SLOVENSKI STANDARD
SIST EN 13976-1:2011

01-julij-2011

Nadomešča:
SIST EN 13976-1:2004

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

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

Rettungssysteme - Inkubatortransport - Teil 1: Anforderungen an Schnittstellen

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

Ta slovenski standard je istoveten z: EN 13976-1:2011

ICS:

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

SIST EN 13976-1:2011 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 13976-1

May 2011

ICS 11.040.10; 11.160

Supersedes EN 13976-1:2003

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 14 April 2011.

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 CEN-CENELEC 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 CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of 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 United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN 13976-1:2011: E

Contents

Page

Foreword 3

Introduction 4

1 Scope 5

2 Normative references 5

3 Terms and definitions 6

4 Requirements 8
4.1 Interface between transport incubator system and ambulance 8
4.1.1 Fixation 8
4.1.2 Electricity 8
4.1.3 Gas supply 9

Annex A (informative) **Rationale regarding power use** 10

Annex ZA (informative) **Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices** 11

Bibliography 12

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

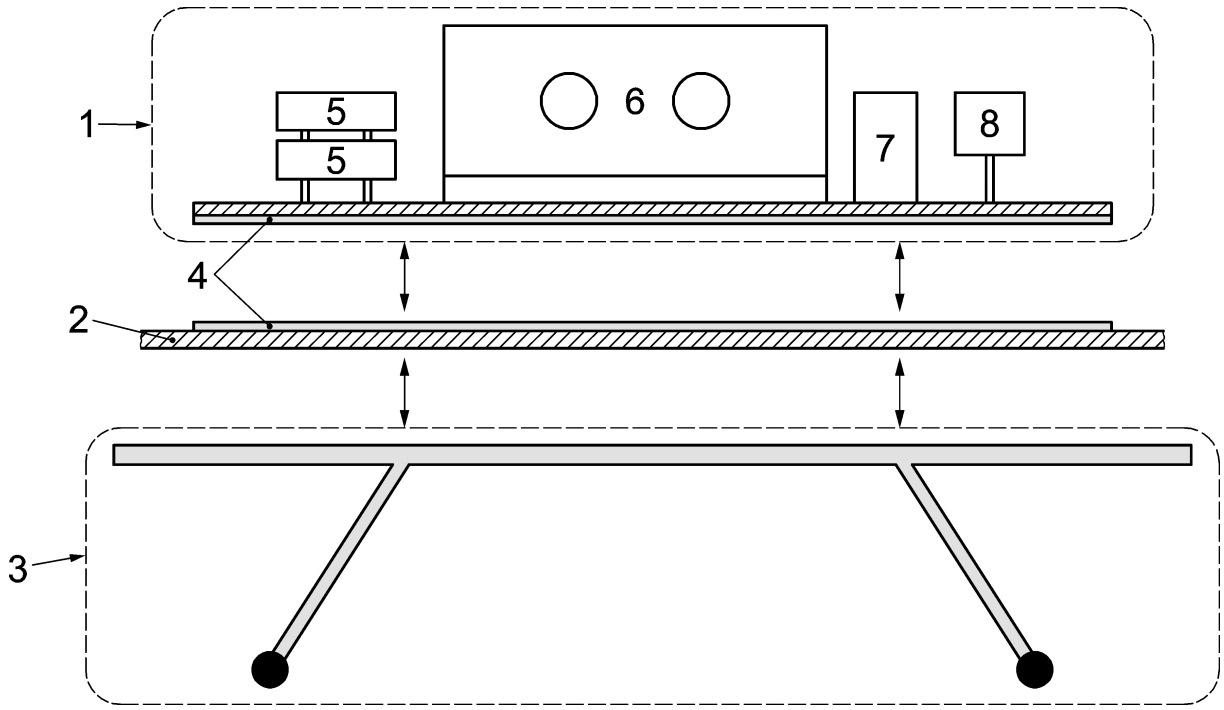
[EN 60601-2-20:2009]

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]