BS EN 13718-2:2015

BSI Standards Publication

Medical vehicles and their equipment — Air ambulances

Part 2: Operational and technical requirements for air ambulances

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National foreword

This British Standard is the UK implementation of EN 13718-2:2015. It supersedes BS EN 13718-2:2008 which is withdrawn.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.

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Medical vehicles and their equipment - Air ambulances - Part 2: Operational and technical requirements for air ambulances

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Medizinische Fahrzeuge und ihre Ausrüstung - Luftfahrzeuge zum Patiententransport - Teil 2: Operationelle und technische Anforderungen an Luftfahrzeuge zum Patiententransport

This European Standard was approved by CEN on 26 December 2014.

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Foreword

This document (EN 13718-2:2015) 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of an identical text or by endorsement, at the latest by September 2015, and conflicting national standards shall be withdrawn at the latest by September 2015.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 13718-2:2008.

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

EN 13718-2:2008 has been technically revised. The following points represent the most important changes in the revision:

a) clarified unclear issues in this part of the standard and between the two parts of the standard (for example requirements for patient's compartment illumination);

b) changed text related to enhancing safety related to the risk from rotors on helicopters;

c) clarified the requirements for the patient compartment;

d) the standard has been 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 ambulance:*

— *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 provides requirements for air ambulances, and in particular covers requirements for the ambulance role of the aircraft.

Air ambulances are equipped with medical devices as well as drugs and rescue equipment to be used by medical personnel. Requirements for medical devices intended for use in air ambulances are provided in EN 13718-1. This standard is supplementary to several European Standards as well as laws and regulations providing the requirements for aircraft in order to provide continuous patient care and monitoring during transport in and between various ambulance types and hospitals. The requirements cover ambulance flights in general. Several national and regional rules and regulations apply to aircraft being used as ambulances. This part of EN 13718 gives information on these in the annexes and in notes throughout the text. Provisions for the safety and care both of the patient as well as of the crew and the medical personnel are contained in existing national and international laws, regulations and guidelines.

This part of EN 13718 provides some general requirements for the safe operation of aircraft being used as ambulances. These requirements are not covered by the scope of the Medical Devices Directive or by international agreements for craft, transportation and traffic. They are provided in order to secure the safe and secure handling of patients. In order to accommodate continuity of patient care between different kinds of ambulances, some specific requirements are given. Requirements are set in order to secure safe use and handling of medical devices.

Aircraft being used as ambulances are equipped with medical devices, medicinal products and rescue equipment to enable the medical personnel to provide continuous patient care. The minima for the medical devices are specified in Annex A. The requirements set out in this part of EN 13718 give the minimum provisions for an ambulance service to provide satisfactory care and medical attention to emergency patients as well as other patients during transportation. The requirements are based on the state of the art of today and common practice in Europe.

This European Standard 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 linked with the Medical Devices Directive (see Annex ZA and Bibliography [1]).

This European 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 ambulances. The requirements set are carefully selected to ensure interoperability and continuous patient care.

Medical devices need to conform to the applicable essential requirements in the Medical Devices Directive, 93/42/EEC. The essential requirements are listed in Annex I of the Medical Devices Directive. Annex ZA in this European Standard lists the essential requirements that are covered 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 part of EN 13718 specifies the requirements for performance and equipping for air ambulances, including requirements for interfaces to medical devices used for the transport and treatment of sick or injured persons. This part of EN 13718 is applicable to air ambulances capable of transporting at least one person on a stretcher.

NOTE Requirements are specified for categories of air ambulances based on the different intended use. These are the helicopter emergency medical service (HEMS) the helicopter intensive care medical service (HICAMS) and the fixed wing air ambulance (FWAA).

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 3-7:2004+A1:2007, *Portable fire extinguishers — Part 7: Characteristics, performance requirements and test methods*

EN 3-8:2006, *Portable fire extinguishers — Part 8: Additional requirements to EN 3-7 for the construction, resistance to pressure and mechanical tests for extinguishers with a maximum allowable pressure equal to or lower than 30 bar*

EN 3-9:2006, *Portable fire extinguishers — Part 9: Additional requirements to EN 3-7 for pressure resistance of CO2 extinguishers*

EN 3-10:2009, *Portable fire extinguishers — Part 10: Provisions for evaluating the conformity of a portable fire extinguisher to EN 3-7*

EN 143:2000, *Respiratory protective devices — Particle filters — Requirements, testing, marking*

EN 374-1:2003, *Protective gloves against chemicals and micro-organisms — Part 1: Terminology and performance requirements*

EN 455-1:2000, *Medical gloves for single use — Part 1: Requirements and testing for freedom from holes*

EN 455-2:2009+A2:2013, *Medical gloves for single use — Part 2: Requirements and testing for physical properties*

EN 455-3:2006, *Medical gloves for single use — Part 3: Requirements and testing for biological evaluation*

EN 794-3:1998+A2:2009, *Lung ventilators — Part 3: Particular requirements for emergency and transport ventilators*

EN 1618:1997, *Catheters other than intravascular catheters — Test methods for common properties*

EN 1707:1996, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Lock fittings*

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

EN 13718-1:2014, *Medical vehicles and their equipment — Air ambulances — Part 1: Requirements for medical devices used in air ambulances*

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

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

EN 14605:2005+A1:2009, *Protective clothing against liquid chemicals — Performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only (Types PB [3] and PB [4])*

EN 20594-1:1993, *Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements (ISO 594-1:1986)*

EN 60601-2-4:2011, *Medical electrical equipment — Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators (IEC 60601-2-4:2010)*

EN 60601-2-12:2006, *Medical electrical equipment — Part 2-12: Particular requirements for the safety of lung ventilators — Critical care ventilators (IEC 60601-2-12:2001)*

EN 60601-2-24:1998, *Medical electrical equipment — Part 2-24: Particular requirements for the safety of infusion pumps and controllers (IEC 60601-2-24:1998)*

EN 60601-2-34:2014, *Medical electrical equipment — Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment (IEC 60601-2-34:2014)*

EN 80601-2-30:2010, *Medical electrical equipment — Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers (IEC 80601-2-30:2009)*

EN ISO 5356-1:2004, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets (ISO 5356-1:2004)*

EN ISO 5359:2014, *Anaesthetic and respiratory equipment — Low-pressure hose assemblies for use with medical gases (ISO 5359:2014)*

EN ISO 5361:2012, *Anaesthetic and respiratory equipment — Tracheal tubes and connectors (ISO 5361:2012)*

EN ISO 5364:2011, *Anaesthetic and respiratory equipment — Oropharyngeal airways (ISO 5364:2008)*

EN ISO 5366-1:2009, *Anaesthetic and respiratory equipment — Tracheostomy tubes — Part 1: Tubes and connectors for use in adults (ISO 5366-1:2000)*

