SLOVENSKI STANDARD
SIST EN 80601-2-59:2010

01-marec-2010

Medicinska elektriļ na oprema - 2-59. del: Posebne zahteve za osnovno varnost in bistvene lastnosti presejalnih termografov za spremljanje ļ lovekove temperature pri mrzlici (IEC 80601-2-59:2008 + popravek Apr. 2009)

Medical electrical equipment - Part 2-59: Particular requirements for basic safety and essential performance of screening thermographs for human febrile temperature screening (IEC 80601-2-59:2008 + corrigendum Apr. 2009)

Medizinische elektrische Geräte - Teil 2-59: Besondere Anforderungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Wärembildkameras für Reihenuntersuchungen von Menschen auf Fieber (IEC 80601-2-59:2008 + corrigendum Apr. 2009)

Appareils électromédicaux - Partie 2-59: Exigences particulières pour la sécurité de base et les performances essentielles des imageurs thermiques pour le dépistage des humains fébriles (CEI 80601-2-59:2008 + corrigendum Apr. 2009)

Ta slovenski standard je istoveten z: **EN 80601-2-59:2009**

ICS:

11.040.55	Diagnostiļ na oprema	Diagnostic equipment

SIST EN 80601-2-59:2010 **en,fr**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 80601-2-59

December 2009

ICS 11.040.55

English version

Medical electrical equipment - Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening

(IEC 80601-2-59:2008 + corrigendum 2009)

Appareils électromédicaux -
Partie 2-59: Exigences particulières
pour la sécurité de base
et les performances essentielles
des imageurs thermiques
pour le dépistage des humains fébriles
(CEI 80601-2-59:2008
+ corrigendum 2009)

Medizinische elektrische Geräte -
Teil 2-59: Besondere Anforderungen
für die Sicherheit einschließlich
der wesentlichen Leistungsmerkmale
von Wärmebildkameras
für Reihenuntersuchungen
von Menschen auf Fieber
(IEC 80601-2-59:2008
+ Corrigendum 2009)

This European Standard was approved by CENELEC on 2009-11-17. CENELEC 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 Central Secretariat or to any CENELEC 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 CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Central Secretariat: Avenue Marnix 17, B - 1000 Brussels

Ref. No. EN 80601-2-59:2009 E

Foreword

The text of document 62D/697/FDIS, future edition 1 of IEC 80601-2-59, prepared by SC 62D, Electromedical equipment, of IEC TC 62, Electrical equipment in medical practice, and SC 3, Lung ventilators and related equipment, of ISO TC 121, Anaesthetic and respiratory equipment, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 80601-2-59 on 2009-11-17.

The following dates were fixed:

– latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2010-09-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2012-12-01

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive MDD (93/42/EEC). See Annex ZZ.

In this standard, the following print types are used:

– Requirements and definitions: roman type.

– *Test specifications: italic type.*

– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

– “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

– “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

− “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;

− “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

− “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

Annexes ZA and ZZ have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 80601-2-59:2008 + corrigendum April 2009 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following note has to be added for the standard indicated:

ISO/IEC 17025	NOTE	Harmonized as EN ISO/IEC 17025:2005 (not modified).

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

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.

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Annex ZA of EN 60601-1:2006 applies, except as follows:

Publication	Year	Title	EN/HD	Year
Addition:				
ISO/TR 13154	-[1)]	Medical electrical equipment - Deployment, implementation and operational guidelines for indentifying febrile humans using a screening thermograph	-	-
ASTM E1213-97	2002	Standard Test Method for Minimum Resolvable Temperature Difference for Thermal Imaging Systems	-	-

[1)] Undated reference.

Annex ZZ
(informative)

Coverage of Essential Requirements of EC Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex I of the EC Directive 93/42/EEC with the exception of Essential Requirements 3 and 10.1.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.

IEC 80601-2-59

Edition 1.0 2008-10

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Medical electrical equipment –
Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening

Appareils électromédicaux –
Partie 2-59: Exigences particulières pour la sécurité de base et les performances essentielles des imageurs thermiques pour le dépistage des humains fébriles

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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International standard IEC 80601-2-59 has been prepared by a Joint Working Group of IEC subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice, and of ISO subcommittee SC3: Lung ventilators and related equipment, of ISO technical committee 121: Anaesthetic and respiratory equipment.

The text of this particular standard is based on the following documents:

FDIS	Report on voting
62D/697/FDIS	62D/720/RVD

Full information on the voting for the approval of this particular standard can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by 12 P-members out of 15 having cast a vote.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

– Requirements and definitions: roman type.

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An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 series, published under the general title: *Medical electrical equipment*, can be found on the IEC website

The committee has decided that the contents of this publication will remain unchanged until the maintenance result date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

The contents of the corrigendum of April 2009 have been included in this copy.

INTRODUCTION

The minimum safety requirements specified in this particular standard are considered to provide for a practical degree of safety in the operation of ME EQUIPMENT for human febrile temperature screening.

This document describes ME EQUIPMENT that uses infrared technology to detect naturally emitted heat at the skin surface of the FACE. Such ME EQUIPMENT can be useful at ports-of-entry or ports-of-exit and the entrances to buildings under indoor environmental conditions to separate febrile from afebrile individuals to help prevent the spread of communicable diseases. Care can be needed when evaluating individuals under changing environmental conditions, but the inner canthus of the eye has been demonstrated to be a robust measurement site and is supplied by the internal carotid artery. [40] 1)

A body core temperature of 38 °C or above was used as the criterion to restrict traveling during the SARS (severe acute respiratory syndrome) epidemic (April 2003). [73] The US Center for Disease Control advises that SARS typically begins with a temperature above 38 °C, which is 1 °C higher than normal human body core temperature which averages around 37 °C. [29] It is hard to give an accurate assessment of how many people were checked by infrared temperature measurements in China during the SARS epidemic. There is official Chinese government data indicating that during a two-month period in the spring of 2003, 30 million travelers were screened in China. From this cohort, 9 292 travelers with elevated temperature were detected and 38 were suspected of being SARS carriers. SARS was diagnosed in 21 of these cases. All elevated temperatures were confirmed using traditional clinical temperature measurements of body temperature. Although it is hard to determine the human body's core temperature accurately by infrared measurement of SKIN TEMPERATURE, it is a potential method for screening for elevated temperature values. [36] [73] [75]

This particular standard amends and supplements IEC 60601-1 (third edition, 2005): Medical electrical equipment – Part 1: General requirements for safety and essential performance, hereinafter referred to as the General Standard (see 1.4).

The requirements are followed by specifications for the relevant tests.

A "General guidance and rationale" section giving some explanatory notes, where appropriate, about the more important requirements is included in annex AA. It is considered that knowledge of the reasons for these requirements will not only facilitate the proper application of the standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, this annex does not form part of the requirements of this standard.

1) Figures in square brackets refer to the Bibliography.