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Ambulantna vozila za zrak, vodo in težke terene - 1. del: Zahteve za povezave medicinske opreme za nenehno oskrbo bolnikov

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

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

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

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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of an identical text or by endorsement, at the latest by February 2003, and conflicting national standards shall be withdrawn at the latest by February 2003.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.*

3 Terms and definitions

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

3.1
ambulance
road, air, water and difficult terrain vehicle intended to be staffed by at least two medically trained personnel to accommodate at least one stretcher patient

3.2
medical device
any 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;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
- investigation, replacement or modification of the anatomy or of a physiological process;
- control of conception;

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

3.3
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 vehicle or craft

3.4
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

4 General requirements for interfaces of medical devices with air, water and difficult terrain ambulances

4.1 General

This part of the standard provides requirements for interfaces of medical devices intended for use within air, water and difficult terrain ambulances. The ambient conditions are characterised by conditions prevailing inside the ambulances under transport and in situations outside hospitals and clinics, differing from normal indoor conditions.

Specific additional requirements relevant to performance within various types of ambulances, are provided in clause 5.

NOTE A major consideration when selecting medical devices, intended by their manufacturer to be suitable for use in air, water, and difficult terrain ambulances, is the advantage of such devices having been designed with a lowest weight and smallest size as possible. These considerations are of particular importance when considering suitability for use in emergency helicopter ambulances.

4.1.1 User interface

If a medical device is designated as "portable" it shall be possible for it to be carried by one person, and if needed it shall be capable of normal functioning whilst being carried.

If powered, it shall have its own built-in power supply, and if needed it shall be capable of being used outside the ambulance.

NOTE Relevant requirements can be found in EN 60601-1.

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

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 Harmonised 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.

4.2 Environmental conditions and performance of medical devices

4.2.1 General requirements

The medical devices shall conform to the requirements below.

NOTE A comparison of requirements in other standards is provided as information in annex C.

4.2.2 Functional temperature range

The 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, unless the device is otherwise marked.

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

NOTE Particular medical devices, not complying with these requirements, can be evident. If these medical devices are being used, information on applicability should be provided.

4.2.3 Humidity and ingress

Medical devices shall conform to clauses 10 and 44 of EN 60601-1:1990 and other standards in the series EN 60601-2 when applicable.

Medical devices shall function as intended at between 5 % to 95 % RH within the temperature range of 0 °C to 40 °C, unless otherwise marked on the device.

4.2.4 Variable atmospheric pressures

The operating range shall be stated, and if readings 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 pressurised 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.

4.3 Electrical power driven medical devices

Medical devices shall be IPX4 rated according to EN 60529, unless the device is otherwise marked.

Life supporting devices shall be capable of operating with 12 V_{DC} power input, see also EN 60601-1.

NOTE 1 This requirement is deemed essential to interoperability.

Electrical power driven medical devices shall have a connector that is lockable in order to prevent the risk of short-circuiting.

NOTE 2 Connectors complying with MIL-C26482 or EN 60309-1, -2 are recommended for this use.

The requirements of EN 60601-1 shall apply. In addition the following requirements apply:

4.3.1 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.

4.3.2 Medical devices with 24 V power input

The 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.

4.3.3 Internal electrical power source

Medical devices with internal rechargeable batteries shall be rechargeable using power from the vehicle or craft.

NOTE 1 Requirements for vehicle or craft are provided in prEN 13718-2 and EN 1789 (see Bibliography).

Rechargeable batteries for medical devices shall be “non dangerous”.

NOTE 2 Batteries are considered to be “non dangerous”, if at a temperature of 55 °C, the electrolyte does not flow from a ruptured or cracked case. There should be no free flow of liquid and terminals should be protected from short circuit.

NOTE 3 Batteries conforming to IATA, UN 2800-A67 fulfil this requirement.

4.4 Electromagnetic interference of medical devices

The level of electromagnetic energy from medical devices shall be specified by the manufacturer (see also Introduction).

NOTE 1 Relevant minimum requirements for electromagnetic compatibility testing of medical devices intended for ambulances are provided by annex B. Complying with these tests would allow a comparable compliance to relevant requirements for electronically powered equipment within aircraft, thereby establishing common test requirements (see 5).

NOTE 2 Cables can function as antennas and induce disturbances.

NOTE 3 Relevant requirements for the vehicles and crafts are provided by EN 1789 and prEN 13718-2 (see Bibliography).

4.5 Gas-supply

4.5.1 General

Medical devices supplying medical gases shall conform to relevant European Standards (see clause 2).

4.5.2 Source of supply

The sources of supply for medical gases and vacuum shall conform to relevant clauses of EN 737-3 (as far as applicable), see also 4.7 and annex A.

4.5.3 Gas leakage

Means shall be provided to minimise the leakage of medical gases and vacuum into the environment. The permitted leakage from the components of the supply systems to the atmosphere shall be as specified in the relevant European Standards (see clause 2).

NOTE National and/or regional requirements for the protection of workers can be applicable (see Bibliography).