EN ISO 5367:2014, *Anaesthetic and respiratory equipment — Breathing sets and connectors (ISO 5367:2014)*

EN ISO 6009:1994, *Hypodermic needles for single use — Colour coding for identification (ISO 6009:1992)*

EN ISO 7376:2009, *Anaesthetic and respiratory equipment — Laryngoscopes for tracheal intubation (ISO 7376:2009)*

EN ISO 7396-1:2007, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum (ISO 7396-1:2007)*

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

EN ISO 7864:1995, *Sterile hypodermic needles for single use (ISO 7864:1993)*

EN ISO 7886-1:1997, *Sterile hypodermic syringes for single use — Part 1: Syringes for manual use (ISO 7886-1:1993, including Technical Corrigendum 1:1995)*

EN ISO 7886-2:1997, *Sterile hypodermic syringes for single use — Part 2: Syringes for use with power-driven syringe pumps (ISO 7886-2:1996)*

EN ISO 8537:2008, *Sterile single-use syringes, with or without needle, for insulin (ISO 8537:2007)*

EN ISO 9170-1:2008, *Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases and vacuum (ISO 9170-1:2008)*

EN ISO 9360-1:2009, *Anaesthetic and respiratory equipment — Heat and moisture exchangers (HMEs) for humidifying respired gases in humans — Part 1: HMEs for use with minimum tidal volumes of 250 ml (ISO 9360-1:2000)*

EN ISO 10079-1:2009, *Medical suction equipment — Part 1: Electrically powered suction equipment — Safety requirements (ISO 10079-1:1999)*

EN ISO 10079-2:2014, *Medical suction equipment — Part 2: Manually powered suction equipment (ISO 10079-2:2014)*

EN ISO 10079-3:2014, *Medical suction equipment — Part 3: Suction equipment powered from a vacuum or positive pressure gas source (ISO 10079-3:2014)*

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

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

EN ISO 10555-1:2013, *Intravascular catheters — Sterile and single-use catheters — Part 1: General requirements (ISO 10555-1:2013, Corrected version 2014-01-15)*

EN ISO 10555-3:2013, *Intravascular catheters — Sterile and single-use catheters — Part 3: Central venous catheters (ISO 10555-3:2013)*

EN ISO 10555-5:2013, *Intravascular catheters — Sterile and single-use catheters — Part 5: Over-needle peripheral catheters (ISO 10555-5:2013)*

EN ISO 11070:2014, *Sterile single-use intravascular introducers, dilators and guidewires (ISO 11070:2014)*

EN ISO 13688:2013, *Protective clothing — General requirements (ISO 13688:2013)*

EN ISO 15002:2008, *Flow-metering devices for connection to terminal units of medical gas pipeline systems (ISO 15002:2008)*

EN ISO 18777:2009, *Transportable liquid oxygen systems for medical use — Particular requirements (ISO 18777:2005)*

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

EN ISO 23328-1:2008, *Breathing system filters for anaesthetic and respiratory use — Part 1: Salt test method to assess filtration performance (ISO 23328-1:2003)*

EN ISO 23328-2:2009, *Breathing system filters for anaesthetic and respiratory use — Part 2: Non-filtration aspects (ISO 23328-2:2002)*

EN ISO 80601-2-55:2011, *Medical electrical equipment — Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors (ISO 80601-2-55:2011)*

EN ISO 80601-2-56:2012, *Medical electrical equipment — Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement (ISO 80601-2-56:2009)*

EN ISO 80601-2-61:2011, *Medical electrical equipment — Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment (ISO 80601-2-61:2011)*

EN ISO 81060-1:2012, *Non-invasive sphygmomanometers — Part 1: Requirements and test methods for non-automated measurement type (ISO 81060-1:2007)*

EN ISO 81060-2:2014, *Non-invasive sphygmomanometers — Part 2: Clinical investigation of automated measurement type (ISO 81060-2:2013)*

IEC 60601-1-12:2014, *Medical electrical equipment — Part 1-12: General requirements for basic safety and essential performance — Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment*

European Aviation Safety Agency (EASA) Certification Specifications CS-23, *Normal, Utility, Aerobatic, and Commuter Category Aeroplanes*

European Aviation Safety Agency (EASA) Certification Specifications CS-25, *Large Aeroplanes*

European Aviation Safety Agency (EASA) Certification Specifications CS-27, *Small Rotorcraft*

European Aviation Safety Agency (EASA) Certification Specifications CS-29, *Large Rotorcraft*

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 medically trained personnel equipped and intended for the transportation of at least one stretcher patient who will receive medical treatment during transport

3.2
fixed wing air ambulance
FWAA
aircraft especially equipped for transportation, medical treatment and care of patients, including patients requiring intensive care treatment

3.3
flight crew
members of the crew intended to operate the aircraft

Note 1 to entry: See Commission Regulation (EU) No 1178/2011.

3.4
helicopter emergency medical service
HEMS
flight by a helicopter, the purpose of which is to facilitate emergency medical assistance, where immediate and rapid transportation is essential, by carrying:

— medical personnel;

— medical supplies (equipment, blood, organs, drugs);

— ill or injured persons and other persons directly involved

3.5
helicopter intensive care medical service
HICAMS
flight by a helicopter, especially staffed and equipped for the transportation, medical treatment and care of patients requiring intensive care treatment, mainly in inter-hospital transfers

3.6
interchangeability
facility to transfer patients between scenes of emergencies, ambulances and hospitals as well as between hospitals, including transport between countries, providing continuous patient care, treatment and monitoring

3.7
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

[SOURCE EN 13976-1:2011, definition 3.1]

3.8
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

3.9
medical crew
qualified members of the crew intended to provide patient care

3.10
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

3.11
patient compartment
defined space which provides the possibility to install and transport one or more patient(s), a medical crew, medical devices, systems and installations which are required during flight to properly treat and care for the patient

3.12
patient treatment area
area located within the patient compartment which is required to carry a patient on a stretcher as well as the area in the vicinity to the stretcher enabling the medical crew to properly care and treat a patient

4 General requirements for air ambulances

4.1 General

Air ambulances shall be designed to enable fast and safe access of medical personnel to people in need of medical attention at sites outside of hospitals, to and between hospitals.

Intensive care patients transportation requires specially trained personnel.

Air ambulances shall be designed to accommodate the personnel, creating the safe and healthy working environment. Air ambulances shall allow treatment for at least one stretcher patient.

Air ambulances shall be equipped with medical devices in accordance with Annex A and other life supporting equipment in accordance with Annex B, in order to provide continuous patient care. Equipment and systems shall be selected and designed to enable interchangeability and interoperability (see 3.6 and 3.8, respectively).

The installation of medical devices and equipment shall be in accordance with the applicable airworthiness requirements (EASA CS-23, CS-25, CS-27, CS-29).

4.2 Environmental conditions in the patient compartment

4.2.1 Temperature and humidity

A heating system shall be provided capable of raising the temperature in the patient compartment from 0 °C to + 18 °C in less than 30 min when the outside air temperature is 0 °C.

