SLOVENSKI STANDARD
SIST EN 13976-2:2004

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Reševalni sistemi – Prevoz inkubatorjev – 2. del: Zahteve za sistem

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

Rettungssysteme - Inkubatortransport - Teil 2: Anforderungen an Transportsysteme

Systémes de sauvetage - Transport d'incubateurs - Partie 2: Exigences relatives au systéme

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11.040.10	Anestezijska, respiratorna in reanimacijska oprema	Anaesthetic, respiratory and reanimation equipment
11.160	Prva pomoļ	First aid

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

Systémes de sauvetage - Transport d'incubateurs - Partie 2: Exigences relatives au systéme

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

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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 Management Centre has the same status as the official versions.

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Contents

Foreword

This document (EN 13976-2:2003) 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of an identical text or by endorsement, at the latest by June 2004, and conflicting national standards shall be withdrawn at the latest by June 2004.

Annex A is normative and annex B is informative.

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.

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 including the interactions 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.

It also 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 standard also stipulates that the equipment or systems shall 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 455-1, *Medical gloves for single use — Part 1: Requirements and testing for freedom from holes.*

EN 455-2, *Medical gloves for single use — Part 2: Requirements and testing for physical properties.*

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

EN 794-1, *Lung ventilators — Part 1: Particular requirements for critical care ventilators.*

EN 794-3, *Lung ventilators — Part 3: Particular requirements for emergency and transport ventilators.*

EN 864, *Medical electrical equipment — Capnometers for use with humans – Particular requirements.*

EN 865, *Pulse oximeters — Particular requirements.*

EN 1060-1, *Non-invasive sphygmomanometers — Part 1: General requirements.*

EN 1060-2, *Non-invasive sphygmomanometers — Part 2: Supplementary requirements for mechanical sphygmomanometers.*

EN 1281-1, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets.*

EN 1281-2, *Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors.*

EN 1615, *Enteral feeding catheters and enteral giving sets for single use and their connectors - Design and testing*

EN 1617, *Sterile drainage catheters and accessory devices for single use.*

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

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

EN 1733, *Suction catheters for use in the respiratory tract.*

EN 1782, *Tracheal tubes and connectors.*

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

EN 1819, *Laryngoscopes for tracheal intubation — Particular requirements.*

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

EN 12342, *Breathing tubes intended for use with anaesthetic apparatus and ventilators.*

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 continuity of patient care.*

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

EN 60601-1:1990, *Medical electrical equipment — Part 1: General requirements for safety (IEC 60601-1:1988).*

EN 60601-1-2, *Medical electrical equipment — Part 1-2: General requirements for safety. Collateral standard: Electromagnetic compatibility — Requirements and tests (IEC 60601-1-2:2001).*

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

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

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 60601-2-30:1999).*

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

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

EN ISO 7886-1, *Sterile hypodermic syringes for single use — Part 1: Syringes for manual use (ISO 7886-1:1993).*

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

EN ISO 8185, *Humidifiers for medical use — General requirements for humidification systems (ISO 8185:1997).*

EN ISO 8537, *Sterile single-use syringes, with or without needle, for insulin (ISO 8537:1991).*

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

EN ISO 10079-2, *Medical suction equipment — Part 2: Manually powered suction equipment (ISO 10079-2:1999).*

EN ISO 10555-1, *Sterile, single-use intravascular catheters — Part 1: General requirement (ISO 10555-1:1995).*

EN ISO 10555-3, *Sterile, single-use intravascular catheters — Part 3: Central venous catheters (ISO 10555-3:1996).*

EN ISO 10555-5, *Sterile, single-use intravascular catheters — Part 5: Over-needle peripheral catheters (ISO 10555-5:1996).*

3 Terms and definitions

For the purposes of this European Standard, the terms and definitions given in EN 13976-1 apply.

4 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.

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, water and difficult terrain ambulances and in EN 1865 for stretchers.

Any medical device which is part of the transport incubator system shall conform with annex A and 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, air, water and difficult terrain vehicles and labelled according to the standard.

4.2 Suspension/noise/comfort (shock-absorption)

Ear defenders, shall be used if the infant will be exposed to noise over 60 dB(A). Noise from additional equipment shall not exceed 60 dB(A) as set by EN 60601-2-20.

NOTE Vibration and noise may interfere with the general comfort and well-being of infants. Therefore the vibration to which they are exposed shall be as low as possible. The transportation of the baby shall be at an appropriate speed to ensure comfort of the baby. High speeds are rarely necessary. Baby ear defenders may be used when necessary to lower noise exposure.

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 should 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 fulfils this standard only with an additional accessory or procedure, the manufacturer shall describe in the accompanying documents how to fulfil this standard.

4.5 Humidity

All equipment forming part of the transport incubator system shall conform to EN 60601-1:1990, 10.2.1.g.

4.6 Protection against electrical shock

All electrical equipment forming part of the transport incubator system shall conform to EN 60601-1.