SLOVENSKI STANDARD
SIST EN 13976-2:2018

01-september-2018

Nadomešča:
SIST EN 13976-2:2011

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

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

Ta slovenski standard je istoveten z: EN 13976-2:2018

ICS:

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

SIST EN 13976-2:2018 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 13976-2

June 2018

ICS 11.040.10; 11.160

Supersedes EN 13976-2:2011

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 4 September 2017.

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN 13976-2:2018 E

Contents

Page

European foreword

This document (EN 13976-2:2018) 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 December 2018, and conflicting national standards shall be withdrawn at the latest by December 2019.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN not be held responsible for identifying any or all such patent rights.

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.

This document supersedes EN 13976-2:2011.

The following points represent the most important technical changes in the revision:

a) clarified unclear issues about mass of the transport incubator system;

b) a requirement for the infant restraint system was included.

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

— *Part 1: Interface requirements*

— *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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey 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 infants.

Interface requirements 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 specifies that the equipment or systems shall not interfere with the functions of the road and air 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 documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 1789:2007+A2:2014, *Medical vehicles and their equipment — Road ambulances*

EN 1865-1:2010+A1:2015, *Patient handling equipment used in road ambulances — Part 1: General stretcher systems and patient handling equipment*

EN 1865-2:2010+A1:2015, *Patient handling equipment used in road ambulances — Part 2: Power assisted stretcher*

EN 13718-1:2014, *Medical vehicles and their equipment — Air ambulances — Part 1: Requirements for medical devices used in air ambulances*

EN 13718-2:2015, *Medical vehicles and their equipment — Air ambulances — Part 2: Operational and technical requirements for air ambulances*

EN 13976-1:2018, *Rescue systems — Transportation of incubators — Part 1: Interface requirements*

EN 60529:1991,[1] *Degrees of protection provided by enclosures (IP Code) (IEC 60529:1989 + A1:1999 + A2:2013)*

EN 60601-1:2006,[2] *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005+Cor.:2006+Cor.:2007+A1:2012)*

EN 60601-1-2:2015, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests (IEC 60601-1-2:2014)*

---

[1] As impacted by EN 60529:1991/corrigendum May 1993, EN 60529:1991/A1:2000, EN 60529:1991/A2:2013 and EN 60529:1991/AC:2016-2.

[2] As impacted by EN 60601-1:2006/corrigendum Mar. 2010, EN 60601-1:2006/A1:2013, EN 60601-1:2006/A1:2013/AC:2014 and EN 60601-1:2006/A12:2014

EN 60601-1-12:2015, *Medical electrical equipment — Part 1-12: General requirements for basic safety and essential performance — Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment (IEC 60601-1-12:2014)*

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

European Aviation Safety Agency (EASA) Certification Specifications CS-23, *Normal, Utility, Aerobatic, and Commuter Category Aeroplanes*[3]

European Aviation Safety Agency (EASA) Certification Specifications CS-25, *Large Aeroplanes*[3]

European Aviation Safety Agency (EASA) Certification Specifications CS-27, *Small Rotorcraft*[3]

European Aviation Safety Agency (EASA) Certification Specifications CS-29, *Large Rotorcraft*[3]

RTCA DO 160G:2010, Radio Technical Commission for Aeronautics — Environmental conditions and test procedures for airborne equipment[4]

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN 13976-1:2018 apply.

4 General requirements

4.1 System combination

Requirements for interfaces are found in EN 13976-1:2018 and basic requirements for transport incubators are described in EN 60601-2-20:2009.

Any medical device which is part of the transport incubator system shall be designed for use with neonates and infants and for use during transportation. The transport should be performed minimizing manual lifting, lowering or carrying by personnel. All of the equipment that is 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 that is part of the 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 1789:2007+A2:2014 for road ambulances, in EN 13718–1:2014 and EN 13718–2:2015 for air ambulances and in EN 1865 series 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 specified in EN 60601-2-20:2009.

---

[3] EASA constitutes the European governments transport aircraft airworthiness approval Regulations, and can be obtained from: European Aviation Safety Agency (EASA), Otto Platz 1, Postfach 101253, D-50452 Cologne, Germany, or at www.easa.europa.eu.

[4] Publication available at the RTCA Secretariat, Suite 500, 1425 K Street, N.W. Washington DC, 20005, USA http://www.rtca.org/

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 should be at an appropriate speed to ensure the comfort of the infant. High speeds are rarely necessary.

4.3 Temperature conditions

4.3.1 The transport incubator system shall comply with the relevant requirements of EN 60601-2-20:2009 as a minimum standard with regard to controlling the internal temperature.

4.3.2 If 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 comply to IPX3 according to EN 60529:1991[5].

If the equipment complies with this standard 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 1789:2007+A2:2014 or EN 13718-1:2014.

4.6 Mechanical integrity

All equipment forming part of the transport incubator system shall comply with EN 60601-1:2006[6]. EN 60601-2-20:2009 applies for transport incubators. EN 60601-1-12:2015 applies for hand-held equipment.

4.7 EMC

All equipment forming part of the transport incubator system shall comply with EN 60601-1-2:2015 and EN 60601-2-20:2009. Equipment used during air transportation shall comply with RTCA DO 160G:2010, Section 20 and 21, Category M.

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.

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 1865-1:2010+A1:2015 and EN 1865-2:2010+A1:2015 is 150 kg

[5] As impacted by EN 60529:1991/corrigendum May 1993, EN 60529:1991/A1:2000, EN 60529:1991/A2:2013 and EN 60529:1991/AC:2016-2.

[6] As impacted by EN 60601-1:2006/corrigendum Mar. 2010, EN 60601-1:2006/A1:2013, EN 60601-1:2006/A1:2013/AC:2014 and EN 60601-1:2006/A12:2014