There should be an auxiliary system to heat/cool the patient compartment when stationary.

Normal ambient humidity conditions for patient treatment should be aimed at.

4.2.2 Air conditioning system (ACS)

In some regions of Europe, the outside air temperature can be extremely high.

For helicopters operating in those areas where the maximum external reference temperature was above 35 °C for more than 15 days per year, during at least the past 10 years, the helicopter shall be equipped with an Air Conditioning System.

NOTE The maximum external reference temperature is the maximum temperature determined for that area by the relevant National Weather Institution, based on the previous 10 years record available.

According to the mission and medical operation requirements, the ACS shall be capable of maintaining the working environment, for the crew and for the patient, at an acceptable temperature level.

4.2.3 Variable atmospheric pressure

Air ambulances which operate regularly at flight altitude above 15 000 feet shall have a pressurized cabin system. The operating pressure in the patient compartment above 15 000 feet shall be equivalent to the operating pressure at 3 500 feet.

4.2.4 Interior light

Lighting shall be provided in accordance with Table 1.

Table 1 — Patient's compartment illumination

Type	Illuminance (minimum)	Spot light
Stretcher area	300 lx	400 lx
Patient compartment	50 lx	

The spot light shall provide an illuminated area with a diameter of at least 200 mm.

NOTE The colour temperature of the light will change the appearance of skin and organs. Therefore, it is important that the interior lighting is suitable for patient care during transport. It is believed that it is not necessary in ambulance use to define "daylight" or "natural colour balance" in a more exact way other than the colour temperature. Regarding the colour temperature a comparison can be that examining lights in hospitals are normally between 3 800 K and 4 300 K.

4.2.5 Ventilation

Means shall be provided for the patient compartment to be ventilated. Ventilation systems shall be designed to prevent draught to the patient(s) and crew.

4.2.6 Noise exposure

If noise exposure to the patient compartment during transport exceeds 85 dB (A), protection to both patient(s) and personnel shall be established and available.

NOTE 1 Patients, in particular children, can need specially designed protection.

NOTE 2 Specific requirements for sound protection in a working environment exist in some countries or regions.

Sound protection shall allow communication between the medical personnel, the pilot and the patient(s) when experiencing ambient noise conditions greater than 85 dB (A).

4.3 Requirements for electrical power supply for medical devices in the patient compartment

A minimum of four separately protected 12 V DC outlets shall be available. Optionally one additional outlet may be supplied by a separate battery, dedicated to medical devices. The outlets shall be available for medical equipment and located in the area of storage and/or use of the medical device.

The nominal voltage shall be 13,8 V.

The voltage shall be between 12,4 V and 15,1 V (see EN 13718-1:2014, 4.5.2, and IEC 60601-1-12:2014).

The outlets shall have as a minimum the capacity of delivering: 1 each 14 A and 3 each 7 A.

NOTE 1 Not simultaneously.

The total available current shall be at least 25 A.

The power supply shall continuously supply medical devices with electrical power with engines running.

The outlets for the medical devices shall be labelled with the nominal voltage and current rating.

Outlets should have a visible indication under intended operational conditions in order to show if the power is switched on.

If 24 VDC is available for use with medical devices, the nominal voltage should be 27,5 V. At least one outlet shall be rated 10 A.

Electrical outlets for medical devices shall be female and have means for locking the connectors to the outlets.

If AC power is provided by an inverter and available for use with medical devices, the voltage supplied by the inverter shall comply with the range required in EN 13718-1:2014, 4.5.4. The inverter shall have the capacity to deliver at least 1500 W. The inverter is to be considered as an accessory to the medical devices.

Any AC inverter shall be connected to the airframe ground with two independent connections. The touch current between the inverter and any part of the airframe ground in the patient compartment shall be less than 100 uA at no fault condition.

NOTE 2 Further information of safe installation of AC inverters can be found in EN 60601–1:2006, Clause 16; ME systems.

Connectors shall be designed to prevent short-circuiting under the environmental conditions prevailing in the air ambulances.

Connectors conforming to MIL-DTL-26482 may be used (see EN 13718–1).

The aircraft shall, when parked on ground, be provided with an external single-point-connection to enable charging of batteries in electro medical devices which are connected to 12 VDC outlets.

When the aircraft is connected to AC mains on the ground means should be provided to prevent earth leakage currents.

4.4 Electromagnetic interference

Electromagnetic disturbances caused by the aircraft shall not influence the safe operation of the medical device and vice versa.

Medical devices intended for use in air ambulances should conform to ISO 7137.

4.5 Rail systems

If rail systems are used, they shall be in accordance with the applicable airworthiness requirements (EASA CS-23, CS-25, CS-27, CS-29).

If rail clamps are used they shall conform to EN ISO 19054:2006 with additional fixation requirements in accordance with the applicable airworthiness requirements (EASA CS-23, CS-25, CS-27, CS-29).

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

NOTE A typical rail system consists of for example rail supports, rail, rail clamps, equipment mount holders, equipment mounts and equipment pin holders and equipment mount pins.

4.6 Mechanical vibration

Mechanical vibration shall be kept to a minimum in all phases of the flight.

NOTE Vibration-absorbing devices can prove useful both for patient(s) and personnel. Requirements can be found in ISO 2631-1.

4.7 Requirements for fixation of medical devices

All medical devices shall be either fitted to or stowed in the aircraft securely.

A location in the aircraft shall be specified for the stowage and efficient use of medical devices. Essential medical devices for the management of vital functions, including airway management and ventilation shall be in reach of the medical personnel while seated. Medical devices required for use outside the aircraft shall be easily accessible. All medical devices shall be securely and safely stowed.

4.8 Restraint systems in the patient compartment

During transport, a certified restraint system shall be available to secure the patient(s) and personnel, as well as the medical devices and other equipment.

Requirements for fixing and restraint systems according to the type of aircraft shall apply.

Requirements for medical devices that are brought into an aircraft should follow the minimum requirements for the stowage of baggage and cargo.

4.9 Patient compartment

4.9.1 General

The patient compartment shall provide at least:

— two seats (for the medical personnel allowing direct access to the stretcher patient);

— one stretcher.

If more than one stretcher patient is being carried, the following rules shall be applied:

a) HEMS: It shall be possible to provide adequate treatment to all patients transported.

b) FWAA: During transport of more than one patient, the minimum available space between patients shall be 400 mm. Placing patients side by side in the compartment is allowed provided that the minimum space between the patients is maintained.

The patient compartment including the aircraft storage areas, shall be designed and constructed to accommodate the devices listed in Annex A and Annex B.

The medical device and its position in the patient compartment shall allow free access and interaction by medical personnel in a treatment, monitoring and care situation. The positioning of medical devices shall allow the operation of the devices without obstructing aisles, emergency exits or patient loading and unloading sites.

