

Air, water and difficult terrain ambulances —

Part 1: Medical devices interface requirements for the continuity of patient care

The European Standard EN 13718-1:2002 has the status of a British Standard

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National foreword

This British Standard is the official English language version of EN 13718-1:2002.

The UK participation in its preparation was entrusted to Technical Committee CH/239, Rescue systems, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

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Air, water and difficult terrain ambulances - Part 1: Medical device interface requirements for the continuity of patient care

Ambulances aériennes, maritimes et de terrain difficile -
Partie 1: Exigences relatives à l'interface de dispositifs
médicaux assurant la continuité des soins

Patiententransportmittel in der Luft, auf dem Wasser und in
schwierigem Gelände - Teil 1: Besondere Anforderungen
an die Schnittstellen von Medizinprodukten für die
kontinuierliche Patientenbetreuung

This European Standard was approved by CEN on 23 June 2002.

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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 Management Centre has the same status as the official versions.

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Foreword

This document EN 13718-1:2002 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of an identical text or by endorsement, at the latest by February 2003, and conflicting national standards shall be withdrawn at the latest by February 2003.

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.

Annex A is normative. The annexes B and C are informative.

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 gives requirements for interfaces of medical devices intended for air, water and difficult terrain 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 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, water, and difficult terrain ambulances. The requirements set are carefully selected to ensure interoperability and continuous patient care.

This standard was derived from the work developed during the establishment of requirements for the vehicles or crafts being used as air, water and difficult terrain ambulances. The scope covers interface requirements for medical devices intended to be used in pre-hospital and ambulatory activities. The medical devices are being used by the services in air, water and difficult terrain ambulances as well as on special units such as motorcycles, bicycles and other transport vehicles as deemed practical.

Requirements for physical design are given as performance requirements in this standard.

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.

In general, the manufacturer of a medical device is responsible for the device as presented to the market, and users should ensure that devices are used in compliance with manufacturer's instructions and in accordance with their intended use. According to the Medical Device Directive (93/42/EEC), the responsibility of the manufacturer is assumed by a person, who permits unauthorised adjustments, repairs and use of a medical device.

Medical devices shall conform to the essential requirements that are relevant. 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 standard.

The environmental conditions for medical devices in air, water, and difficult terrain vehicles 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 vehicles, variable atmospheric pressures and electromagnetic disturbances between the vehicle and the medical device.

At present, no common test requirements exist for the testing of electromagnetic compatibility (EMC) between medical devices and the particularly aircraft. An ad hoc group of EMC experts has developed a suggestion for a merger of test requirements deriving from European Standards and regulations covering aircraft operations in order to establish common and applicable testing routines.

1 Scope

This European Standard specifies minimum performance requirements for interfaces of medical devices used within air, water, and difficult terrain ambulances.

Exclusions:

the standard specifically excludes consideration of the design and ergonomic requirements of the vehicle or craft. Specific requirements for permanent outdoor use and storage of medical devices are excluded from this standard.

NOTE Requirements for road ambulances and air, water and difficult terrain ambulances can be found in EN 1789 and prEN 13718-2 (see Bibliography).

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).

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

EN 737-3, *Medical gas pipeline systems – Part 3: Pipelines 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 738-3, *Pressure regulators for use with medical gases – Part 3: Pressure regulators integrated with cylinder valves.*

EN 739:1998, *Low-pressure hose assemblies for use with medical gases.*

EN 849, *Transportable gas cylinders - Cylinder valves - Specification and type testing.*

EN 850, *Transportable gas cylinders - Pin-index, yoke-type valve outlet connections for medical use.*

EN 980, *Graphical symbols for use in the labelling of medical devices.*

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

EN 12218, *Rail systems for supporting medical equipment.*

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

EN 60601-1:1990, *Medical electrical equipment - Part 1: General requirements for safety (IEC 60601-1:1988).*

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

EN 60068-2-6, *Environmental testing - Part 2: Tests - Tests Fc: Vibration (sinusoidal) (IEC 60068-2-6:1995 + Corrigendum 1995).*

EN 60068-2-29, *Basic environmental testing procedures - Part 2: Tests - Test Eb and guidance: Bump (IEC 60068-2-29:1987).*

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

EN 60068-2-64, *Environmental testing - Part 2: Test methods - Test Fh: Vibration, broad-band random (digital control) and guidance (IEC 60068-2-64:1993 + Corrigendum 1993).*

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