BS EN 13976-2:2011

BSI Standards Publication

Rescue systems — Transportation of incubators

Part 2: System requirements

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National foreword

This British Standard is the UK implementation of EN 13976-2:2011. It supersedes BS EN 13976-2:2003 which is withdrawn.

BSI, as a member of CEN, is obliged to publish BS EN 13976-2 as a British Standard. However, attention is drawn to the fact that the UK committee voted against its approval as a European standard. This negative vote was the result of a new requirement introduced in subclause 4.7 ('EMC') of the final draft, which now states that 'Equipment used during air transportation shall comply with RTCA DO 160.

RTCA DO 160 describes a series of test methods for the environmental testing of avionics hardware. Whereas equipment can be tested in accordance with RTCA DO 160, it does not contain any requirements itself, and therefore it is not possible for manufacturers to comply with RTCA DO 160.

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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English Version

Rescue systems - Transportation of incubators - Part 2: System requirements

Systèmes de sauvetage - Transport d'incubateurs - Partie 2: Exigences relatives au système

Rettungssysteme - Inkubatortransport - Teil 2: Anforderungen an Transportsysteme

This European Standard was approved by CEN on 14 April 2011.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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Foreword

This document (EN 13976-2:2011) 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 November 2011, and conflicting national standards shall be withdrawn at the latest by November 2011.

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 13976-2:2003.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

EN 13976-2:2003 has been technically revised. The following points represent the most important changes in the revision:

1) clarified ambiguous and unclear issues between the two parts (requirements for the transport incubator system interface conditions and system requirements, respectively);

2) proposed items in order to improve fixation, interchangeability and interoperability of the transport incubator system when transported in hospitals and between hospitals using different ambulances and air crafts;

3) adapted the standard to developments in neonatal intensive care;

4) excluded proposals on standards for stretchers, vehicles or medical devices.

EN 13976 consists of the following parts, under the general title: *Rescue systems — Transportation of incubators*:

— *Part 1: Interface conditions*

— *Part 2: System requirements.*

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

Introduction

This European Standard gives the requirements for a transport incubator system that will ensure its interchangeability as well as its safe and effective function in different vehicles or crafts. Such systems are essential in allowing the uninterrupted care of patients. Requirements for interface conditions are given in part 1 (EN 13976-1).

1 Scope

This European Standard specifies the requirements for a transport incubator system needed for care and treatment of infants, used in emergency or planned transport.

It specifies the particular requirements needed to ensure the proper function of equipment during transportation (e.g. monitors, respirators, infusion pumps, extra corporeal lung support- (ECLS-) systems, gas supply) and to provide safe transportation for infants and operators.

This European Standard also stipulates that the equipment or systems shall not interfere with the functions of the ambulance providing transportation.

This European Standard does not give requirements for the vehicles, crafts, devices or incubators as such, these requirements are found in other standards. However, transport incubators are normally combined with other equipment to form a “transport incubator system”.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 1789, *Medical vehicles and their equipment — Road ambulances*

EN 1865 (all parts), *Patient handling equipment used in road ambulances*

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

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

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

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

EN 60601-1-2, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests (IEC 60601-1-2:2007, modified)*

EN 60601-2-20, *Medical electrical equipment — Part 2-20: Particular requirements for basic safety and essential performance of infant transport incubators (IEC 60601-2-20:2009)*

RTCA DO 160, Radio Technical Commission for Aeronautics — Environmental conditions and test procedures for airborne equipment (corresponding to EUROCAE ed-14) [publication available at the RTCA Secretariat, Suite 500, 1425 K Street, N.W. Washington DC, 20005, USA]

RTCA DO 199, Radio Technical Commission for Aeronautics — Potential interference to aircraft electronic equipment from devices carried on board [publication available at the RTCA Secretariat, Suite 500, 1425 K Street, N.W. Washington DC, 20005, USA]

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN 13976-1:2011 apply.

4 General requirements

4.1 System combination

Requirements for interfaces are found in part 1 of this standard (EN 13976-1) and basic requirements for transport incubators are described in EN 60601-2-20.

Any medical device which is part of the transport incubator system shall be designed for use with neonates and infants and for use in transport settings. All of the equipment that is integrated or part of the system shall be tested according to the existing standards relevant to the type of vehicle in which it is to be used. Equipment employed as part of transport incubator system shall be specified by the manufacturer as having an intended use in transportation by road and air ambulances and labelled according to the standard.

NOTE Basic requirements for vehicles used as ambulances and medical devices in these vehicles are described in EN 1789 for road ambulances, in EN 13718-1 and EN 13718-2 for air ambulances and in EN 1865 for stretchers.

4.2 Suspension/noise/comfort (shock-absorption)

Ear defenders for the infants shall be used during all transports. Noise from additional equipment shall not exceed 60 dB(A) as set by EN 60601-2-20.

NOTE Vibration and noise can interfere with the general comfort and well-being of infants. Therefore the vibration to which they are exposed should be as low as possible. The transportation of the baby should be at an appropriate speed to ensure the comfort of the baby. High speeds are rarely necessary.

4.3 Temperature conditions

4.3.1 The transport incubator system shall comply with the relevant requirements of EN 60601-2-20 as a minimum standard with regard to controlling the internal temperature.