If classified drugs are to be stored on board, a fixed lockable container shall be available. Means shall be provided for keeping temperature sensitive drugs cool.

The interior of the patient compartment shall be designed to minimize the risk of injury. Drawers shall be secured to prevent self-opening. The edges of surfaces shall be designed and/or sealed in such a way that no fluid can infiltrate.

Open shelves should be constructed with rounded edges and made from energy absorbent material.

The floor shall be sealed to the structure of the aircraft and designed to allow fluids to drain. Floor coverings, also when wet, shall provide adequate grip for the attendant and shall be durable and easy to clean and disinfect.

4.9.2 Hygienic

The ceiling, the interior walls and the doors of the patient compartment shall be fully lined with hygienic surfaces and to provide insulation. Disinfection of the patient compartment shall be possible and easy to perform.

4.9.3 Patient loading and unloading

The safe loading and unloading of patients shall be possible under all operational conditions.

Provisions should be provided to support safe loading/unloading of the patient on the stretcher to ensure a maximal ergonomic loading.

Loading/unloading should be possible in horizontal and upright position of the patient. This is especially important in FWAA.

There shall be a sufficient space from the top of the stretcher mattress to the top of the door opening where the patient is loaded to avoid implications to the patient.

Transfer of patients shall be undertaken using one or more of the medical devices listed in Table A.1.

NOTE For information about stretchers, see EN 1865–1.

4.9.4 Communication systems

Air ambulances shall be equipped with a communication system accessible to medical personnel.

NOTE Attention is drawn to national and/or regional legislation regarding communication systems.

4.9.5 Fire safety requirements

Interior materials shall meet the flammability requirements according to EASA CS-23, CS-25, CS-27 and CS-29.

NOTE Fire safety requirements are defined in EASA OPS – Part-CAT.

4.9.6 Emergency exit

The aircraft shall have emergency exit(s).

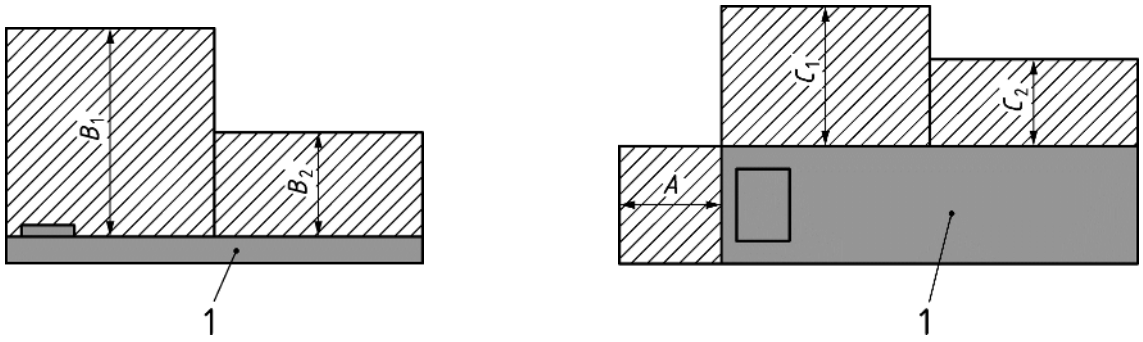
4.10 Patient treatment area

4.10.1 General

The patient treatment area shall enable free access to the vital body parts of the patient or patients e.g. including the head, chest, abdomen and pelvis, in order to ensure adequate treatment, monitoring and care. Cardiopulmonary resuscitation, airway treatment and elevation of the upper body and/or legs of the patient should be possible during the flight

4.10.2 Dimensions

The patient treatment area dimensions, functionalities and shape are defined in Figures 1 and 2 and in Tables 2 and 3. Alternative layouts and minimum dimensions of the patient treatment area are possible when they provide for an equivalent performance level as detailed in 4.10.1.



a) Patient treatment area **b) Patient treatment area top view**

Key

1 stretcher

A space in the longitudinal head end of the stretcher

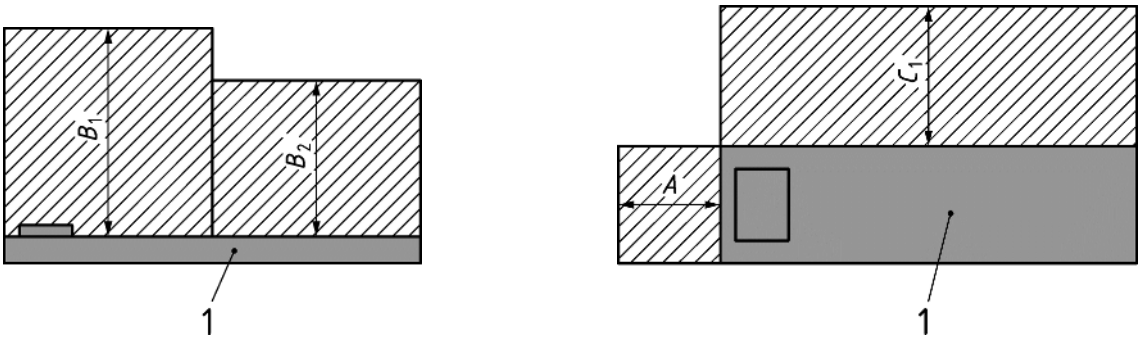
B_1 space from the top of the stretcher to the ceiling

B_2 space from the top of the stretcher to the ceiling

C_1 space on the side of the stretcher which the treatment is given

C_2 space, on same side as C_1 of the stretcher

Figure 1 — HEMS configuration



a) Patient treatment area **b) Patient treatment area top view**

Key

1 stretcher

A space in the longitudinal head end of the stretcher

B_1 space from the top of the stretcher to the ceiling

B_2 space from the top of the stretcher to the ceiling

C_1 space on the side of the stretcher which the treatment is given

Figure 2 — HICAMS/FWAA configuration

Table 2 — Patient treatment area — Minimum dimensions

Dimensions in millimetres

Key	HEMS	HICAMS	FWAA
A	400	400	400
B_1	970	970	970
B_2	500	700	700
C_1	600	600	600
C_2	400	-	-

Table 3 — Definitions of the patient treatment area

Key	Dimension (minimum)	Definitions	Functionalities
A	See Table 2	Space in the longitudinal head end of the stretcher maintained across the width of the stretcher.	Airway treatment
B_1	See Table 2	Space from the top of the stretcher to the ceiling. (For HEMS: minimum from the head end of the stretcher to the middle of the stretcher).	CPR
B_2	See Table 2	Space from the top of the stretcher to the ceiling. (maximum from aft end to middle of the stretcher)	Access to lower body part
C_1	See Table 2	Space on the side of the stretcher which the treatment is given (for HEMS: minimum from the head end to the middle of the stretcher). Including seats for medical crew and working space to the stretcher.	General patient care and treatment
C_2	See Table 2	Space, on same side as C_1, of the stretcher (maximum from the end to middle of the stretcher).	Access to lower body part

NOTE 1 For reference of stretcher size, EN 1865–1 states a length of 1 950 mm (+20 mm/ −50 mm).

