SLOVENSKI STANDARD
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Ambulantna vozila za zrak, vodo in težke terene - 2. del: Opreravitne in tehnične zahteve za nenehno oskrbo bolnikov

Air, water and difficult terrain ambulances - Part 2: Operational and technical requirements for the continuity of patient care

Patiententransportmittel in der Luft, auf dem Wasser und in schwierigem Gelände - Teil 2: Operationelle und technische Anforderungen für die kontinuierliche Patientenbetreuung

Ambulances aériennes, maritimes et de terrain difficile - Partie 2: Exigences opérationnelles et techniques assurant la continuité des soins

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Foreword

This document EN 13718-2:2002 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of an identical text or by endorsement, at the latest by February 2003, and conflicting national standards shall be withdrawn at the latest by February 2003.

The annexes A and B are normative.

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, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

This European Standard provides requirements for air, water, and difficult terrain vehicles, and in particular covers requirements for the ambulance role of these vehicles and craft when in operation.

Air, water, and difficult terrain ambulances are equipped with medical devices as well as drugs and rescue equipment to be used by medically trained personnel. Requirements for interfaces for medical devices intended for use in ambulances are provided in prEN 13718-1 *Air, water, and difficult terrain ambulances – Part 1: Medical device interface requirements for the continuity of patient care*. Specific interface requirements for medical devices to be used in road ambulances as well as performance requirements for road ambulances are provided by EN 1789 (see Bibliography).

This standard is supplementary to several European Standards as well as laws and regulations providing the necessary requirements for the vehicles or craft in order to provide continuous patient care and monitoring during transport in and between various ambulance types and hospitals. The requirements set cover both emergency (primary missions) and prepared activities (secondary missions). Several specific requirements relate to the conditions prevailing in air, water, and difficult terrain ambulances. Several national and regional rules and regulations apply to air, water, and difficult terrain ambulances. This standard gives information on these in the annexes and in notes throughout the text. Provisions for the safety and care both to the patient as well as to the crew and the medical personnel are contained in existing national and international laws, regulations and guidelines.

This standard provides some general requirements for the safe operation of air, water, and difficult terrain ambulances. These requirements are not covered by the scope of the Medical Device Directive or by international agreements for craft and vessels, transportation and traffic. They are provided in order to secure the safe handling of patients. In order to accommodate continuity of patient care between different kinds of ambulances, some specific requirements are given. Requirements are set in order to secure safe use and handling of medical devices.

Air, water, and difficult terrain ambulances are equipped with medical devices, drugs, and rescue equipment to enable the medically trained personnel to provide continuous patient care. The recommended minima for the relevant devices are listed in annex A. The requirements set out in this part of the standard give the necessary minimum provisions for an ambulance service to provide satisfactory care and medical attention to emergency patients as well as other patients during transport. The requirements are based on the state of the art of today and common practice in Europe.

1 Scope

This European Standard specifies minimum requirements for dedicated ambulance services covering air, water, and difficult terrain vehicles and craft in particular.

Exclusions:

requirements for road ambulances are excluded from this standard. Non-dedicated vehicles and craft are excluded from this standard, such as search and/or rescue units.

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 (including amendments).

prEN 13718-1, *Air, water, and difficult terrain ambulances – Part 1: Medical device interface requirements for the continuity of patent care.*

EN 737-1, *Medical gas pipeline systems – Part 1: 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 12218, *Rail systems for supporting medical equipment.*

EN 1865, *Specifications for stretchers and other patient handling equipment used in road ambulances.*

EN 60601-2-19, *Medical electrical equipment – Part 2: Particular requirements for the safety of baby incubators (IEC 60601-2-19:1990).*

3 Terms and definitions

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

3.1
primary mission
immediate medical assistance to scenes of emergencies where rapid treatment and/or transportation is essential in order to convey medically trained personnel, equipment and/or supplies, as well as transport of ill and/or injured patients to places where appropriate further treatment can be received

3.2
secondary mission
transport of a patient, usually planned in advance, normally between sites of hospitals, to provide medical assistance and the appropriate equipment in order to maintain continuity of patient care, including intensive care treatment

3.3
air, water, and difficult terrain ambulance
dedicated vehicle or craft, which under operational conditions accommodates appropriate treatment, monitoring, care and transport and are designed and constructed to gain access to locations not possible or practicable to reach by road ambulances

3.4
emergency helicopter ambulance
rotor wing (RW) aircraft specifically designed and equipped to provide “Helicopter Emergency Medical Service” (HEMS) operating mainly on primary missions

NOTE Requirements for HEMS flights are given in JAR-OPS 3 subpart B, Appendix 1 (see Bibliography).