4.3.2 Where the transport incubator system is to be used at extremes of temperature, additional test data shall be supplied in the accompanying documents. These should include, where relevant, information about operation during exposure up to + 40 °C for 15 min and –30 °C for 15 min. The effect of wind chill at intermediate temperatures should be considered.

4.4 Ingress of liquids

All equipment forming part of the transport incubator system shall be drip-proof according to EN 60601-2-20.

If the equipment complies with this standard only with an additional accessory or procedure, the manufacturer shall describe in the accompanying documents how to comply with this standard.

4.5 Vibration

All equipment forming part of the transport incubator system shall comply with EN 1789 or EN 13718-1 and EN 13718-2.

4.6 Mechanical integrity

All equipment forming part of the transport incubator system shall comply with EN 60601-1.

EN 60601-2-20 applies for transport incubators.

The free fall test in EN 1789 applies (i.e. 0,75 m) for hand-held equipment.

4.7 EMC

All equipment forming part of the transport incubator system shall comply with EN 60601-1-2 and EN 60601-2-20. Equipment used during air transportation shall comply with RTCA DO 160.

For equipment used for transportation, each user shall carry out mutual compatibility assessments when required to ensure that all medical equipment functions correctly in each mode of transport and with every type of equipment for communication and/or navigation to be used during the transport.

NOTE The manufacturer should include the requirement for mutual compatibility assessments in the instructions for use.

4.8 Mass

The mass of the transport incubator system including its rail parts shall not exceed 140 kg. The requirement for stretchers defined in EN 1865 is 150 kg minimum loading capacity, a margin of 10 kg for the interface is used. The TIS shall be marked with its weight.

NOTE 1 This clause does not apply for cases where the trolley is an integral part of the TIS.

NOTE 2 In all cases the mass should be as low as possible. In cases where the TIS has to be transported in air ambulances more restrictive weight limits may apply.

4.9 Electricity

The transport incubator system shall be capable of operating on 12 V DC, 24 V DC or, 24VDC and 230 V AC/50 Hz power supplies during transport.

The electrical system shall be designed to prevent the vehicle from draining electrical power from the transport incubator system or its interface equipment.

4.10 Fixation of component parts

All component parts of the transport incubator system shall be securely fixed in road ambulances in conformity with EN 1789 and test criteria for the vehicle used or for aircraft as specified by the aviation authorities in accordance with EN 13718-1.

4.11 Modifications

Where a transport incubator system is modified by someone other than the original manufacturer of the transport incubator system, the modifier shall confirm that any additional device is appropriately secured (according to EN 1789, EN 60601-1) and that the fixation of the transport incubator system to the vehicle can still safely carry the extra load (EN 1789 and EN 13718-1 and EN 13718-2).

Annex A
(informative)

Ergonomics

A.1 Space

A.1.1 In all vehicles used for incubator transport e.g. road ambulances, air ambulances, helicopters, the transport incubator system should be placed so that the attending medical staff can monitor and care for the infant, the monitors, and the pumps, and easily perform nursing and medical interventions.

A.1.2 In a road ambulance the incubator should be positioned transversally along the front bulk-head or longitudinally along the side wall to provide a space of at least 450 mm between the seats for attending staff and the incubator. See EN 1789.

A.2 Loading

Arrangements to load the equipment into the ambulance should not compromise EC/national regulations regarding manual handling. The total weight of the medical devices should not affect the stability or operation of the ambulance, or cause the ambulance to exceed its maximum design weight limits.

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 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.

If a transport incubator system is placed on the market as a system or procedure pack then the rules of Article 12 in Directive 93/42/EEC medical device directive would apply.

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

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4.2	12.7.3	
4.4	7.6	Ingress of liquids only

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

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[4] EN 794-1, Lung ventilators — Part 1: Particular requirements for critical care ventilators

[5] EN 794-3, Lung ventilators — Part 3: Particular requirements for emergency and transport ventilators

[6] EN 864, Medical electrical equipment — Capnometers for use with humans – Particular requirements

[7] EN ISO 21647:2004, Medical electrical equipment — Particular requirements for the basic safety and essential performance of respiratory gas monitors (ISO 21647:2004, including Cor 1:2005)

[8] EN ISO 9919:2005, Medical electrical equipment — Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use (ISO 9919:2005)

[9] EN 1060-1, Non-invasive sphygmomanometers — Part 1: General requirements

[10] EN 1060-2, Non-invasive sphygmomanometers — Part 2: Supplementary requirements for mechanical sphygmomanometers

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

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[13] EN 60529, Degrees of protection provided by enclosures (IP code) (IEC 60529:1989)

[14] EN 1615, Enteral feeding catheters and enteral giving sets for single use and their connectors — Design and testing

[15] EN 1617, Sterile drainage catheters and accessory devices for single use

[16] EN 1618, Catheters other than intravascular catheters — Test methods for common properties

[17] EN 1707, Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Lock fittings

[18] EN ISO 8836:2009, Suction catheters for use in the respiratory tract (ISO 8836:2007, corrected version 2008-03-15)

[19] EN 1782, Tracheal tubes and connectors

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

[21] EN 12342, Breathing tubes intended for use with anaesthetic apparatus and ventilators

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[23] EN 60601-2-30, Medical electrical equipment — Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment (IEC 60601-2-30)

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