NOTE 2 For reference of stretcher size, EN 1865–1 states a width of 550 mm (±20 mm).

NOTE 3 To provide a dedicated HICAMS service for the transportation of intensive care patients, additional space above the minimum definition of a HEMS aircraft will be required to accommodate additional equipment and specialized personnel.

4.11 Lists of equipment

Air ambulances shall have medical devices, medicinal products and equipment according to Annex A and Annex B.

NOTE Specific requirements for transport incubator interfaces can be found in EN 13976–2:2011.

5 Air ambulances, operation and performance requirements

5.1 Personnel

5.1.1 Flight crew

The roles and responsibilities of flight crew members are outlined in the regulations EASA OPS – Part-CAT, EASA OPS – Part SPA and EASA Air Crew – Part-FCL.

Flight crew should be able to assist the medical personnel.

5.1.2 Medical crew

All medical personnel who deal with a regular work with air ambulance services.

The medical crew normally consists of two persons, one as a specially trained physician medical practitioner. In fixed wing air ambulances the medical crew normally consists of a physician and specially trained nurse or medical practitioner in addition if needed.

NOTE 1 In HEMS operation one crew member has the function as a HEMS crew member (according to EASA OPS – Part-SPA). National regulations allow different specification/medical qualification of the personnel.

NOTE 2 The flight training and duty times of medical personnel are not regulated by aviation authorities.

5.2 Specific requirements for helicopters operated in Helicopter Emergency Medical Service (HEMS)

HEMS helicopters shall meet all the requirements in EASA OPS – Part-SPA.

Helicopters operated in Helicopter Emergency Medical Service (HEMS) shall be able to land on various surfaces including sloping and rough terrain.

Helicopters operated in normal HEMS mission configuration should have minimum endurance of 1,5 h.

Both main and tail rotor systems on helicopters present hazards to flight crew and ground personnel when the rotors are turning. High main and tail-rotor ground clearance provides enhanced safety for EMS teams and bystanders while on the ground. To mitigate the risk of tail rotor hazards during HEMS operations, guarded tail rotor systems should be considered. During HEMS operations into confined areas rotor brake may be used to shut down the rotors after landing.

Operators should establish procedures to minimize possible exposure to the hazards of a rotors running helicopter, and should include as a minimum the following:

— defined crew responsibilities and procedures during all ground operations, coordinated by the aircraft commander;

— air and ground crew guidance and procedures for safe approach paths to a rotors running helicopter, at both unprepared sites and heliports;

— recurrent training of air and ground crews in the established approach and loading procedures during HEMS operations.

NOTE National legislation can apply.

5.3 Specific requirements for Helicopter Intensive Care Medical Service (HICAMS)

HICAMS helicopters shall meet all the requirements in EASA OPS – Part CAT and EASA OPS – Part-SPA.

HICAMS shall be operated within the defined conditions and shall be able to carry and treat one intensive care patient.

The choice of aircraft for air ambulance missions should be based on the capacity of the aircraft to:

a) minimize the time taken for the entire flight;

b) limit the number of ground stops;

c) ensure comfort for patient and crew;

d) convey specially trained personnel for the transport and treatment of intensive care patients.

5.4 Specific requirements for Fixed Wing Air Ambulances (FWAA)

Fixed wing air ambulances shall have more than one engine and a pressurized cabin and shall have the capacity to carry the flight crew and medical crew according to their mission.

Fixed wing air ambulances should have a minimum endurance of three-hour flight time.

The choice of aircraft should be based on the capacity of the aircraft to:

a) minimize the time taken for entire flight;

b) limit the number of ground stops;

c) ensure comfort for patient, crew and escort.

d) the interior noise level shall not exceed 85 dB(A) during cruise flight.

6 Gas installations in air ambulances

6.1 System components

The supply system shall consist of oxygen cylinder or liquid oxygen system.

The following may also be provided:

a) air compressor system;

b) medical air cylinder(s);

c) anaesthetic gas scavenging system;

d) vacuum pump system.

6.2 General requirements

6.2.1 Capacity and pressure operating range

All sections of pipeline distribution systems for compressed medical gases shall withstand a pressure of 1,43 times the maximum pressure which can be applied to that section in single fault condition.

The maximum pressure during single fault condition shall never exceed 1 000 kPa.

The capacity of any supply system shall be determined using risk management principles.

The expected range of transportation distance, the gas consumption and the possibility of exchange of gas cylinders should be considered when determining the capacity.

Air ambulances equipped with a compressed medical gas system using terminal units shall comply with the following requirements:

— the range of operating pressure shall be from 400 kPa to 500 kPa;

— the pressure at any terminal unit shall not be greater than 110 % of the nominal distribution pressure with the system operating at zero flow. The pressure at any terminal unit shall not be less than 90 % of the nominal distribution pressure with the system operating at design flow of 40 l/min at that terminal unit (see EN ISO 7396-1:2007).

6.2.2 Continuity of supply

The supply system shall be designed to achieve continuity of system design flow at a distribution pressure conforming to 6.2.1 to the terminal units in normal condition and single fault condition.

NOTE Loss of electrical power or breakdown of one of the air ambulance engine is a single fault condition.

6.3 Supply systems with gas cylinders

A supply system with gas cylinders shall comprise

a) at least one primary gas cylinder,

b) a reserve gas cylinder.

Means shall be provided to prevent back flow from a full to any empty gas cylinder.

NOTE 1 A non-return valve can be sufficient for this purpose.

A filter having a pore size no greater than 100 µm shall be provided between the cylinder(s) and the first pressure regulator.

NOTE 2 If the regulator is equipped with this filter no extra filter is required.

Mobile and stationary cryogenic vessels and their components shall conform to EN ISO 18777:2009.

Any portion of pipeline within a supply system with non-cryogenic liquid cylinders where non-cryogenic liquid can be entrapped between two isolation valves shall be provided with means to relieve excess pressure arising from the vaporization of entrapped non-cryogenic liquid.

It shall be possible to see the remaining amount of oxygen in the cryogenic cylinder in the patient compartment.

A pressure gauge or a display, displaying the amount in litres may be used for this purpose.

The pilot, co-pilot or crew member shall have the possibility to close the outlet of any cylinder at the site of the cylinder in case of emergency.

6.4 Supply systems for compressed medical air

A supply system for medical air shall be one of the following:

a) supply system with cylinders as specified in 6.3;

b) supply system with air compressors as specified in 6.5.

If medical air or air for driving medical devices is provided for other purposes, such as anaesthetic gas scavenging systems or breathing air for medical personnel, means shall be provided to prevent backflow into the pipeline. The gas flow requirements of these applications shall be considered.