3.5
air ambulance
emergency helicopter ambulance or a fixed wing (FW) aircraft ambulance especially those equipped and designed for the transportation, medical treatment and care of patients mainly on secondary missions, including patients requiring intensive care treatment

3.6
water ambulance
vessel or craft designed and equipped to transport patients in coastal areas and on inland lakes and rivers, to convey medically trained personnel to scenes of emergencies for the rapid treatment and/or transportation of critically ill and/or injured persons

3.7
difficult terrain ambulance
vehicle specifically designed and equipped to operate in off-road locations, to convey medically trained personnel to scenes of emergencies for the rapid treatment and/or transportation of critically ill and/or injured persons

3.8
non-dedicated vehicles or craft
vehicle or craft equipped and staffed mainly for rescue and/or transportation purposes, not specifically designed and equipped to provide adequate medical treatment, monitoring and continuity of patient care

NOTE For example SAR (Search and Rescue) units covered by IMO (International Maritime Organization) and ICAO (International Civil Aviation Organization), (see Bibliography).

3.9
interchangeability
facility to transfer patients between scenes of emergencies, ambulances and hospitals as well as between hospitals, including transport between countries, providing continuous patient care, treatment and monitoring

4 General requirements for interchangeability between air, water, and difficult terrain ambulances

4.1 General

Attention is drawn to the need for vehicles and craft intended for ambulance services in the air, on water or in off-road locations, to conform to the relevant rules and regulations pertaining to each vehicle or craft.

Ambulances shall be constructed to enable fast and safe access of medically trained personnel to people in need of medical attention at sites outside hospitals and between hospitals.

Air, water, and difficult terrain ambulances shall be equipped with medical devices and other life supporting equipment in order to provide continuous patient care. These ambulances shall be capable of carrying two appropriately medically trained personnel and at least one stretcher patient within the patient compartment.

The ambulance shall be designed and constructed to accommodate the devices listed under the relevant column in the tables of annex A and annex B.

NOTE There can be circumstances under which the ambulance should operate, and that would permit the trained personnel to act as appropriate using whatever staff and equipment that can be available at that particular moment. This is covered by any incident deemed as being a ‘force majeure’.

4.2 Environmental conditions in the patient compartment

4.2.1 Temperature

A heating system shall be provided capable of raising the temperature in the patient compartment from 0 ^{o}C to + 18 ^{o}C within 10 min, when the outdoor temperature is 0 ^{o}C.

NOTE There should be an auxiliary system to heat/cool the patient compartment when stationary and/or to preheat the engine, when relevant.

4.2.2 Humidity

No particular requirements are given.

NOTE Normal ambient humidity conditions for patient treatment should be aimed at.

4.2.3 Variable atmospheric pressure

No particular requirements are given.

NOTE It is essential to secure a stable atmospheric pressure within the patient compartment, as applicable, for the vehicle or craft. In the event of any significant deviation an indicating system should be employed.

4.2.4 Interior light

Lighting shall be provided as set out in Table 1.

Table 1 – Interior light

Type	**air, water, and difficult terrain ambulances**
Patient area, minimum (lux)	300 [a]
Surrounding area, minimum (lux)	50
[a] Means shall be provided to switch the lighting level down to 10 lux.	

4.2.5 Ventilation

Means shall be provided for a vented patient compartment. Ventilation systems shall be designed to prevent draught to the patient (-s) and crew.

4.2.6 Noise exposure

If noise exposure to the patient compartment during transport exceeds 85 dB_A, relevant protection to both patient(-s) and personnel shall be established and available (see Bibliography).

NOTE 1 Patients, in particular children, can need specially designed protection.

NOTE 2 Specific requirements for sound protection in a working environment exist in some countries or regions.

When relevant, sound protection shall allow communication between the medically trained personnel, the pilot or driver and the patient (-s) under conditions of high ambient noise, e.g. over 85 dB_A.

4.3 Requirements for electrical power source for medical devices in the patient compartment

The patient compartment shall have available a minimum of two available 12 V_{DC} outlets and one additional outlet supplying the battery voltage of the vehicle or craft, dedicated to medical devices. The outlets shall be available for medical equipment and located in the area of storage and/or use of the medical device.

The outlets for the medical devices shall be labelled with the nominal voltage and current rating.

NOTE 1 Outlets should have a visible indication under intended operational conditions in order to show if the power is switched on.

NOTE 2 If mains voltage (AC) is provided and available for use with medical devices, means should be provided to limit earth leakage current.

NOTE 3 Supply mains for medical devices with 24 V_{DC} power input should be constructed for a nominal voltage of U_{nom} = 27,5 V. The internal batteries should be charged in the voltage range of U_{var} = 24,8 - 30,3 V. Functioning according to the manufacturer's specifications should remain at a minimum voltage of U_{min} = 20,0.

