

**Päästesüsteemid. Inkubaatorite transportimine. Osa 2:
Nõuded süsteemile**

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

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 13976-2:2011 sisaldab Euroopa standardi EN 13976-2:2011 ingliskeelset teksti.

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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 14 April 2011.

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Foreword

This document (EN 13976-2:2011) 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of an identical text or by endorsement, at the latest by November 2011, and conflicting national standards shall be withdrawn at the latest by November 2011.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 13976-2:2003.

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 13976-2:2003 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 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 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 stipulates that the equipment or systems shall not interfere with the functions of the 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 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.

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

EN 1865 (all parts), *Patient handling equipment used in 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 13976-1:2011, *Rescue systems — Transportation of incubators — Part 1: Interface conditions*

EN 60601-1, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005)*

EN 60601-1-2, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests (IEC 60601-1-2:2007, modified)*

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)*

RTCA DO 160, *Radio Technical Commission for Aeronautics — Environmental conditions and test procedures for airborne equipment (corresponding to EUROCAE ed-14) [publication available at the RTCA Secretariat, Suite 500, 1425 K Street, N.W. Washington DC, 20005, USA]*

RTCA DO 199, *Radio Technical Commission for Aeronautics — Potential interference to aircraft electronic equipment from devices carried on board [publication available at the RTCA Secretariat, Suite 500, 1425 K Street, N.W. Washington DC, 20005, USA]*