Medical air and air for driving medical equipment shall not be provided for applications such as general workshop use, motor repair workshop use, spray painting, tyre inflation and reservoirs for pressurization of hydraulic fluids, or uses which might impose unforeseen demands, which could prejudice the availability and/or quality of air for normal patient care purposes.

6.5 Supply systems with air compressor

Medical air produced by a supply system with air compressor(s) shall conform to regional or national regulations.

Where such regulations do not exist, medical air shall conform to the following:

a) oxygen concentration: between 20,4 % V/V and 21,4 % V/V;
b) maximum total oil concentration: 0,1 mg/m^3 measured at ambient pressure;
c) maximum carbon monoxide concentration: 5 ml/m^3;
d) maximum carbon dioxide concentration: 500 ml/m^3;
e) maximum water vapour concentration: 67 ml/m^3;
f) maximum sulfur dioxide: 1 ml/m^3;
g) maximum $NO+NO_2$: 2 ml/m^3.

NOTE 1 Oil can be present as liquid, aerosol and vapour.

NOTE 2 These values are taken from the European Pharmacopoeia 7th. Edition 2011 (Ph. Eur. 7.0), Supplement 7.1–7.6.

Medical air supplied by the compressor systems shall be filtered to maintain the particulate contamination below the level provided by Class P3 in EN 143:2000.

Means shall be provided to indicate the status of filter elements, e.g. by measuring the pressure drop across the filter.

NOTE 3 In some countries, national requirements for particulate contamination might apply.

Air for driving surgical tools produced by a compressor system shall conform to the following:

a) maximum total oil concentration: 0,5 mg/m^3 measured at ambient pressure;
b) maximum water vapour concentration: 67 ml/m^3.

NOTE 4 For air for driving medical devices, low water content is required to prevent the formation of water or ice (from cooling due to adiabatic expansion) which might damage equipment.

6.6 Pipeline distribution system

Pipeline distribution system shall be in accordance with the applicable airworthiness requirements (EASA CS-23, CS-25, CS-27, CS-29).

Pressure regulators and regulators with flow metering devices shall conform to EN ISO 10524 series.

Terminal units and probes shall conform to national standards.

The number of terminal units shall be sufficient to serve the medical equipment listed in Annex A.

To reduce the risk of ignition caused by friction of the flow the pipeline shall be dimensioned to make sure that the maximum gas velocity is 25 m/s.

Piping or tubing shall be installed and mounted in a way that prevents deterioration by vibration or mechanical wear.

6.7 Marking and colour coding

Internal pipelines shall be marked with the gas name and/or symbol adjacent to shut-off valves, at junctions and changes of direction, and adjacent to terminal units. All fixed installations shall be in accordance with the applicable airworthiness requirements (Reference EASA CS-23, CS-25, CS-27, CS-29).

NOTE 1 Typical examples of marking methods are metal tags, stencilling, stamping and adhesive markers.

Marking shall:

a) be in accordance with EN ISO 5359:2014,

b) use letters not less than 6 mm high,

c) be applied with the gas name and/or symbol along the longitudinal axis of the pipeline,

d) include arrows denoting direction of flow.

If colour coding is used for pipelines, it shall conform to EN ISO 5359:2014 or regional or national regulations.

NOTE 2 The colours specified in EN ISO 5359:2014 are also used for non-medical applications.

6.8 Alarms

If alarms are provided as part of the gas installation, they shall conform to EN ISO 7396-1:2007, 6.3 to 6.6.

6.9 Testing

6.9.1 General

The following combination of tests and inspections shall be carried out:

a) test for mechanical integrity of compressed gas systems (see 6.9.2);

b) test for leakage on all pipeline systems and for mechanical integrity of vacuum pipeline systems (see 6.9.3 and 6.9.4);

c) inspection of marking and pipeline supports;

d) test for cross connection (see 6.9.5).

Intermittent purging of the pipeline to remove particulate matter is recommended at this stage.

6.9.2 Test for mechanical integrity for compressed medical gas systems

Apply for 5 min a pressure of not less than 1,43 times the maximum pressure which could occur under single fault condition in each section of pipeline distribution system.

Check for the integrity of the pipeline distribution system and its components.

6.9.3 Test for leakage on all pipeline systems and for mechanical integrity of vacuum pipeline systems

The pressure drop during a test period of 2 h to 24 h shall be less than 0,025 % of the initial test pressure per hour. The pressure drop shall be corrected for variations due to temperature according to the ideal gas laws.

The test pressure shall be a minimum of 1,5 times the nominal distribution pressure for compressed medical gas pipelines and 500 kPa for vacuum pipelines.

6.9.4 Leakage from the compressed medical gas pipelines

The leakage from the medical gas pipeline system shall be measured from the whole system or from all portion(s) of the system downstream of each area shut-off valve with the source of test gas disconnected.

When the whole system is tested, the following applies.

— The pressure drop during a test period of 2 h to 24 h shall be less than 0,025 % of the initial test pressure per hour. The pressure drop shall be corrected for variations due to temperature according to the ideal gas laws.

— The test pressure shall be a minimum of 1,5 times the nominal distribution pressure.

6.9.5 Test for cross connection

Means shall be provided to prevent cross connections between pipelines for different gases or vacuum.

6.10 Maintenance

The air ambulance manufacturer shall supply instructions for carrying out preventive maintenance. These instructions shall include at least:

— interval between maintenance;

— description of parts that have to be changed;

— calibration instructions;

— test instructions and protocol for the test.

Annex A
(normative)

Medical devices in air ambulances

A.1 Introduction

Table A.1 to Table A.7 specify the minimum number of medical devices to be available inside the ambulance for the medical personnel in order to provide treatment, monitoring and care of at least one patient. The list has been developed in order to establish common basic and minimum provisions to enable ambulances to provide continuous patient care between different types of ambulances, countries and hospitals. The devices shall be usable for all sizes and ages of patients. “X” in place of number of items/sets indicates that local practices are to be followed.

Table A.1 — Patient transfer devices

Generic device group	Standards	HEMS	HICAMS	FWAA
Main stretcher	-	1	1	1
Undercarriage	EN 1865–1:2010	X	X	X
Vacuum mattress	EN 1865–1:2010	X	1	1
Foldable carrying chair / non-foldable carrying chair / chair stretcher	EN 1865–1:2010	X	X	X
Carrying sheet or transfer mattress	EN 1865–1:2010	1	1	1
Long spinal board [a]	EN 1865–1:2010	X	X	X
Pick up stretcher	EN 1865–1:2010	X	X	X
[a] Long spinal board, with head immobilizer and securing straps.				

