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Ambulantna vozila in njihova oprema - Ambulantna zračna vozila - 2. del: Operativne in tehnične zahteve za ambulantna zračna vozila

Medical vehicles and their equipment - Air ambulances - Part 2: Operational and technical requirements of air ambulances

Medizinische Fahrzeuge und ihre Ausrüstung - Luftfahrzeuge zum Patiententransport - Teil 2: Operationelle und technische Anforderungen an Luftfahrzeuge zum Patiententransport

Véhicules sanitaires et leur équipement - Ambulances aériennes - Partie 2 : Exigences opérationnelles et techniques pour les ambulances aériennes

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Medical vehicles and their equipment - Air ambulances - Part 2: Operational and technical requirements of air ambulances

Véhicules sanitaire et leur équipement - Ambulances aérienne - Partie 2: Exigences techniques et opérationnelles pour les ambulances aériennes

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Foreword

This document (EN 13718-2:2008) 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of an identical text or by endorsement, at the latest by February 2009, and conflicting national standards shall be withdrawn at the latest by February 2009.

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 supersedes EN 13718-2:2002.

EN 13718 *Medical vehicles and their equipment — Air ambulances* consists of the following parts:

— *Part 1: Requirements of medical devices used in air ambulances*;

— *Part 2: Operational and technical requirements of air ambulances*.

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

Introduction

This European Standard provides requirements for air ambulances, and in particular covers requirements for the ambulance role of the aircraft.

Air ambulances are equipped with medical devices as well as drugs and rescue equipment to be used by medical personnel. Requirements for medical devices intended for use in ambulances are provided in EN 13718-1 *Medical vehicles and their equipment — Air ambulances — Part 1: Requirements for medical devices used in air ambulances*. This standard is supplementary to several European Standards as well as laws and regulations providing the requirements for aircraft in order to provide continuous patient care and monitoring during transport in and between various ambulance types and hospitals. The requirements sets covers ambulance flights in general. Several national and regional rules and regulations apply to aircrafts being used as ambulances. This European Standard gives information on these in the annexes and in notes throughout the text. Provisions for the safety and care both of the patient as well as of the crew and the medical personnel are contained in existing national and international laws, regulations and guidelines.

This European Standard provides some general requirements for the safe operation of aircrafts being used as ambulances. These requirements are not covered by the scope of the Medical Device Directive or by international agreements for craft, 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.

Aircraft being used as ambulances are equipped with medical devices, medicinal products and rescue equipment to enable the medical personnel to provide continuous patient care. The minima for the medical devices are specified in Annex A. The requirements set out in this European Standard give the minimum provisions for an ambulance service to provide satisfactory care and medical attention to emergency patients as well as other patients during transportation. The requirements are based on the state of the art of today and common practice in Europe.

1 Scope

This European Standard specifies the requirements for design, performance and equipping of air ambulances used for the transport and treatment of sick or injured persons. This European Standard is applicable to air ambulances capable of transporting at least one person on a stretcher.

NOTE Requirements are specified for categories of air ambulances based on the different intended use. These are the helicopter emergency medical service (HEMS) the helicopter intensive care medical service (HICAMS) and the fixed wing air ambulance (FWAA).

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 143:2000, *Respiratory protective devices — Particle filters — Requirements, testing, marking*

EN ISO 5359, *Low-pressure hose assemblies for use with medical gases*

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

EN 13718-1, *Medical vehicles and their equipment — Air ambulances — Part 1: Requirements for medical devices used in air ambulance*

EN 13976-1, *Rescue systems — Transportation of incubators — Part 1: Interface conditions*

EN 13976-2, *Rescue systems — Transportation on incubators — Part 2: System requirements*

EN ISO 7396-1:2007, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum (ISO 7396-1:2007)*

EN ISO 10524 (all parts), *Pressure regulators for use with medical gases (ISO 10524)*

EN ISO 18777, *Transportable liquid oxygen systems for medical use — Particular requirements (ISO 18777:2005)*

