



SLOVENSKI STANDARD

SIST EN 13976-1:2004

01-februar-2004

Reševalni sistemi – Prevoz inkubatorjev – 1. del: Vmesni pogoji

Rescue systems - Transportation of incubators - Part 1: Interface conditions

Rettungssysteme - Inkubatortransport - Teil 1: Anforderungen an Schnittstellen

Systemes de sauvetage - Transport d'incubateurs - Partie 1: Conditions d'interface

Ta slovenski standard je istoveten z: EN 13976-1:2003

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ICS:

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| 11.040.10 | Anestezijska, respiratorna in reanimacijska oprema | Anaesthetic, respiratory and reanimation equipment |
| 11.160 | Účel [{ [| First aid |

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EUROPEAN STANDARD
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EN 13976-1

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English version

**Rescue systems - Transportation of incubators - Part 1:
Interface conditions**

Systèmes de sauvetage - Transport d'incubateurs - Partie
1: Conditions d'interface

Rettungssysteme - Inkubatortransport - Teil 1:
Anforderungen an Schnittstellen

This European Standard was approved by CEN on 3 November 2003.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Management Centre or to any CEN member.

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 Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and United Kingdom.

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Foreword

This document (EN 13976-1:2003) 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 June 2004, and conflicting national standards shall be withdrawn at the latest by June 2004.

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.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and the United Kingdom.

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Introduction

This European Standard gives the requirements for the interfaces required in the transport of an incubator. These include those between the incubator and the vehicle or craft 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 the system are given in part 2 (EN 13976-2).

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

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1 Scope

This European Standard specifies the requirements for the interface between the vehicle or craft and the incubator and the associated equipment, needed for care and treatment of infants, used in emergency or planned transport.

The standard also specifies requirements for the safe transportation using equipment or systems that do not interfere with the functions of the vehicle or craft providing transportation.

This 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

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

EN 737-1, *Medical gas pipeline systems — Part 1: Terminal units for compressed medical gases and vacuum.*

EN 737-2, *Medical gas pipeline systems — Part 2: Anaesthetic gas scavenging disposal systems - Basic requirements.*

EN 737-3, *Medical gas pipeline systems — Part 3: Pipelines for compressed medical gases and vacuum*

EN 737-4, *Medical gas pipeline systems — Part 4: Terminal units for anaesthetic gas scavenging systems.*

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

EN 740 *Anaesthetic workstations and their modules — Particular requirements.*

EN 850, *Transportable gas cylinders — Pin-index, yoke-type valve outlet connections for medical use.*

EN 1789:1999, *Medical vehicles and their equipment — Road ambulances.*

EN 1865, *Specifications for stretchers and other patient handling equipment used in road ambulances.*

EN 13718-1, *Air, water and difficult terrain ambulances — Part 1: Medical device interface requirements for the continuity of patient care.*

EN 13718-2, *Air, water and difficult terrain ambulances — Part 2: Operational and technical requirements for the continuity of patient care.*

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

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

EN 60601-2-20:1996, *Medical electrical equipment — Part 2: Particular requirements for safety of transport incubators (IEC 60601-2-20:1990 + A1:1996).*

EN 13976-1:2003 (E)

3 Terms and definitions

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

NOTE Other definitions are included within existing standards.

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 craft or vehicle

3.2

auxiliary equipment

equipment not included in an incubator transport system but used for special indications during transport

3.3

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 60601-2-20:1996]

3.4

transport incubator system

system produced or arranged to serve as a complete unit for the care of an infant in a vehicle or craft. The system typically includes one or more of the following: an incubator, monitors, respirator, device(s) for infusion and suction as well as basic supplies of electricity and medical gas and a stretcher and/or trolley

3.5

vehicle or craft

means for carrying people or goods from one place to another, for road, air, water or difficult terrain

4 Requirements

4.1 General requirements for transport incubator systems

4.1.1 Vehicles

The basic requirements for vehicles, crafts and interfaces described in EN 1789 for road ambulances, in EN 13718-1 and EN 13718-2 for air, water and difficult terrain ambulances and in EN 1865 for stretchers shall apply. The system requirements are found in part 2 of this standard (EN 13976-2) and basic requirements for transport incubators are described in EN 60601-2-20. The requirements below are additional requirements needed for transport incubator system interfaces.

Vehicles or crafts employed in the transportation of infants shall be designed for the safe carriage of a transport incubator system and continuity of care of the patient.

4.1.2 Loading

Arrangements to load the equipment into the vehicle shall not compromise EC/national regulations regarding manual handling. The total weight of the medical devices shall not compromise the function of the craft or vehicle.

4.1.3 Placement

The transport incubator system shall be capable of being positioned such that, once loaded into the vehicle or craft, at least two operators can have access to and sight of the infant to perform medical intervention with ease.

NOTE Experience shows a clear preference for the transport incubator system to be positioned transversely in the ambulance compartment of the vehicle because of:

- a) safety of staff;
- b) reduced motion sickness (i.e. staff can face forwards);
- c) optimum access to the baby.

4.2 Interface between transport incubator, medical devices and vehicle

4.2.1 Fixation

4.2.1.1 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 13718-1:2002, 4.8.

4.2.1.2 The weight of the transport incubator system shall not exceed 140 kg. Fixation of the transport incubator system in a road ambulance shall conform with EN 1789 and in air, water and difficult terrain 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.

4.2.1.3 The device locking the transport incubator system within the vehicle or craft shall have more than one fixation point between the vehicle and the transport system. Fixation points to the transport incubator system shall be described by the manufacturer, and marked on each transport incubator system.

4.2.1.4 To ensure continuity and interchangeability between different vehicles or crafts at least one of the following options shall be used:

- a) floor mounted tracking system as used in aircraft according to, 505 mm between centres and min. 1300 mm length;
- b) using the existing stretcher or trolley of the vehicle equipped with the same tracking system as defined above;
- c) using an alternative floor mounted system interfaced to the transport incubator system.

The manufacturer of the transport incubator system shall show that the fixation will comply with requirements in EN 1789 and for other vehicles those in EN 13718-1 and EN 13718-2.

4.2.1.5 Where a transport incubator system is modified by someone other than the original manufacturer of the transport incubator system, the modifier shall be obliged to confirm that any additional device is appropriately secured (according to EN 1789, EN 60601-1-1) 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).

4.2.2 Electricity

4.2.2.1 The transport incubator system shall be capable of operating on 12 V DC, 24 V DC or 230 V AC power supplies during transport.