Table A.2 — Isolated extremity and upper spinal immobilisation devices

Generic device group	Standards	HEMS	HICAMS	FWAA
Traction device	-	X	X	X
Immobilisation set for fractures	-	1	X	1
Cervical upper spinal immobilisation devices / C-cervical collar-set	-	1	1	1
Extraction upper spinal immobilisation device / extension devices / short spinal board (one of these devices)	-	1	X	X

Table A.3 — Ventilation devices

Generic device group	Standards	HEMS	HICAMS	FWAA
Installed (Stationary) oxygen supply, with a quick-connection	EN ISO 15002:2008 EN ISO 5359:2014 EN ISO 9170-1:2008 EN ISO 7396-1:2007 EN ISO 7396-2:2007 EN ISO 10524-1:2006	2 000 l	3 000 l	3 000 l
Portable oxygen supply, with a quick-connection	EN ISO 9170-1:2008 EN ISO 10524-1:2006	400 l	400 l	400 l
Nebulization device	-	X	1	1
Transport ventilator with controlled and assisted ventilation	EN 794–3:1998+A2:2009	1	1	1
CPAP-systems [a]	-	X	1	1
PEEP-valve [b], adjustable or set	-	1	1	1
Intensive care ventilator	EN 60601–2-12:2006	-	X	X
Stationary suction device [c]	EN ISO 10079-1:2009 EN ISO 10079-3:2014	1	1	1
Portable suction device	EN ISO 10079-2:2014	1	1	1
Intubation devices [d]	EN ISO 7376:2009 EN ISO 5356-1:2004 EN ISO 5367:2014	1	1	1
Endotracheal tubes with connectors	EN ISO 5366-1:2009 EN ISO 5361:2012	1	1	1
Oropharyngeal airways	EN ISO 5364:2011	1	1	1
HME-filter	EN ISO 23328-1:2008 EN ISO 23328-2:2009 EN ISO 9360-1:2009	1	1	1
Tracheostomy kit [e]	-	1	1	1
Tube fixing materials	-	1	1	1

a Continuous Positive Airway Pressure.

b Positive End Expiratory Pressure.

c Stationary non-manual suction device with a minimum negative pressure of 40 kPa, with a collection container with a minimum capacity of 1 l, can be portable.

d Intubation devices to include laryngoscope handle(s) with suitable blades.

e Insertion stylets, inflation tube clamp, inflation syringe, Magill forceps etc.

Table A.4 — Medical devices for diagnosis and monitoring

Generic device group	Standards	HEMS	HICAMS	FWAA
Invasive BP monitor	EN 60601-2-34:2014	X	1	1
Non-invasive BP Monitor	EN ISO 81060-1:2012 EN ISO 81060-2:2014 EN 80601-2-30:2010	1	1	1
Pulse oximeter	EN ISO 80601-2-61:2011	1	1	1
Capnometer	EN ISO 80601-2-55:2011	1	1	1
Stethoscope	-	1	1	1
Thermometer, min. range 15 °C to 42 °C	EN ISO 80601-2-56:2012	1	1	1
Diagnostic light	-	1	1	1
Glucometer	-	1	1	1

Table A.5 — Devices for injection and infusion

Generic device group	Standards	HEMS	HICAMS	FWAA
Devices for injections and infusions [a]	EN 1707:1996 EN 20594–1:1993 EN ISO 7886-1:1997, EN ISO 7886-2:1997 EN ISO 7864:1995 EN ISO 10555-1:2013, EN ISO 10555-3:2013, EN ISO 10555-5:2013 EN ISO 6009:1994 EN ISO 8537:2008 EN ISO 11070:2014	1	1	1
Infusion container temperature regulated [b] Not required to be portable	-	1	1	1
Volumetric infusion device (syringe pump)	EN 60601–2-24:1998	2	2	2
Automatic infusion device w/ volumetric properties	-	X	X	X
Pressure infusion device	-	1	1	1

[a] Selection according to local practice.

[b] The device shall permit the administration of infusion fluids with a temperature of 37 °C ± 2 °C.

Table A.6 — Devices for managing life-threatening problems

Generic device group	Standards	HEMS	HICAMS	FWAA
Defibrillator with rhythm display, recording and documentation of patient data	EN 60601–2-4:2011	1	1	1
External pacing facility	-	X	1	1
Portable Advanced Resuscitation System (P.A.R.S.): Contents of Manual resuscitators, Airways, Aspirator, and Suction catheter and Parts of A.6.	-	1	1	1
Thorax drainage kit	-	1	1	1
Central venous catheters	-	1	1	1

Table A.7 — Bandaging and nursing devices

Generic device group	Standards	HEMS	HICAMS	FWAA
Wound treatment materials	-	1	1	1
Treatment materials for wounds caused by burns and corrosives	-	1	1	1
Adhesive fixing materials	-	1	1	1
Replantation bag with outer cover to keep the temperature at 4 °C ± 2 °C for at least 6 h	-	X	X	X
Kidney bowl	-	2	2	2
Gastric tube with accessories	EN 1618:1997	1	1	1
Sterile surgical gloves, pairs	EN 455–1:2000 EN 455–2:2009+A2:2013 EN 455–3:2006	5	5	5
Emergency delivery set	-	X	X	X
Small surgical kit [a]	-	1	1	1
Skin cleaning and disinfection material	[b]	1	1	1

[a] e.g. scalpels, suture holder, forceps, scissors, clamps according to local needs.

[b] e.g. standards from CEN/TC 216 “Chemical disinfectants and antiseptics”

A.2 Additional equipment

Provision for the transportation of incubators shall be in accordance with EN 13976-1:2011 and EN 13976-2:2011.

Annex B
(normative)

Medicinal products and equipment additional to medical devices in air ambulances

B.1 Introduction

Table B.1 to Table B.3 specify the minima for equipment not defined as medical devices according to the Medical Devices Directive. The tables list the equipment and drugs, for use by the medical personnel in order to provide treatment, monitoring and care of at least one patient. The lists have been developed in order to establish common basic and minimum provisions to enable the provisions of continuous patient care between different types of ambulances, countries and hospitals. The requirements shall be adapted to all sizes and ages of patients. “X” in place of number of items/sets indicates that local practices are to be followed.

Table B.1 — Medicinal products (drugs)

Groups according to the ATCC system [a]	HEMS	HICAMS	FWAA
General anaesthetic	1	1	1
Local analgesics (N 01 B) and general analgesics (N 02)	X	X	X
Infusion solutions (B 05 B B), litres	X	X	X
Resuscitation drugs	X	X	X
[a] Anatomical Therapeutic Chemical Classification System for pharmaceuticals.			