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

ISO 3795:1989, *Road vehicles, and tractors and machinery for agriculture and forestry — Determination of burning behaviour of interior materials*

European Aviation Safety Agency, *EASA Part 21 Certification of aircraft and related products, parts and appliances, and of design and production organisations* [1)]

European Aviation Safety Agency, *EASA CS-23 Certification Specification for Normal, Utility, Aerobatic and Commuter Category Aeroplanes* [1)]

European Aviation Safety Agency, *EASA CS-25 Certification Specification for Large Aeroplanes* [1)]

European Aviation Safety Agency, *EASA CS-27 Certification Specification for Small Rotorcraft* [1)]

European Aviation Safety Agency, *EASA CS-29 Certification Specifications for Large Rotorcraft* [1)]

1) http://www.easa.eu.int/home/index.html

Joint Aviation Authorities, *JAR-OPS (Joint Aviation Regulations-Operational Specifications) 3 Commercial Air Transportation (Helicopters) (publication available at Information Handling Services, Global Engineering Documents, 15 Inverness Way East, Englewood, Colorado 80112-5776, USA)* [2)]

3 Terms and definitions

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

3.1
air ambulance
aircraft designed to be normally staffed by two medically trained personnel equipped and intended for the transportation of at least one stretcher patient who will receive medical treatment during transport

3.2
medical device
instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of diagnosis, prevention, monitoring, treatment or alleviation of disease and injury

3.3
helicopter emergency medical service flight
HEMS flight
flight by a helicopter operating under a HEMS approval, the purpose of which is to facilitate emergency medical assistance, where immediate and rapid transportation is essential, by carrying:

— medical personnel and/or

— medical supplies (equipment, blood, organs, drugs) and/or

— ill or injured persons and other persons directly involved.

3.4
helicopter intensive care medical service flight
HICAMS flight
flight by a helicopter operating under a HEMS approval, especially staffed and equipped for the transportation, medical treatment and care of patients requiring intensive care treatment, mainly in inter-hospital transfers

3.5
fixed wing air ambulance
FWAA
aircraft especially equipped for transportation, medical treatment and care of patients, including patients requiring intensive care treatment

3.6
interface
means or place of interaction between one or more of the medical devices, the ambient conditions, the user, the patient, and when relevant, the various kinds of ambulances

3.7
interoperability
facility to connect various medical devices that are fixed to patients, into connections of associated medical devices including the possibility of connecting powered medical devices to various kinds of ambulances

2) http://www.jaa.nl/publications/publications.html

3.8
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

3.9
flight crew
members of the crew intended to operate the aircraft

NOTE See JAR-OPS 1 or 3, JAR-FCL 1 or 2.

3.10
medical crew
members of the crew intended to provide patient care

NOTE The medical crew normally consists of two persons, one as a specially trained physician and/or medical practitioner. In fixed wing air ambulances the medical crew normally consists of a physician and specially trained nurse or medical practitioner in addition if needed.

In HEMS operation one crew member has the function as a HEMS crew member (JAR-OPS 3). National regulations allow different specification/medical qualification of the personnel.

4 General requirements for air ambulances

4.1 General

Air ambulances should be designed to enable fast and safe access of medical personnel to people in need of medical attention at sites outside hospitals and between hospitals.

Intensive care patients transportation usually requires specially trained personnel.

Air ambulances should be designed to accommodate the personnel, creating the safe and effective working environment. Air ambulances should allow treatment for at least one stretcher patient.

Air ambulances shall be equipped with medical devices in accordance with Annex A and other life supporting equipment in accordance with Annex B, in order to provide continuous patient care. Equipment and systems should be selected and designed to enable interoperability and interchangeability (see 3.7 and 3.8).

4.2 Environmental conditions in the patient compartment

4.2.1 Temperature and humidity

A heating system shall be provided capable of raising the temperature in the patient compartment from 0 °C to + 18 °C within 20 min, when the outside air temperature is 0 °C.

