

This is a preview of "BS EN 13718-1:2014". [Click here to purchase the full version from the ANSI store.](#)

BS EN 13718-1:2014



BSI Standards Publication

Medical vehicles and their equipment — Air ambulances

Part 1: Requirements for medical devices used in air ambulances

bsi.

...making excellence a habit.™

This is a preview of "BS EN 13718-1:2014". [Click here to purchase the full version from the ANSI store.](#)

This British Standard is the UK implementation of EN 13718-1:2014. It supersedes BS EN 13718-1:2008 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/239, Rescue systems.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

© The British Standards Institution 2014. Published by BSI Standards Limited 2014

ISBN 978 0 580 81504 1

ICS 11.040.01; 11.160; 49.020

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 September 2014.

Amendments issued since publication

Date	Text affected
------	---------------

This is a preview of "BS EN 13718-1:2014". [Click here to purchase the full version from the ANSI store.](#)

EUROPÄISCHE NORM

September 2014

ICS 11.040.01; 11.160; 49.020

Supersedes EN 13718-1:2008

English Version

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

Véhicules sanitaire et leur équipement - 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

This European Standard was approved by CEN on 25 July 2014.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

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-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

This is a preview of "BS EN 13718-1:2014". [Click here to purchase the full version from the ANSI store.](#)

Contents

Page

Foreword.....	3
Introduction	4
1 Scope	5
2 Normative references	5
3 Terms and definitions	6
4 Requirements for medical devices for air ambulances	6
4.1 General.....	6
4.2 Patient and personnel safety.....	7
4.3 User interface.....	7
4.4 Environmental conditions and performance of medical devices intended for use in air ambulances	7
4.4.1 Functional temperature range	7
4.4.2 Humidity.....	8
4.4.3 Variable atmospheric pressures	8
4.5 Electrically-powered medical devices	8
4.5.1 General.....	8
4.5.2 Medical devices with 12 V DC power input	8
4.5.3 Medical devices with 24 V DC power input	8
4.5.4 Medical devices with 230 V AC power input	9
4.5.5 Short time voltage drop	9
4.5.6 Internal electrical power source.....	9
4.5.7 Electromagnetic interference of medical devices	9
4.6 Medical gas supply	9
4.6.1 General.....	9
4.6.2 Gas leakage	9
4.6.3 Pressure regulators and flow metering devices.....	9
4.6.4 Pneumatic power	10
4.6.5 Cylinder valves.....	10
4.6.6 Low pressure hose assemblies.....	10
4.7 Mechanical strength	10
4.7.1 General.....	10
4.7.2 Vibration and bump	10
4.7.3 Free fall	10
4.8 Fixation of medical devices in air ambulances	10
4.9 Fire resistance.....	10
4.10 Information to be supplied by the manufacturer	11
5 Test methods.....	11
5.1 General.....	11
5.2 Ambient conditions	11
5.3 Test method for durability of markings and colour coding	11
5.4 Free fall	11
Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical Devices	13
Bibliography	15

This is a preview of "BS EN 13718-1:2014". [Click here to purchase the full version from the ANSI store.](#)

Foreword

This document (EN 13718-1:2014) 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 supersedes EN 13718-1:2008.

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

This is a preview of "BS EN 13718-1:2014". [Click here to purchase the full version from the ANSI store.](#)

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.

This is a preview of "BS EN 13718-1:2014". [Click here to purchase the full version from the ANSI store.](#)

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 documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

EN 13718-2:2008,¹⁾ *Medical vehicles and their equipment — Air ambulances — Part 2: Operational and technical requirements of air ambulances*

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

EN 60529:1991, *Degrees of protection provided by enclosures (IP Code) (IEC 60529:1989)*

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

EN ISO 407:2004, *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 10297:2006, *Transportable gas cylinders — Cylinder valves — Specification and type testing (ISO 10297:2006)*

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)*

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 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)*

ISO 7000:2012, *Graphical symbols for use on equipment — Registered symbols*

1) EN 13718-2:2008 is bound to be superseded with a new edition.