SLOVENSKI STANDARD
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Ambulantna vozila in njihova oprema - Ambulantna zračna vozila - 1. del: Zahteve za medicinsko opremo, ki se uporablja pri ambulantnih zračnih vozilih

Medical vehicles and their equipment - Air Ambulances - Part 1: Requirements of medical devices used in air ambulances

Medizinische Fahrzeuge und ihre Ausrüstung - Luftfahrzeuge zum Patiententransport - Teil 1: Anforderungen an medizinische Geräte, die in Luftfahrzeugen zum Patiententransport verwendet werden

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Véhicules sanitaires et leur équipement - Ambulances aériennes - Partie 1 : Exigences pour les dispositifs médicaux utilisés dans les ambulances aériennes

Ta slovenski standard je istoveten z: **EN 13718-1:2008**

ICS:

11.160	Prva pomoč	First aid
43.160	Vozila za posebne namene	Special purpose vehicles

SIST EN 13718-1:2008 **en,fr,de**

2003-01.Slovenski inštitut za standardizacijo. Razmnoževanje celote ali delov tega standarda ni dovoljeno.

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EUROPEAN STANDARD

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Medical vehicles and their equipment - Air ambulances - Part 1: Requirements for medical devices used in air ambulances

Véhicules sanitaire et leur équipment - Ambulances aérienne - Partie 1: Exigences pour les dispositifs médicaux utilisés dans les ambulances aérienne

Medizinische Fahrzeuge und ihre Ausrüstung - Luftfahrzeuge zum Patiententransport - Teil 1: Anforderungen an medizinische Geräte, die in Luftfahrzeugen zum Patiententransport verwendet werden

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN Management Centre has the same status as the official versions.

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Foreword

This document (EN 13718-1:2008) 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of an identical text or by endorsement, at the latest by February 2009, and conflicting national standards shall be withdrawn at the latest by February 2009.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 13718-1:2002.

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.

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

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— *Part 1: Requirements for medical devices used in air ambulance*;

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

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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.

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Introduction

This European Standard gives minimum requirements for interfaces and compatibility of medical devices used in air ambulances. The standards work was called for by the EU Commission by a mandate from the Medical Device Directive (see Bibliography and Annex ZA).

This European Standard is supplementary to several other European Standards and gives requirements for medical devices when used in situations where the ambient conditions differ from the normal indoor conditions prevailing within the health care system. Several specific requirements are related to the conditions prevailing in air ambulances. The requirements set are carefully selected to ensure interoperability and continuous patient care.

The medical devices are being used by the services in air ambulances. Air ambulances carry medical devices as well as medicinal products and rescue equipment to be used by medical personnel.

Medical devices need to conform to the applicable essential requirements. The essential requirements are listed in Annex I to the Medical Device Directive (MDD). Annex ZA indicates related essential requirements that are addressed in identified clauses of this European Standard.

The environmental conditions for medical devices used in air ambulances are different from those expected in a normal hospital environment. In particular, this implies environmental conditions such as temperature and humidity, vibration and shock caused by movement of the air ambulances, variable atmospheric pressures and electromagnetic disturbances between the air ambulances and the medical device.

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1 Scope

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

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.

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

EN 980, *Symbols for use in the labelling of medical devices*

EN 1041, *Information supplied by the manufacturer with medical devices*

EN 13220, *Flow-metering devices for connection to terminal units of medical gas pipeline systems*

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EN 13718-2, *Medical vehicles and their equipment — Air ambulances — Part 2: Operational and technical requirements of air ambulances*

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EN 60601 (all parts), *Medical electrical equipment*

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EN 60529, *Degrees of protection provided by enclosures (IP code) (IEC 60529:1989)*

EN 60068-2-32:1993, *Basic environmental testing procedures — Part 2: Tests — Test Ed: Free fall (IEC 60068-2-32:1975 + A1:1982 + A2:1990)*

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

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

EN ISO 10297, *Transportable gas cylinders — Cylinder valves — Specification and type testing (ISO 10297:2006)*

EN ISO 10524-1, *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, *Pressure regulators for use with medical gases — Part 3: Pressure regulators integrated with cylinder valves (ISO 10524-3:2005)*

EN ISO 14971, *Medical devices — Application of risk management to medical devices (ISO 14971:2007)*

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

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

ISO 7000, *Graphical symbols for use on equipment — Index and synopsis*

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ISO 7137, *Aircraft — Environmental conditions and test procedures for airborne equipment*

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

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 medical 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

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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:

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— medical personnel and/or

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

— ill or injured persons and other persons directly involved

3.4
air ambulance flight
usually planned flight with an aircraft which is equipped with medical devices and installations, which are to facilitate medical assistance, where immediate and rapid transportation is not essential by carrying:

— medical personnel and/or

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

— ill or injured persons and other persons directly involved

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

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3.5
non-dedicated aircraft for patient transportation
aircraft equipped and staffed mainly for technical rescue, evacuation 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), ICAO (International Civil Aviation Organization).

