BS EN 13976-1:2011

BSI Standards Publication

Rescue systems — Transportation of incubators

Part 1: Interface conditions

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National foreword

This British Standard is the UK implementation of EN 13976-1:2011. It supersedes BS EN 13976-1:2003 which is withdrawn.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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Rettungssysteme - Inkubatortransport - Teil 1: Anforderungen an Schnittstellen

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Foreword

This document (EN 13976-1:2011) 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of an identical text or by endorsement, at the latest by November 2011, and conflicting national standards shall be withdrawn at the latest by November 2011.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 13976-1:2003.

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 13976-1:2003 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 the interfaces required in the transport of a transport incubator system. The standard include interfaces between the incubator and the ambulance as well as those between the various items of equipment used to make up the transport incubator system. They are essential in order to ensure interchangeability and a safe and effective function in different vehicles, allowing the uninterrupted care of patients. Requirements for interface conditions are given in this part 1 (EN 13976-1). Requirements for the system are given in part 2 (EN 13976-2).

Fixation, monitoring, supply of gas and electricity are maintained through the use of the same standard interfaces as defined in this document.

1 Scope

This European Standard specifies the requirements for the interface between the ambulance and the incubator and the associated equipment, needed for care and treatment of infants, used in emergency or planned transports to ensure interchangeability and interoperability and to provide uninterrupted care of patients.

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.

ENV 737-6*, Medical gas pipeline systems — Part 6: Dimensions and allocation of probes for terminal units for compressed medical gases and vacuum*

EN 1789, *Medical vehicles and their equipment — 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 60309-1, *Plugs, socket-outlets and couplers for industrial purposes — Part 1: General requirements (IEC 60309-1:1999)*

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

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)*

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

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

MS 33601, *Track and Stud Fitting for Cargo Transport Aircraft, Standard Dimensions for FSC 1560*

3 Terms and definitions

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

3.1
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 ambulance

3.2
transport incubator
enclosure intended to contain a baby, and having transparent section(s) which allow(s) for viewing of the baby, provided with means to control the environment of the baby, primarily by heated air within the enclosure, and suitable for the safe conveyance of a baby

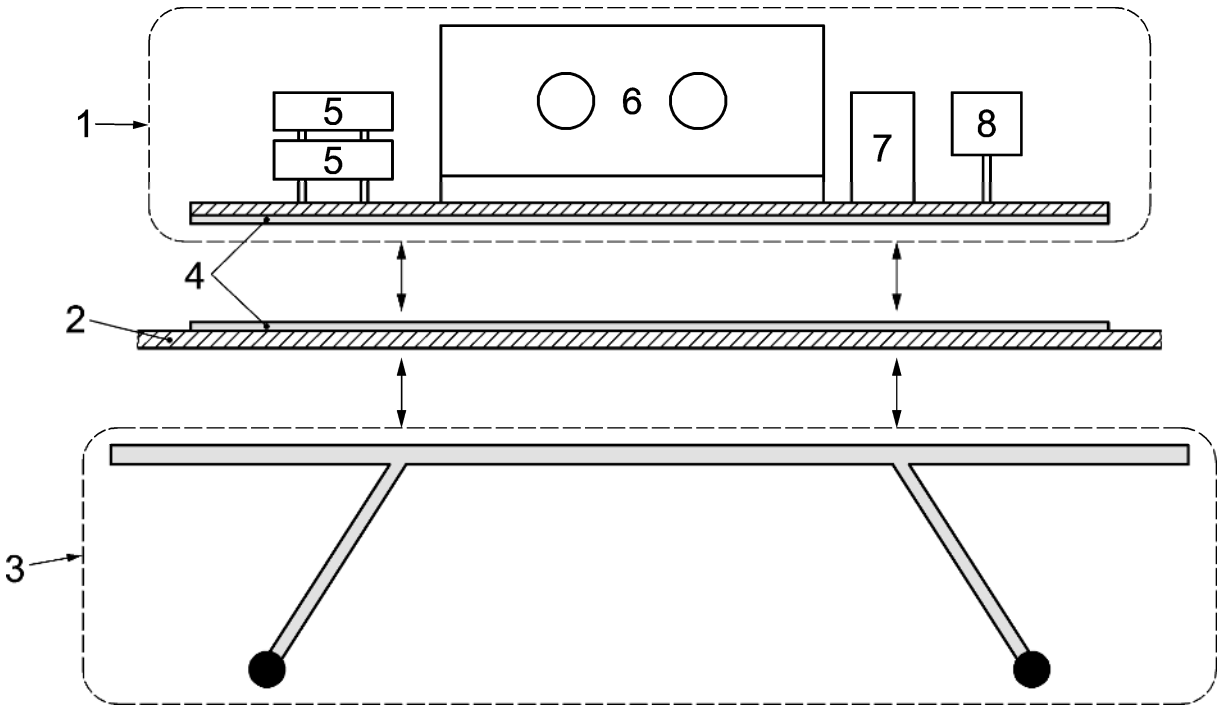
[EN 60601-2-20:2009]

