SLOVENSKI STANDARD
SIST EN IEC 80601-2-59:2019

01-december-2019

Nadomešča:
SIST EN 80601-2-59:2010

Medicinska električna oprema - 2-59. del: Posebne zahteve za osnovno varnost in bistvene lastnosti presejalnih termografov za spremljanje človekove temperature pri mrzlici (IEC 80601-2-59:2017)

Medical electrical equipment - Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening (IEC 80601-2-59:2017)

Medizinische elektrische Geräte - Teil 2-59: Besondere Anforderungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Wärmebildkameras für Reihenuntersuchungen von Menschen auf Fieber (IEC 80601-2-59:2017)

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 (IEC 80601-2-59:2017)

Ta slovenski standard je istoveten z: **EN IEC 80601-2-59:2019**

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11.040.55	Diagnostična oprema	Diagnostic equipment

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 80601-2-59

October 2019

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Supersedes EN 80601-2-59:2009 and all of its amendments and corrigenda (if any)

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 80601-2-59:2017)

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
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(IEC 80601-2-59:2017)

This European Standard was approved by CENELEC on 2017-10-24. 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.

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

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

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

Ref. No. EN IEC 80601-2-59:2019 E

European foreword

The text of document 62D/1501/FDIS, future edition 2 of IEC 80601-2-59, prepared by SC 62D "Electromedical equipment" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 80601-2-59:2019.

The following dates are fixed:

• latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2020-04-11
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2022-10-11

This document supersedes EN 80601-2-59:2009.

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

Endorsement notice

The text of the International Standard IEC 80601-2-59:2017 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

ISO 80601-2-56	NOTE	Harmonized as EN ISO 80601-2-56
IEC 60601-1-10	NOTE	Harmonized as EN 60601-1-10

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

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

Publication	Year	Title	EN/HD	Year
Replacement				
IEC 60601-1-2	2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	EN 60601-1-2	2015
IEC 60601-1-6	2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	EN 60601-1-6	2010
IEC 60601-1-8	2006	Medical electrical equipment_- Part_1-8:- General requirements for basic safety and essential performance_- Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems		-
Addition				
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
			+A12	2014
			+EN 60601-1:2006/corrigendum Mar. 2010	2010
			+AC	2014
ISO/TR 13154	-	Medical electrical equipment --- Deployment, implementation and operational guidelines for indentifying febrile humans using a screening thermograph		-

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INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

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 –
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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.

This second edition cancels and replaces the first edition published in 2008. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) updates of the normative references and the bibliography;

b) expansion of the applicability to pandemic infectious diseases in general.

The text of this document is based on the following documents:

FDIS	Report on voting
62D/1501/FDIS	62D/1515/RVD

Full information on the voting for the approval of this document can be found in the report on voting indicated in the above table.

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

In this document, 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 DOCUMENT OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this document, 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 document are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular document are by number only.

In this document, 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 document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this document ;
– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document ;
– "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.

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 stability 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.

NOTE The attention of National Committees and Member Bodies is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC or ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committees that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

INTRODUCTION

The minimum safety requirements specified in this document 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 controlled 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 region medially adjacent to the inner canthus of the eye has been demonstrated to be a robust measurement site and is supplied by the internal carotid artery. [1][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). [2] The US Centers 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. [3] 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 travellers were screened in China. From this cohort, 9 292 travellers 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 can be used for screening for elevated temperature values. [2] [4] [5] Improved rates of detection may result from improved techniques.[6]

International travellers were screened during the 2009 H1N1 influenza outbreak. [7] [8] The pandemic potential of other influenzas such as H7N9 [9] is of concern to the World Health Organization (WHO). [10]

Middle East Respiratory Syndrome Coronavirus (MERS-CoV) was first reported in Saudi Arabia in 2012, and a total of 1 026 laboratory-confirmed cases resulting in at least 376 deaths (36,7%) have been confirmed by the World Health Organization (WHO) as of 25 February 2015. [11] Most identified cases have had fever, although some mild and/or asymptomatic cases have been reported. [11] [12] [13] [14] The possibility of widespread dissemination of MERS-CoV during religious pilgrimage [11] and other regional travel has been investigated, but appears to be under control [15], although WHO continues to express concern. [13] [14] Fever screening at airports has also been employed during outbreaks of Dengue in Taiwan. [16] [17]

The 2014 Ebola outbreak originating in West Africa has brought issues of the potential for global pandemic to the forefront. [18] [19] [20] [21] Controversy has arisen over the effectiveness of thermography for fever screening at airports and other checkpoints [22] [23], while empirical data has demonstrated the effectiveness of this technology when used in compliance with appropriate international standards [24] [25] [26] [27] and WHO guidance. [10] [20] [21]

This document is intended to be applicable for thermographic fever screening devices for the above-mentioned and any other fever-producing infectious diseases. [10] [15] [28] [29].

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1 Figures in square brackets refer to the Bibliography