3.6
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

3.7
fixed wing air ambulance
FWAA
aircraft especially equipped for transportation, medical treatment and care of patients, including patients requiring intensive care treatment

3.8
interface
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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

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3.9
interoperability
facility to connect various medical devices that are fixed to patients, into relevant connections of associated medical devices including the possibility of connecting powered medical devices to various kinds of ambulances

3.10
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

3.11
flight crew
member of the crew intended to operate the aircraft

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

3.12
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.

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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 Requirements for medical devices for air ambulances

4.1 Patient and personnel safety

Risks associated with medical devices shall be minimized, using risk management process in accordance with EN ISO 14971, taking account of the intended application of the devices and of known and foreseeable hazards in both normal and fault conditions. When risk analyses are performed, they shall reflect storage, installation, operation in normal use and maintenance according to the instructions of the manufacturer and the ambient conditions of an air ambulance.

4.2 User interface

A medical device designated as "portable" shall be:

— able to be carried inside and outside the aircraft;

— able to be carried by one person.

NOTE See Directive 90/269/EEC for information.

Buttons, switches, indicators, controls etc. shall be accessible and readable under the intended operational conditions.

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NOTE Intended operational conditions are described as requirement in EN 13718-2.

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Medical devices with alarms and signals shall provide a clear visual signal under the intended operational conditions.

When markings and instructions for the use of medical devices are present they shall conform to EN 1041 and EN 980. Graphical symbols shall be derived from harmonized standards when available. Any other symbols used shall be clear in their intentions, and there shall be a description of the meaning on the label or associated literature.

4.3 Environmental conditions and performance of medical devices intended for use in air ambulances[2)]

4.3.1 Functional temperature range

The medical devices shall function throughout the temperature range from 0 °C to 40 °C and shall function for at least 20 min when placed in an environment at -5 °C after storage at room temperature (20 ± 2) °C.

Following storage under extreme temperature conditions ranging from -30 °C to +70 °C, a medical device shall function within 10 min as intended and for at least 20 min when the medical device is returned to room temperature (20 ± 2) °C.

Devices which cannot satisfy the above requirements shall be marked appropriately, e.g. by symbol ISO 7000/0434 “Caution” in combination with symbol ISO 7000/0632 “Temperature limitation”.

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2) A comparison of requirements in other standards is provided as information in Annex A.

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4.3.2 Humidity

Medical devices shall function as intended between 5 % RH to 95 % RH (relative humidity) within the temperature range of 0 °C to 40 °C. ISO 7137 may be used.

4.3.3 Variable atmospheric pressures

The medical equipment shall function and present correct data as specified by the manufacturer at pressures between sea level and an altitude of 4 000 m.

The operating range shall be stated, and if readings or performance vary, a table of correcting values shall be attached. The table shall state, in accordance with the prevailing atmospheric conditions, the extent of discrepancy between the actual values and the values indicated by the device.

NOTE Medical devices intended to endure sub-atmospheric or pressurized chambers should have a table to cover correcting values, the pressure range given should be as appropriate. As an example, for pressures between 600 hPa and 2 500 hPa, the correcting values should be presented in increments of 100 hPa.

4.4 Electrical power driven medical devices

4.4.1 General

Electrical power driven medical devices shall conform to EN 60601, all parts.

Medical devices shall be IPX4 rated according to EN 60529.

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Life supporting devices shall be capable of operating with 12 V DC power input.

Life supporting equipment shall function as intended during loading, transport and unloading. Life supporting medical devices shall have changeable batteries or means for external 12 V DC in order to prevent interruption of the power supply.

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NOTE 1 This requirement is deemed essential to interoperability.

NOTE 2 Connectors conforming to MIL-C26482 or EN 60309-1, -2 can be used.

NOTE 3 Most equipment will have to meet the requirements of EN 60601-1:2006 and the related collateral and particular standards in EN 60601-1 series and EN 60601-2 series that are relevant to the specific type of equipment. Where the relevant particular standard in the EN 60601-2 series has not yet been revised to relate to EN 60601-1:2006, the previous edition of the general standard EN 60601-1:1990 will apply, together with relevant collateral standards related to that edition.

4.4.2 Medical devices with 12 V DC power input

The medical device shall be constructed for a voltage of U = 13,8 V. The internal batteries shall be charged in the voltage range of U_{var} = 12,4 V to 15,1 V. It shall operate as specified by the manufacturer independently of voltage fluctuation at shorttime voltage drop to 10 V.

NOTE Aircraft can, like vehicles, have a power supply with nominal voltage of 12 V DC. The normal voltage will, typically, fluctuate from 12,4 V to 15,1 V. 13,8 V DC is, for this purpose, identified as the normal voltage.

4.4.3 Medical devices with 24 V DC power input

The medical device shall be constructed for a voltage of U = 27,5 V. The internal batteries shall be charged in the voltage range of U_{var} = 24,8 V to 30,3 V. It shall operate as specified by the manufacturer independently of voltage fluctuation at shorttime voltage drop to 20 V.