3.3
ambulance
vehicle or craft intended to be crewed by a minimum of two appropriately trained staff for the provision of care and transport of at least one stretchered patient

[EN 1789]

3.4
transport incubator system
TIS
system produced or arranged to serve as a complete unit for the care of an infant during transport

NOTE The system typically includes one or more of the following: an incubator, vital signs monitor, ventilator, device(s) for infusion and suction as well as basic supplies of electricity and medical gas. In some cases a trolley will form an integral part of the TIS.



Key

1 transport incubator system based on a self-containing structure with rails attached underneath as specified in 4.1.1.3

2 interface to be used if rails can not be fixed directly to the stretcher system. If the interface is to be attached to undercarriage, original attachment points on the undercarriage should be used.

3 stretcher system (stretcher/undercarriage/trolley/stretcher support, etc.)

4 rails (grey)

5 syringe pump

6 incubator

7 ventilator

8 monitor

NOTE In some cases a trolley (3) will form an integral part of the transport incubator system (1).

Figure 1 — Transport incubator system with undercarriage fixation

3.5
interoperability
facility to connect various medical devices that are fixed to patients, into relevant connections of associated medical devices including the possibility of connecting powered medical devices to various kinds of ambulances

[EN 13718-2]

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

[EN 13718-2]

4 Requirements

4.1 Interface between transport incubator system and ambulance

4.1.1 Fixation

4.1.1.1 Fixation of the transport incubator system in a road ambulance shall comply with EN 1789 and in air ambulances with EN 13718-1 and EN 13718-2, irrespective of whether the transport incubator system is supported by a stretcher, trolley, frame or other supporting construction.

4.1.1.2 Fixation points to the transport incubator system shall be described by the manufacturer, and marked on each transport incubator system.

4.1.1.3 If there is a requirement for the incubator to be interchangeable between road ambulances and other vehicles or craft then to ensure interoperability and interchangeability, a rail system as specified in MS 33601 (MIL-standard) shall be used.

The mounting points for the rail shall be (400 ± 0,25) mm between centres and minimum 1300 mm length.

This rail system shall be used between the transport incubator system and the stretcher/undercarriage/trolley/stretcher support etc.

4.1.2 Electricity

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

It shall comply with EN 13718-1 regarding DC voltages.

4.1.2.2 The total power consumption of the transport incubator system shall not exceed the specifications in the following table when connected to an external power source.

Table 1 — Electrical power supply

Voltage	Power
230 V AC	1200 W
24 V DC	720 W
12 V DC	360 W

4.1.2.3 Low voltage (12 V/24 V) electrical connectors on the transport incubator system, which are capable of interfacing with the transport vehicle, shall be lockable, enclosed and constructed to prevent them from being incorrectly connected to different voltages. Plugs and connectors shall comply with EN 60309-1 and EN 60309-2.

