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

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National foreword

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 It supersedes BS EN 13718-1:2008 which is withdrawn.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.

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

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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.

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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of an identical text or by endorsement, at the latest by March 2015, and conflicting national standards shall be withdrawn at the latest by March 2015.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.

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

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.

RTCA DO-160G:2010,[2] *Environmental Conditions and Test Procedures for Airborne Equipment*

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
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.

[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.

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It is available on the RTCA store: http://www.rtca.org/store_product.asp?prodid=770.

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 EN 62366:2008 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 EN 13718-2:2008.

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 1041:2008+A1:2013 and EN ISO 15223-1:2012. 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.

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 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 ISO 7000:2012, 0434 “Caution” in combination with symbol ISO 7000:2012, 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,[3)] Section 6 Category A, may be used to fulfil the requirement.

4.4.3 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.

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 EN 60529:1991.

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 EN 13718-2:2008.

4.5.2 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. Basic safety and essential performance shall be maintained during and following a 30 s dip to 10 V in the 12 V power supply.

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.

4.5.3 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. Basic safety and essential performance shall be maintained during and following a 30 s dip to 20 V in the 24 V power supply.

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

NOTE Aircraft can have a power supply with nominal voltage of 24 V DC. The normal voltages will, typically, fluctuate from 24,8 V to 30,2 V. 27,5 V DC is, for this purpose, identified as the normal voltage.

4.5.4 Medical devices with 230 V AC power input

The medical device shall be constructed for a voltage of U = 230 V. It shall maintain normal operation and charging of the internal batteries in the voltage range of U +10 % to −15 %.

4.5.5 Short time voltage drop

Electro medical devices shall maintain basic safety and essential performance during and following a 30 s dip to 10 V from a 12 V d.c. supply mains and a 30 s dip to 20 V for operation from a 24 V d.c. supply mains.

4.5.6 Internal electrical power source

Medical devices with internal rechargeable batteries shall be rechargeable using power from the aircraft under normal operation conditions.

Rechargeable batteries shall be such that, 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 Batteries conforming to IATA, UN 2800-A67, fulfil this requirement.

4.5.7 Electromagnetic interference of medical devices

The radio frequency susceptibility of medical devices shall conform to RTCA DO-160G:2010,[4)] Section 20.

The emission of radio frequency energy from medical devices shall conform to RTCA DO-160G:2010,[5)] Section 21 Category M.

4.6 Medical gas supply

4.6.1 General

Devices requiring gas supply shall be compatible with the installations specified in EN 13718-2:2008.

4.6.2 Gas leakage

Means shall be provided to minimize the leakage of medical gases into the environment. The permitted leakage from the gas supplied equipment to the atmosphere shall conform to EN ISO 5359:2008 and EN ISO 10297:2006.

NOTE Attention is drawn to any national and/or regional requirements regarding the protection of workers.

4.6.3 Pressure regulators and flow metering devices

Pressure regulators and pressure regulators with flow metering devices shall conform to EN ISO 10524-1:2006 or EN ISO 10524-3:2006. The pressure regulators shall be directly connected to the source of supply.

Flow metering devices for connection to terminal units shall conform to EN ISO 15002:2008.

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

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

4.6.4 Pneumatic power

The medical equipment shall function during single fault condition in the gas installation, i.e. 1 000 kPa.

4.6.5 Cylinder valves

Cylinder valves shall conform to EN ISO 10297:2006. If pin-index valves are used, their outlet connection shall conform to EN ISO 407:2004.

4.6.6 Low pressure hose assemblies

Low pressure hose assemblies for connecting medical devices to terminal units shall conform to EN ISO 5359:2008.

If flexible hoses are used between the pressure regulators and the terminal units, the requirements of EN ISO 5359:2008, except for 4.4.2.1, shall apply. The minimum bursting pressure of such hoses shall be not less than 8 000 kPa at +23 °C and not less than 6 400 kPa at +40 °C.

NOTE See also EN ISO 11197:2009, 59.101.1 c).

4.7 Mechanical strength

4.7.1 General

The medical equipment shall function within its specification after being submitted to tests according to Clause 5.

NOTE Requirements for installation of medical devices are described in EN 13718-2:2008.

4.7.2 Vibration and bump

The medical device shall conform to RTCA DO-160G:2010, [6)] Section 7 Category A and Section 8 Category U/U2.

4.7.3 Free fall

The medical device shall conform to 5.4.

NOTE This clause applies to the portable medical equipment only.

4.8 Fixation of medical devices in air ambulances

Manufacturers of the aircraft installation and of the medical devices intended for transport and use within air ambulances shall provide recommendations for the proper attachment of the medical device.

NOTE Requirements for installation of medical devices are described in EN 13718-2:2008.

