SLOVENSKI STANDARD
SIST EN 13718-1:2015+A1:2020

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Nadomešča:

SIST EN 13718-1:2015

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

Medical vehicles and their equipment - Air ambulances - Part 1: Requirements for 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

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

Ta slovenski standard je istoveten z: **EN 13718-1:2014+A1:2020**

ICS:

11.160	Prva pomoč	First aid
49.020	Letala in vesoljska vozila na splošno	Aircraft and space vehicles in general

SIST EN 13718-1:2015+A1:2020 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 13718-1:2014+A1

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ICS 11.040.01; 11.160; 49.020

English Version

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

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

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This European Standard was approved by CEN on 25 July 2014 and includes Amendment 1 approved by CEN on 16 December 2019.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (EN 13718-1:2014+A1:2020) 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of an identical text or by endorsement, at the latest by October 2020, and conflicting national standards shall be withdrawn at the latest by October 2020.

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

This document includes Amendment 1 approved by CEN on 2019-12-16.

This document supersedes A1 EN 13718-1:2014. A1

The start and finish of text introduced or altered by amendment is indicated in the text by tags A1 A1.

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, see informative Annex ZA, which is an integral part of this document.

EN 13718-1:2008 has been technically revised. The following points represent the most important changes in the revision:

a) normative references were updated;

b) the following terms and definitions were deleted: 3.3 "HEMS flight", 3.4 "air ambulance flight", 3.5 "non-dedicated aircraft for patient transportation", 3.6 "HICAMS flight", 3.7 "fixed wing air ambulance", 3.10 "interchangeability", 3.11 "flight crew", 3.12 "medical crew";

c) a new Subclause 4.5.4 "Medical devices with 230 V AC power input" was introduced;

d) Subclause 4.4.5 "Inverters" was deleted;

e) Subclause 4.5.4 "Pneumatic power supply" (now Subclause 4.6.4) was revised;

f) Subclause 4.8 "Fire resistance" (now Subclause 4.9) was revised;

g) unclear issues were clarified in this part of the standard and between the two parts of the standard (requirements for patient's compartment illumination, respectively);

h) the standard was modified/integrated to meet the Medical Devices Directive 93/42/EEC requirements.

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

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

— *Part 2: Operational and technical requirements for 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, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Introduction

This part of EN 13718 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 Devices Directive (see Bibliography and Annex ZA).

This part of EN 13718 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 that are 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.

The medical devices need to conform to the applicable essential requirements in the Medical Devices Directive. The essential requirements are listed in Annex I of the Medical Devices Directive (MDD). Annex ZA lists the essential requirements that are addressed by the 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.

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

[A1] The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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. [A1]

[A1] *Deleted text* [A1]

[A1] EN 13718-2:2015+A1:2020, *Medical vehicles and their equipment — Air ambulances — Part 2: Operational and technical requirements of air ambulances* [A1]

EN 60068-2-31:2008, *Environmental testing - Part 2-31: Tests - Test Ec: Rough handling shocks, primarily for equipment-type specimens*

[A1] EN 60529:1991/A2:2013, *Degrees of protection provided by enclosures (IP Code) (IEC 60529:1989/A2:2013)* [A1]

[A1] EN 60601-1:2006+Cor.:2010+A1:2013, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005+ Cor.:2006 + Cor.:2007 + A1:2012)* [A1]

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

[A1] EN ISO 5359:2014+A1:2017, Anaesthetic and respiratory equipment — Low-pressure hose assemblies for use with medical gases *(*ISO 5359*:*2014+Amd 1:2017*)* [A1]

[A1] EN ISO 10297:2014+A1:2017, *Gas cylinders — Cylinder valves — Specification and type testing (ISO 10297:2014, Corrected Version 2014-11-01 + Amd.1:2017)* [A1]

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

[A1] EN ISO 10524-3:2006+Amd 1:2013, *Pressure regulators for use with medical gases — Part 3: Pressure regulators integrated with cylinder valves (ISO 10524-3:2005+A1:2013)* [A1]