Coding is required for all accessories having operational voltage not exceeding 50 V. Socket-outlets and connectors for the transport incubator systems shall be coded with their minor key or keyway at the 8 o'clock position. The contact position for 12 V DC is L1 and L2 and the contact position for 24 V DC is L2 and L3. The connectors shall be labelled with the rated voltages. The identification colour for the housing is grey. The 12 V and the 24 V leads shall not be connected at the same time. If an adapter is used, the adapter shall be labelled with the rated maximum rated current.

NOTE An adapter may be used to connect with the electrical supply of the ambulance.

4.1.2.4 The 230 V connector shall comply with national regulations.

NOTE An adapter may be used in cross-border transportation and to connect into the electrical supply of the ambulance. This adapter should also be connected to the earth wiring where applicable.

4.1.3 Gas supply

4.1.3.1 The transport incubator system shall be provided with medical oxygen and medical air for 1 h according to EN 60601-2-20. If a compressor producing medical air substitutes for air cylinders, the European Pharmacopoeia, shall apply. The rated pressure shall be 400 $\pm^{100}_{0}$ kPa with a maximum flow of at least 15 l/min.

4.1.3.2 If Pin-index outlets of cylinder valves are used, they shall comply with EN ISO 407.

4.1.3.3 Connections and fixation for gas supply shall comply with ENV 737-6, EN 1789, EN ISO 9170-1, EN ISO 7396-1 and EN ISO 7396-2.

NOTE An adapter may be used in cross-border transportation and to connect into the gas supply of the ambulance.

Annex A
(informative)

Rationale regarding power use

From experience it is known that transport incubator systems have an increasing need of electrical power for the safe and adequate care of the patient. New medical equipment for the care of patients with more complicated diseases is introduced. Transportations are also more often performed over longer distances. The need for interchangeability is occurring more often.

After discussion the expert group came to the conclusion that a limitation of the electrical power for the transport incubator system is needed.

On one hand there is sufficient power given by the different types of ambulances according to the EN 1789 (700 W for type A and 900 W for type B and 1200 W for type C). However, there are other power-consumers on board which are also important for the care of the patient and for a safe and reliable transportation. Therefore the whole power supply on board can not be used only by the transport incubator system.

On the other hand there are accidents known where power supply of the craft failed because of empty batteries or overheated converters. It is important that this situation is avoided.

Another goal is that the manufacturer of the transport incubator system should be advised to develop future transport incubator system with less power consumption, even when the number of the needed equipment rises.

It is also known that the usage of high currency can result in melted electrical connectors, in hot electrical wires and in switching off (melting) of the fuse. This technical problem commonly occurs due to the use of low DC voltage which is supplied by the ambulances. Therefore the transport incubator system should be able to be supplied by different voltages and the staff should be advised to use the highest voltage.

This was also the reason to require an electrical connector which is able to supply high currency at low voltage.

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.

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
4.1.1, 4.1.2, 4.1.3	9.1	First sentence only
4.1.2.2, 4.1.2.3, 4.1.3.2, 4.1.3.3	12.7.4	

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

Bibliography

[1] 93/42/EEC, Council Directive of 14 June 1993 concerning medical devices, OJ N^{o} L 169, p. 1-43

[2] European Pharmacopoeia, 2010

[3] EN 865, Pulse oximeters — Particular requirements

[4] EN 1865, Specifications for stretchers and other patient handling equipment used in road ambulances

[5] EN 13976-2, Rescue systems - Transportation of incubators - Part 2: System requirements

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

[7] EN 60601-1-1, Medical electrical equipment — Part 1-1: General requirements for safety; Collateral standard: Safety requirements for medical electrical systems (IEC 60601-1-1:2000).

[8] EN ISO 8835-2, Inhalational anaesthesia systems — Part 2: Anaesthetic breathing systems (ISO 8835-2:2007)

[9] EN ISO 8835-3, Inhalational anaesthesia systems — Part 3: Transfer and receiving systems of active anaesthetic gas scavenging systems (ISO 8835-3:2007)

[10] EN ISO 8835-4, Inhalational anaesthesia systems — Part 4: Anaesthetic vapour delivery devices (ISO 8835-4:2004)

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

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