Electrical outlets for medical devices shall have connectors that are lockable.

NOTE 4 Connectors should be designed to prevent short-circuiting under the environmental conditions prevailing in these ambulances. Connectors complying with MIL-C26482 can be recommended for this purpose (see prEN 13718-1).

There shall be an externally mounted connector to enable charging of rechargeable batteries in medical devices.

4.4 Electromagnetic interference

Electromagnetic disturbances caused by the vehicle or craft shall not influence the safe operation of the medical devices and vice versa.

NOTE 1 At present no common specific test method is available, therefore individual operational testing procedures should be performed.

NOTE 2 Information on a general electromagnetic compatibility (EMC)-testing of medical devices intended for air, water, and difficult terrain ambulances is provided by prEN 13718-1.

NOTE 3 Cables can function as antennas and induce disturbances.

4.5 Gas supply

4.5.1 Outlet connectors

Terminal units or gas-specific connection points shall conform to EN 737-1.

4.5.2 Stationary oxygen supply

Pressure regulators with flow metering devices shall comprise of a source with a capacity of at least 2 000 l, at Standard Temperature and Pressure, with a maximum flow of at least 15 l/min and be in conformance with EN 738-1.

NOTE Requirements for the oxygen supply to be "stationary", i.e. not necessarily a permanent installation, is based on the need to obtain sufficient oxygen supply during transportation.

4.5.3 Portable oxygen supply

The portable oxygen supply shall comprise of a source with a capacity of at least 400 l, at Standard Temperature and Pressure, and a pressure regulator with flow metering device with a maximum flow of at least 15 l/min.

4.6 Rail systems

If rail systems for supporting medical devices are used, they shall conform to EN 12218, see also prEN 13718-1.

4.7 Mechanical vibration

Knowledge of the relationship between vibration, its effects during different human health conditions and the physical vibration values is insufficient, and for safety reasons mechanical vibration shall be kept to a minimum.

NOTE Shock-absorbing devices can prove useful both for patient(-s) and personnel. Relevant requirements can be found in ISO 2631-1 (see Bibliography).

4.8 Requirements for fixing of medical devices

The medical devices shall be fitted as applicable to the vehicle or craft.

All medical devices required for a set procedure shall be stowed in a specified location. Essential medical devices for the management of vital functions, including airway management and ventilation shall be in reach of the attendant whilst seated. Essential medical devices required for use outside the vehicle shall be easily accessible. All medical devices shall be securely and safely stowed to prevent damage or injury whilst the vehicle is in motion.

The devices shall be restrained within the vehicle or craft and *g*-load requirements shall be those applicable to the particular class or certification of the craft or vehicle.

Mountings shall be provided to support at least two vertically positioned infusion devices at the maximum available height above the patient(-s) whilst allowing sufficient infusions rates.

4.9 Restraint systems in the patient compartment

During transport, restraint systems shall be available to secure the patient (-s) and personnel, as well as the medical devices and other equipment.

Provisions shall be made to enable the medically trained personnel to be seated in an unimpeded manner. Means shall be provided for the personnel to grip and hold on to during transport, such as handles or similar objects.

NOTE 1 For information on the provisions for safety of workplaces, see Council Directive of 12 June 1989 (see Bibliography).

There shall be a security arrangement to prevent intrusion of items into the pilot's or the driver's area.

NOTE 2 A security wall or grid behind the driver's seat of at least 700 mm width could provide protection for the pilot or driver.

4.10 Patient compartment

4.10.1 General

The compartment shall be constructed to enable free access by the medically trained personnel to the patient(-s)'s vital body parts, e.g. head, chest and abdomen, in order to ensure adequate treatment, monitoring and care.

The patient compartment including the vehicle storage areas, shall be designed and constructed to accommodate the devices listed in annexes A and B in such a way that they may be used as appropriate, see 4.12. The positioning of medical devices shall allow the operation of the device without obstructing aisles, emergency exits or patient loading and unloading sites.

There shall be a lockable compartment available for the storage of drugs.

Windows in the patient compartment shall be positioned or screened to ensure the privacy of patients when required.

The interior of the patient compartment shall be designed to minimise the risk of injury. Drawers shall be secured to prevent self-opening. The ceiling, the interior walls and the doors of the patient compartment shall be fully lined. The edges of surfaces shall be designed and/or sealed in such a way that no fluid can infiltrate.

NOTE Open shelves should be constructed with rounded edges and made from energy absorbent material.

The floor shall be designed to allow fluids to drain. Floor coverings, also when wet, shall provide adequate grip for the attendant and shall be durable and easy to clean.

4.10.2 Patient loading and unloading

The safe loading and unloading of patients shall be possible under all operational conditions.