SLOVENSKI STANDARD
SIST EN 13976-1:2018

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Reševalni sistemi - Prevoz inkubatorjev - 1. del: Pogoji za vmesnike

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 13976-1:2018**

ICS:

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

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

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

Rettungssysteme - Inkubatortransport - Teil 1: Schnittstellenanforderungen

This European Standard was approved by CEN on 10 January 2018.

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European foreword

This document (EN 13976-1:2018) 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of an identical text or by endorsement, at the latest by December 2018, and conflicting national standards shall be withdrawn at the latest by December 2019.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 13976-1:2011.

The following point represents the most important technical change in the revision:

— clarified ambiguous and unclear issues in order to improve interchangeability and interoperability of the transport incubator system when transported in hospitals and between hospitals using different ambulances and air crafts, by specifying the interface for mechanical fixation, gas connector and electrical connector

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 the interfaces required in the transport of a transport incubator system. The standard includes interfaces between the incubator and the ambulance as well as those between the various items of equipment used to form 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 infants. Interface requirements 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 infants.

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.

ENV 737-6:2003, *Medical gas pipeline systems — Part 6: Dimensions and allocation of probes for terminal units for compressed medical gases and vacuum*

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

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 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)*

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

EN ISO 7396-1:2016, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum (ISO 7396-1:2016)*

EN ISO 7396-2:2007, *Medical gas pipeline systems — Part 2: Anaesthetic gas scavenging disposal systems (ISO 7396-2:2007)*

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

ISO 7166:1985, *Aircraft — Rail and stud configuration for passenger equipment and cargo restraint*

MIL-DTL-5015H, *Detail Specification: Connectors, Electrical, Circular Threaded, An Type, General Specification for (18 May 2000) (Superseding MIL-C-5015G)*

3 Terms and definitions

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

3.1
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

[SOURCE: EN 1789:2007+A2:2014, 3.2]

3.2
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

[SOURCE: EN 13718-2:2015, 3.6]

3.3
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

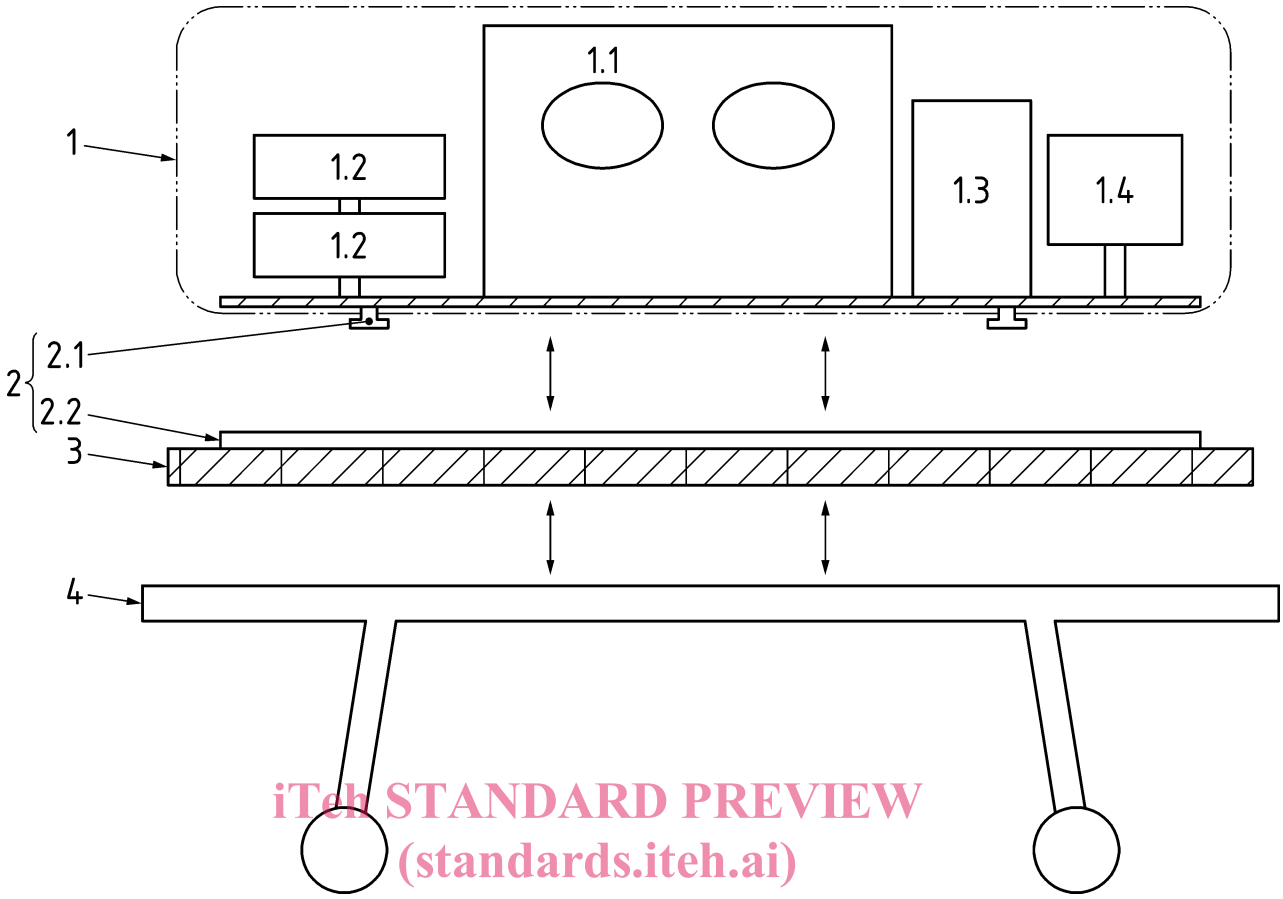
3.4
interoperability
facility to connect various medical devices that are fixed to patients, into relevant connections of associated medical devices including the possibility of connecting powered medical devices to various kinds of ambulances

[SOURCE: EN 13718-2:2015, 3.8]

3.5
transport incubator
device with an enclosure intended to contain an infant with transparent section/s to allow observation of the infant and provide a safe, secure and temperature controlled environment while being transported for medical care and it needs to be possible to provide care and medical intervention should this be required during the journey

3.6
transport incubator system
TIS

system produced or arranged to serve as a complete unit for the care of an infant during transport, see Figure 1



Key

1 Transport incubator system

NOTE Example of components that could be included in a TIS:

1.1 Incubator

1.2 Syringe pump

1.3 Ventilator

1.4 Monitor

2 Track system

2.1 Track studs

2.2 Track rails

3 Interface to be used if track rails cannot be fixed directly to the stretcher system. If the interface is to be attached to undercarriage, original fixation points on the undercarriage should be used

4 Stretcher system (stretcher/undercarriage/stretcher support, etc.)

NOTE When a TIS is permanently fixed to an undercarriage, the undercarriage will form an integral part of the TIS.

Figure 1 — Transport incubator system with undercarriage fixation

4 Requirements

4.1 Fixation

4.1.1 Fixation of the transport incubator system in a road ambulance shall comply with EN 1789:2007+A2:2014 and in air ambulances with EN 13718-1:2014 and EN 13718-2:2015, irrespective of whether the transport incubator system is supported by a stretcher system.