2 Test summary A2	55
Annex B	(informative) A2 Definition of ambulance body styles A2	56
B.1	General	56
B.2	Van based Ambulance	56
B.3	Fully independent box body	57
Annex C	(informative) A2 Recognition A2	58
C.1	Recognition and visibility of ambulances.....	58
C.2	Recognition of personnel	58

EN 1789:2007+A2:2014 (E)

Annex ZA (informative) A1 A2 Relationship between this European Standard and the Essential Requirements of EC Directive 93/42/EEC on Medical Devices and Directive 2007/46/EC of the European Parliament and of the Council of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles A2..... 59

Bibliography..... 60



Foreword

This document (EN 1789:2007+A2:2014) has been prepared by Technical Committee CEN/TC 239 "Rescue systems", the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2015, and conflicting national standards shall be withdrawn at the latest by March 2015.

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

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

This document supersedes A_2 EN 1789:2007+A1:2010 A_2 .

The start and finish of text introduced or altered by amendment is indicated in the text by tags A_1 A_1 and A_2 A_2 .

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

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

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EN 1789:2007+A2:2014 (E)**A₂ Introduction**

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

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

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

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

- EN 1789:2007 has not been applied consistently by notified bodies since the text for verifying compliance is open to interpretation and may cause difficulties to Technical Services (TS) as defined in Directive 2007/46/EC, EN 1789:2007 or local authorities;
- these differences can lead to declarations that the same ambulance complies or does not comply with EN 1789:2007;
- manufacturers of ambulances may have the same problems of interpretation in the design of their ambulances;
- users of ambulances may have the same problems of interpretation that affects their responsibility.

This second amendment¹⁾ gives an answer to questions concerning the application of EN 1789:2007 and avoids differences in interpretation between such notified bodies to check compliance of vehicles specially adapted to medical transportation (road ambulances).

NOTE Such as the demonstration of compliance to the requirements of 4.5.9 or 4.3. A₂

1) A₂ The first amendment published in 2010 only updates Table ZA.1 to consider the revision of Directive 93/42/EEC. A₂

1 Scope

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

This European Standard does not cover the requirements for approval and registration of the vehicle and the training of the staff which is the responsibility of the authority/authorities in the country where the ambulance is to be registered.

This European Standard is applicable to road ambulances capable of transporting at least one person on a stretcher.

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

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

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

EN 420:2003+A1:2009, *Protective gloves — General requirements and test methods*

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

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

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

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

deleted text

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

deleted text

EN 1041:2008+A1:2013, *Information supplied by the manufacturer of medical devices*

EN 1789:2007+A2:2014 (E)

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

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

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

EN 1865-5:2012, *Patient handling equipment used in road ambulances — Part 5: Stretcher support* ^(A2)

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

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

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

EN 14052:2012+A1:2012 ^(A2), *High performance industrial helmets*

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

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

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

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

EN 60601-1, *Medical electrical equipment*

EN 60601-2, *Medical electrical equipment*

EN 60601-2-4:2011, *Medical electrical equipment — Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators (IEC 60601-2-4:2010)* ^(A2)

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

EN ~~ISO 407:2004~~ ^(A2)

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

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

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

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

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

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

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

EN ISO 14971:2012, *Medical devices — Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)*

EN ISO 15002:2008, *Flow-metering devices for connection to terminal units of medical gas pipeline systems (ISO 15002:2008)*

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

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

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

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

deleted text

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

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

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

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ISO 5128:1980, *Acoustics — Measurement of noise inside motor vehicles*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

patient and emergency patient

3.1.1

patient

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

3.1.2

emergency patient

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

EN 1789:2007+A2:2014 (E)

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

3.3 types of road ambulances²⁾

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 a 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

^{A2} deleted text ^{A2}
^{A2} deleted text ^{A2} mass according to 92/21/EEC modified of the road ambulance including the driver taken as 75 kg and all fixed installations

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

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

Note 1 to entry: This represents the mass that may be distributed on the road ambulance such that the permissible axle loads are not exceeded. ^{A2}

^{A2} deleted text ^{A2}

^{A2} **3.6 ^{A2} fixation system**
system or device to ensure the permanent fixation of medical devices or other equipment into the ambulance

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

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

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