NOTE 1 There should be an auxiliary system to heat/cool the patient compartment when stationary.

NOTE 2 Normal ambient humidity conditions for patient treatment should be aimed at.

4.2.2 Variable atmospheric pressure

Air ambulances which operate regularly at flight altitude above 15 000 feet shall have a pressurized cabin system. The operating pressure in the patient compartment above 15 000 feet shall be equivalent to the operating pressure at 3 500 feet.

4.2.3 Interior light

Lighting shall be provided in accordance with Table 1.

Table 1 — Interior light

Type	Illuminance lx, minimum
Patient area	200 [a]
Surrounding area	50
[a] Means shall be provided to switch the lighting level down to 10 lx.	

4.2.4 Ventilation

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

4.2.5 Noise exposure

If noise exposure to the patient compartment during transport exceeds 85 dB(A), protection to both patient(s) and personnel shall be established and available.

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.

Sound protection shall allow communication between the medical personnel, the pilot and the patient(s) when experiencing ambient noise conditions greater than 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 four 12 V DC outlets. Optionally one additional outlet may be supplied by a separate battery, 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.

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

If main voltage (AC) is provided by an inverter and available for use with medical device, the requirements on the AC and the inverter given in EN 13718-1 shall be fulfilled. The inverter is to be considered as an accessory to the medical device.

Supply mains for medical devices with 24 V DC power input should be constructed for a nominal voltage of Unom = 27,5 V. The internal batteries should be charged in the voltage range of Uvar = 24,8 V to 30,3 V. Functioning according to the manufacturer's specifications should remain at a minimum voltage of Umin = 20,0 V.

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

Connectors shall be designed to prevent short-circuiting under the environmental conditions prevailing in the air ambulances.

NOTE Connectors conforming to MIL-C26482 may be used (see EN 13718-1).

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

When the aircraft is connected to mains on the ground means should be provided to prevent earth leak currents.

If internal power supply of the aircraft is used the device requires airworthiness assessment and certification.

4.4 Electromagnetic interference

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

NOTE Medical devices intended for use in air ambulances should conform to ISO 7137.

4.5 Rail systems

The mounts for fixation of medical devices shall conform to EASA Part 21.

If rail systems are used, they shall conform to the EASA Part 21. If rail clamps are used they shall conform to EN ISO 19054 with additional fixation requirements according to EASA Part 21.

Manufacturers of the aircraft installation and/or of the medical devices intended for transport and use within air ambulances shall provide recommendations for the proper attachment of the medical device.

The manufacturer of the medical device shall declare the maximum weight for the device.

NOTE A typical rail system consists of for example rail supports, rail, rail clamps, equipment mount holders, equipment mounts and equipment pin holders and equipment mount pins.

4.6 Mechanical vibration

Mechanical vibration shall be kept to a minimum.

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

4.7 Requirements for fixation of medical devices

All medical devices shall be either fitted to or stowed in the aircraft securely.

A location in the aircraft shall be specified for the stowage and efficient use of medical devices. Essential medical devices for the management of vital functions, including airway management and ventilation shall be in reach of the medical personnel whilst seated. Medical devices required for use outside the aircraft shall be easily accessible. All medical devices shall be securely and safely stowed.

The devices shall be restrained within the aircraft and *g*-load requirements shall be in accordance with the particular class or certification of the aircraft (EASA CS-23, -25, -27 and -29).

4.8 Restraint systems in the patient compartment

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

Requirements for fixing and restraint systems according to the type of aircraft shall apply.

Requirements for medical devices that are brought into an aircraft should follow the minimum requirements for the stowage of baggage and cargo. Requirements for aircraft can be found in JAR-OPS 1 and 3.

NOTE Specific requirements are described in paragraphs 561 and 785 in EASA CS 23 (Normal, Utility, Aerobatic, and Commuter Category Aeroplanes), EASA CS 25 (Large Aeroplanes), EASA CS 27 (Small Rotorcraft) and EASA CS 29 (Large Rotorcraft).