Table B.2 — Rescue and protection equipment etc

Type	Standards	HEMS	HICAMS	FWAA
Light rescue tools, set [a]		1	X	X
Seat belt cutter		1	X	X
Warning lights		1	X	X
Fire extinguisher [d]	EN 3–7:2004+A1:2007 EN 3–8:2006 EN 3–9:2006 EN 3–10:2009	X	X	X
Spotlight		1	X	X
Basic protective clothing including helmets and high visibility reflective jacket or Tabard/per crew member	EN ISO 13688:2013	1	X	X
Advanced protection wear [b], given per crew member	EN 14605:2005+A1:2009	1	X	X
Life jacket/per crew member		X	X	X
Safety/debris gloves, pairs per crew member	EN 374–1:2003	1	1	1
Safety/flight helmet [c]		1	X	X
Vomiting bag		2	2	2
Bed-pan		X	X	1
Non-glass urine bottle		X	X	1
Sharps container		1	1	1
Bedding equipment		1	1	1
Blankets		2	2	2
Waste box/bag		1	1	1

[a] Saw, hammer, axe etc. according to local practice.

[b] Additional to basic equipment, e.g. helmets.

[c] Per crew member.

[d] Where applicable, the methods reported in Advisory Circular AC20–42 by Federal Aviation Administration of Unites States of America shall be taken in account for hand fire extinguisher.

Table B.3 — Communication equipment for medical personnel

Type	Standards	HEMS	HICAMS	FWAA
Fixed mobile radio transceiver [a] and / or portable radio transceiver		2	2	2
Portable alerting system/per person. This could be included in the portable radio receiver		1	1	1
Access to the public telephone network e.g. via the normal radio-transmitter or by mobile (cellular) telephone		1	1	1
Internal communication between the medical personnel, the pilots or driver and the patient(s) under conditions of high ambient noise levels, e.g. over 85 dB(A)		1	1	X

[a] Where a fixed mobile radio transceiver is not available, then a minimum of two portable radio transceivers shall be provided.

Annex C
(informative)

A–deviations

A- deviation: National deviation due to regulations, the alteration of which is for the time being outside the competence of the CEN/ CENELEC member.

This European Standard falls under Directive 93/42/EEC on Medical Devices.

NOTE (from CEN-CENELEC IR Part 2:2011, 2.17) Where standards fall under EU Directives, it is the view of the Commission of the European Communities (OJ No C 59; 1982–03–09) that the effect of the decision of the Court of Justice in case 815/79 Cremonini/Vrankovich (European Court Reports 1980, p. 3583) is that compliance with A-deviations is no longer mandatory and that the free movement of products complying with such a standard should not be restricted except under the safeguard procedure provided for in the relevant Directive.

A-deviations in an EFTA-country are valid instead of the relevant provisions of the European Standard in that country until they have been removed.

C.1 Deviation in Germany

C.1.1 Additional specifications for the medical crew

Clause	National Regulation
5.1.2	The medical crew consists of at least one physician and one paramedic. Both shall know the characteristics of air medical services. Both shall also have a special intensive care qualification for intensive care medical service. Members of the medical crew who operate continuously in the air rescue service shall be especially trained according to EASA OPS Part SPA. NOTE The flight crew should be able to support the medical crew.

Annex ZA
(informative)

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

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
4.3, 6.3, 6.4,6.5, 6.6	9.1, first sentence	Covered as far as the gas installation is concerned.
4.7, 6.3, 6.4, 6.9.4	9.2, first indent	To fully cover this ER, the risk of injury from physical features shall be removed or minimised as far as possible.
4.4, 4.7, 6.3, 6.4, 6.9.4	9.2, second indent	To fully cover this ER, the risks from reasonably foreseeable environmental conditions shall be removed or minimised as far as possible. Partly covered for pressure, acceleration and electromagnetic only.
6.6	9.3	To fully cover this ER, risks connected with fire or explosion shall be minimised
4.4	12.5	
6.10	13.6 d)	Maintenance and calibration only.

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

Bibliography

This bibliography provides 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] *Council Directive 93/42/EEC of 14 June 1993 concerning medical devices*, OJ L 169, 12.7.1993, p. 1-43

[2] *Council Directive 70/156/EEC of 6 February 1970 on the approximation of the laws of the Member States relating to the type-approval of motor vehicles and their trailers*, OJ L 42, 23.2.1970, p. 1–15

[3] *Council Directive 70/157/EEC of 6 February 1970 on the approximation of the laws of the Member States relating to the permissible sound level and the exhaust system of motor vehicles*, OJ L 42, 23.2.1970, p. 16–20

[4] *Council Directive 86/188/EEC of 12 May 1986 on the protection of workers from the risks related to exposure to noise at work*, OJ L 137, 24.5.1986, p. 28–34

[5] *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*, OJ L 183, 29.6.1989, p. 1–8

[6] Council Directive 96/98/EC of 20 December 1996 on marine equipment, OJ L 46, 17.2.1997, p. 25–56

[7] Commission Regulation (EC) No 748/2012 of 03/08/2012 laying down implementing rules for the airworthiness and environmental certification of aircraft and related products, parts and appliances, as well as for the certification of design and production organisations, OJ L 224, 21.8.2012, p.1-85

[8] *Commission Regulation (EC) No 859/2008 of 20 August 2008 amending Council Regulation (EEC) No 3922/91 as regards common technical requirements and administrative procedures applicable to commercial transportation by aeroplane – ANNEX III – Common technical requirements and administrative procedures applicable to commercial transportation by aircraft, OPS 1: Commercial air transportation (aeroplanes)*, OJ L 254, 20.9.2008, p. 1–238

[9] *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*, OJ L 311, 25.11.2011, p. 1–193

[10] OPERATIONS F.A. COMMISSION REGULATION (EU) *No 965/2012 of 5 October 2012 laying down technical requirements and administrative procedures related to air operations pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council, Annex IV - PART-CAT (Commercial Air Transport Operations), Annex V - PART-SPA (Specific Approvals)* [1)]

[11] EN 1789:2007+A2:2014, *Medical vehicles and their equipment — Road ambulances*

[12] EN 1865-2:2010+A1:2015, *Patient handling equipment used in road ambulances — Part 2: Power assisted stretcher*

1) referred to as "EASA Air Crew – Part-CAT" and "EASA OPS – Part Spa" in this document, can be received under http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:296:0001:0148:EN:PDF

[13] EN 1865-3:2012+A1:2015, *Patient handling equipment used in road ambulances — Part 3: Heavy duty stretcher*

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

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

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

[17] EN 60601-2-27:2006, *Medical electrical equipment — Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiography monitoring equipment (IEC 60601-2-27:2005)*

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

[20] EN ISO 5356-2:2012, *Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors (ISO 5356-2:2012)*

[21] 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)*

[22] ISO 2631-1:1997, *Mechanical vibration and shock — Evaluation of human exposure to whole-body vibration — Part 1: General requirements*

[23] ISO 3795:1989, *Road vehicles, and tractors and machinery for agriculture and forestry — Determination of burning behaviour of interior materials*

[24] ISO 7137:1995, *Aircraft — Environmental conditions and test procedures for airborne equipment*

[25] 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)

[26] IATA — International Air Traffic Association, Special Provision A67 for batteries (publication available through IHS Nordic, Strandvejen 130, DK-2900 Hellerup)

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