4.9 Fire resistance

Medical devices and other types of equipment used in patient care should, where practical, be fire resistant.

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

NOTE For testing requirements, see RTCA DO-160G:2010,[7)] Section 26.

4.10 Information to be supplied by the manufacturer

Instructions for use shall include information of the products intended use and the environmental conditions.

Instructions for use shall contain all information necessary to use the product in accordance with its specification and shall include an explanation of the function of controls, the sequence of operation and connection and disconnection of detachable parts and accessories.

Instructions for use shall give detailed instructions for the safe performance of cleaning, inspection and preventative maintenance to be performed by the operator or by authorized persons, and shall indicate the recommended frequency or interval of such activities.

Markings and instructions for the use of medical devices shall conform to EN 1041:2008+A1:2013 and EN ISO 15223-1:2012.

The rated (marked) range of nominal voltage on electro medical devices with power inputs shall include at least 12,4 V to 15,1 V for operation from 12 V DC power supply and 24,8 V to 30,3 V for operation from 24 V DC power supply.

The manufacturer of the medical device shall declare the maximum weight and the centre of gravity for the device.

The meaning of figures, symbols, warning statements and abbreviations shall be explained in the instructions for use.

A list of recommended spare parts shall be provided.

5 Test methods

5.1 General

The manufacturer of medical devices is responsible for the testing of medical devices to be used in an air ambulance in accordance with the standards and test procedures of this document.

Medical devices shall be maintained and calibrated in accordance with manufacturer's instructions.

5.2 Ambient conditions

The tests shall be carried out at (23 ± 2) °C.

5.3 Test method for durability of markings and colour coding

Rub markings and colour coding by hand, without undue pressure, first for 15 s with a cloth rag soaked with distilled water, then for 15 s with a cloth rag soaked with ethanol and then for 15 s with a cloth rag soaked with Isopropanol. Carry out the test at an ambient temperature of (23 ± 2) °C.

5.4 Free fall

The medical device shall, while functioning, be submitted to the following test:

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

— free fall according to EN 60068-2-31:2008, Procedure 1;

— height of fall: 0,75 m;

— number of falls: 1 on each of the six surfaces.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical Devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on Medical Devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC on Medical devices

Clause(s)/sub-clause(s) of this European Standard	**Essential requirements (ERs) of Directive 93/42/EEC**	**Qualifying remarks/Notes**
4.5.1	7.2 to 13 (*for electrically-powered medical devices only*)	Subclause 4.5.1 requires electrically-powered medical devices to comply with all relevant parts of the EN 60601 series of standards. For coverage of these ERs, see the Annex ZZs of the standards in the EN 60601 series (*for electrically-powered medical devices only*).
4.6, 4.8	9.1	The requirement to indicate any restrictions on use is not covered (*for non-electrically-powered medical devices*).
4.3	9.2, first indent	Covered for portability of equipment
4.4	9.2, second indent	Temperature and pressure are covered.
4.6	12.7.4	Gas terminals and connectors are covered.
4.10	13	For coverage of these ERs, see EN 1041:2008+A1:2013, Annex ZA.

Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance to the Medical Devices Directive 93/42/EEC. This means that risks have to be reduced ‘as far as possible’, ‘to a minimum’, ‘to the lowest possible level’, ‘minimized’ or ‘removed’, according to the wording of the corresponding essential requirement.

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

Bibliography

This Bibliography serves a list of references for publications relevant to this European Standard. The list is not all inclusive.

NOTE References to international laws and regulations are not all-inclusive. Information is provided by the responsible authority.

[1] EN 1005-2:2003+A1:2008, *Safety of machinery — Human physical performance — Part 2: Manual handling of machinery and component parts of machinery*

[2] EN 1789:2007+A1:2010, *Medical vehicles and their equipment — Road ambulances*

[3] EN 1865-1:2010, *Patient handling equipment used in road ambulances — Part 1: General stretcher systems and patient handling equipment*

[4] EN 1865-2:2010, *Patient handling equipment used in road ambulances — Part 2: Power assisted stretcher*

[5] EN 1865-3:2012, *Patient handling equipment used in road ambulances — Part 3: Heavy duty stretcher*

[6] EN 1865-4:2012, *Patient handling equipment used in road ambulances — Part 4: Foldable patient transfer chair*

[7] EN 1865-5:2012, *Patient handling equipment used in road ambulances — Part 5: Stretcher support*

[8] EN 13976-1:2011, *Rescue systems — Transportation of incubators — Part 1: Interface conditions*

[9] EN 13976-2:2011, *Rescue systems — Transportation of incubators — Part 2: System requirements*

[10] EN 60068-2-6:2008, *Environmental testing — Part 2-6: Tests — Test Fc: Vibration (sinusoidal) (IEC 60068-2-6:2007)*