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)*

[A1] *Deleted text* [A1]

〉A1〈 ISO 7000:2014, *Graphical symbols for use on equipment — Registered symbols* 〉A1〈

RTCA DO-160G:2010,[1)] Environmental Conditions and Test Procedures for Airborne Equipment

3 Terms and definitions

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

〉A1〈 ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp 〉A1〈

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
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

3.3
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

3.4
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

3.5
portable
term referring to transportable equipment that, once installed and placed into service, is intended to be moved from one location to another while being carried by one or more persons

Note 1 to entry: Equipment can refer to accessories or equipment parts.

Note 2 to entry: See the taxonomy in the rationale for Definition 3.63 in EN 60601-1:2006/A1:2013.

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[SOURCE: EN 60601-1:2006/A1:2013, 3.85, modified — The wording of Note 2 to entry has been slightly modified.]

4 Requirements for medical devices for air ambulances

4.1 General

The manufacturers of all medical devices intended to be used in air ambulances shall ensure that the requirements of this standard are met.

4.2 Patient and personnel safety

Risks associated with medical devices shall be minimized, using risk management process in accordance with EN ISO 14971:2012, 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.

4.3 User interface

The user interface of the medical device shall be easy to use in an air ambulance.

NOTE 1 See [A1] EN 62366-1:2015 [A1] and EN 60601–1–6:2010 for detailed information on how to design an easy to use medical device.

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 2 See Directive 90/269/EEC for information.

The manufacturer of the medical device shall carry out a risk assessment of the manual handling of the medical device inside and outside of an air ambulance.

NOTE 3 There are several accepted risk assessments methods to use e.g. Key Item Method (KIM), Manual Handling Assessment Charts and EN 1005–2:2003+A1:2008.

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

NOTE 4 Intended operational conditions are described as requirements in [A1] EN 13718-2:2015+A1:2020. [A1]

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

[A1] Deleted text [A1]

Markings shall remain legible following the test in 5.3.

4.4 Environmental conditions and performance of medical devices intended for use in air ambulances

4.4.1 Functional temperature range

The medical devices shall function as intended 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 −20 °C to +50 °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 ⟨A1⟩ ISO 7000:2014, ⟨A1⟩ 0434 “Caution” in combination with symbol ⟨A1⟩ ISO 7000:2014, ⟨A1⟩ 0632 “Temperature limitation”.

4.4.2 Humidity

Medical devices shall function as intended between 15 % RH to 95 % RH (relative humidity) within the temperature range of −20 °C to +50 °C; non-condensing and a water vapour partial pressure greater than 50 hPa is not required. RTCA DO-160G:2010,[2] Section 6 Category A, may be used to fulfil the requirement.

4.4.3 Variable atmospheric pressures

The medical equipment shall function ⟨A1⟩ as intended ⟨A1⟩ 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.

The increments of pressure in the table should be sufficient to enable accurate corrections to be made over the range of pressure. As an example, for pressures between 600 hPa to 2 500 hPa, the correcting values should be presented in increments of 100 hPa.

4.5 Electrically-powered medical devices

4.5.1 General

Electrically-powered medical devices shall conform to the applicable parts in the EN 60601 series.

Medical devices shall be IPX3 rated according to ⟨A1⟩ EN 60529:1991/A2:2013. ⟨A1⟩

Life supporting medical devices shall function as intended during loading, transport and unloading. In order to prevent interruption of operation life supporting medical devices shall have user changeable batteries and/or be capable of operating on external 12 V DC.

NOTE 1 This requirement is deemed essential to interoperability.

Connectors conforming to MIL-DTL-26482 or EN 60309-1:1999 and EN 60309-2:1999 may be used.

NOTE 2 Requirements for the electrical power supply for medical devices are specified in ⟨A1⟩ EN 13718-2:2015+A1:2020. ⟨A1⟩

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2) http://www.rtca.org/store_product.asp?prodid=770.