[11] EN 60068-2-29:1993, *Environmental testing — Part 2: Tests — Test Eb and guidance: Bump (IEC 60068-2-29:1987)*

[12] EN 60068-2-64:2008, *Environmental testing — Part 2-64: Tests — Test Fh: Vibration, broadband random and guidance (IEC 60068-2-64:2008)*

[13] EN 60309-1:1999, *Plugs, socket-outlets and couplers for industrial purposes — Part 1: General requirements (IEC 60309-1:1999)*

[14] EN 60309-2:1999, *Plugs, socket-outlets and couplers for industrial purposes — Part 2: Dimensional interchangeability requirements for pin and contact-tube accessories (IEC 60309-2:1999)*

[15] EN 60601-1:2006,[8)] *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005)*

[16] EN 60601-1-6:2010, *Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral standard: Usability (IEC 60601-1-6:2010)*

8) EN 60601-1:2006 is impacted by the amendment EN 60601-1:2006/A1:2013, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2006/A1:2013)*.

[17] EN 61000-4-2:2009, *Electromagnetic compatibility (EMC) — Part 4-2: Testing and measurement techniques — Electrostatic discharge immunity test (IEC 61000-4-2)*

[18] EN 61000-4-3:2006, *Electromagnetic compatibility (EMC) — Part 4-3: Testing and measurement techniques — Radiated, radio-frequency, electromagnetic field immunity test (IEC 61000-4-3:2006)*

[19] EN 61000-4-4:2012, *Electromagnetic compatibility (EMC) — Part 4-4: Testing and measurement techniques — Electrical fast transient/burst immunity test (IEC 61000-4-4:2012)*

[20] EN 61000-4-6:2009, *Electromagnetic compatibility (EMC) — Part 4-6: Testing and measurement techniques — Immunity to conducted disturbances, induced by radio-frequency fields (IEC 61000-4-6:2008)*

[21] EN 62366:2008, *Medical devices — Application of usability engineering to medical devices (IEC 62366:2007)*

[22] EN ISO 7396-2:2007, *Medical gas pipeline systems — Part 2: Anaesthetic gas scavenging disposal systems (ISO 7396-2:2007)*

[23] EN ISO 9170-2:2008, *Terminal units for medical gas pipeline systems — Part 2: Terminal units for anaesthetic gas scavenging systems (ISO 9170-2:2008)*

[24] EN ISO 10524-2:2006, *Pressure regulators for use with medical gases — Part 2: Manifold and line pressure regulators (ISO 10524-2:2005)*

[25] EN ISO 10524-4:2008, *Pressure regulators for use with medical gases — Part 4: Low-pressure regulators (ISO 10524-4:2008)*

[26] EN ISO 11197:2009, *Medical supply units (ISO 11197:2004)*

[27] EN ISO 19054:2006, *Rail systems for supporting medical equipment (ISO 19054:2005)*

[28] EN ISO 80601-2 (all subparts), *Medical electrical equipment (ISO 80601-2, all subparts)*

[29] ISO 7637-1:2002, *Road vehicles — Electrical disturbances from conduction and coupling — Part 1: Definitions and general considerations*

[30] ISO 7637-2:2011, *Road vehicles — Electrical disturbances from conduction and coupling — Part 2: Electrical transient conduction along supply lines only*

[31] Council Directive 86/188/EEC of 12 May 1986 on the protection of workers from the risks related to exposure to noise at work

[32] Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work

[33] Council Directive 90/269/EEC of 29 May 1990 on the minimum health and safety requirements for the manual handling of loads where there is a risk particularly of back injury to workers (fourth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC)

[34] Council Directive 93/42/EEC of 14 June 1993 covering medical devices [see Annex ZA]

[35] Directive 95/28/EC of the European Parliament and of the Council of 24 October 1995 relating to the burning behaviour of materials used in the interior construction of certain categories of motor vehicle

[36] U.S. Military standards, MIL-DTL-26482: Connectors, Electrical, (Circular, Miniature, Quick Disconnect, Environment Resisting), Receptacles and Plugs, General Specification For (publication available at IHS offices)

[37] U.S. Military standards, MIL-STD-461B, Electromagnetic Emission and Susceptibility Requirements for the Control of Electromagnetic Interference

[38] U.S. Military standards, MIL-STD-461C, Control of Electromagnetic Interference

[39] U.S. Military standards, MIL-STD-704B, Aircraft Power Limits

[40] U.S. Military standards, MIL-STD-810C. Environmental Test Methods

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[42] COMMISSION REGULATION (EU) No 1178/2011 of 3 November 2011 laying down technical requirements and administrative procedures related to civil aviation aircrew pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council

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