IEC 80601-2-59

Edition 2.0 2017-09

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

IEC 80601-2-59:2017-09(en-fr)

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MEDICAL ELECTRICAL EQUIPMENT –

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

FOREWORD

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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

MEDICAL ELECTRICAL EQUIPMENT –

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

201.1 Scope, object and related standards

Clause 1 of the general standard[2] applies, except as follows:

201.1.1 * Scope

Replacement:

This part of IEC 80601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of SCREENING THERMOGRAPHS intended to be used for the individual non-invasive febrile temperature screening of a human under controlled environmental conditions, hereafter referred to as ME EQUIPMENT. This document sets laboratory characterization test limits for the SCREENING THERMOGRAPH.

NOTE 101 A SCREENING THERMOGRAPH is intended for screening of a human subject and detection of SKIN TEMPERATURE elevated above normal. An elevated SKIN TEMPERATURE needs to be followed up by a subsequent temperature measurement using a clinical thermometer (see ISO 80601-2-56 [30]).

NOTE 102 The main part of such equipment is commonly referred to as an infrared camera.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

201.1.2 Object

Replacement:

The object of this particular document is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for SCREENING THERMOGRAPHS as defined in 201.3.209.

201.1.3 Collateral standards

Addition:

This particular document refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this document.

IEC 60601-1-2:2014, IEC 60601-1-6:2010 and IEC 60601-1-6:2010/AMD1:2013 apply as modified in Clauses 202 and 206 respectively. IEC 60601-1-3, IEC 60601-1-10, IEC 60601-1-11 and IEC 60601-1-12 do not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

[2] The general standard is IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 are referred to in this particular document as the general standard. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this document corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this document addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix “20x”, where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this document addresses the content of Clause 4 of the IEC 60601-1-2 collateral standard, 203.4 in this document addresses the content of Clause 4 of the IEC 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"*Replacement*" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this document.

"*Addition*" means that the text of this document is additional to the requirements of the general standard or applicable collateral standard.

"*Amendment*" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this document.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However, due to the fact that definitions in the general standard are numbered 3.1 through 3.147, additional definitions in this document are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this document" is used to make reference to the general standard, any applicable collateral standards and this particular document taken together.

Where there is no corresponding clause or subclause in this document, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this document.

201.2 Normative references

NOTE Informative references are listed in the Bibliography.

Clause 2 of the general standard applies, except as follows:

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*

IEC 60601-1-6:2010, *Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability*
IEC 60601-1-6:2010/AMD1:2013

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*
IEC 60601-1-8:2006/AMD1:2012

Addition:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012

ISO/TR 13154, *Medical electrical equipment – Deployment, implementation and operational guidelines for identifying febrile humans using a screening thermograph*

ASTM E1213-14[3], *Standard Test Method for Minimum Resolvable Temperature Difference for Thermal Imaging Systems*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions specified in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

NOTE An index of defined terms is found beginning on page 40.

Addition:

201.3.201
CALIBRATION
set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument, or measuring system, or values represented by a material measure or a reference material and the corresponding values realized by standards

[3] ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA, 19428-2959 USA or https://www.astm.org/

201.3.202
CALIBRATION SOURCE
infrared radiation blackbody reference source of known and traceable temperature and EMISSIVITY

201.3.203
DETECTOR
infrared thermal sensor or array of sensors able to detect infrared thermal energy radiating from the surface of the FACE or other object

Note 1 to entry: The DETECTOR responds to the net infrared radiation and converts that response into electrical signals.

201.3.204
EMISSIVITY
ratio of the emitted thermal rate of propagation of electromagnetic energy emitted by an object as a consequence of its temperature propagated in a given direction, per unit solid angle about that direction and per unit area projected normal to the direction of a surface to that of a ideal blackbody at the same temperature and under the same spectral conditions

Note 1 to entry: The EMISSIVITY of wet or dry human skin is accepted to be 0,98. [31] [32]

Note 2 to entry: The properties of an ideal blackbody are described by Planck's Law.

201.3.205
EXTERNAL TEMPERATURE REFERENCE SOURCE
part of the SCREENING THERMOGRAPH that is used to ensure accurate operation between CALIBRATIONS using an infrared radiation source of known temperature and EMISSIVITY

Note 1 to entry: The EXTERNAL TEMPERATURE REFERENCE SOURCE is normally imaged in each thermogram of the FACE or prior to each thermogram of the FACE.

201.3.206
FACE
anterior cranial face of the PATIENT being measured

201.3.207
IMAGE PIXEL
individual infrared thermal detections from the DETECTOR

Note 1 to entry: The number of IMAGE PIXELS is given in an array format. e.g. number of sensors in horizontal (H) by number of sensors in vertical (V) e.g. for a 120 (H) x 120 (V) DETECTOR array, the number of IMAGE PIXELS would be 14 400.

201.3.208
LABORATORY ACCURACY
closeness of the agreement between the result of a measurement (with SCREENING THERMOGRAPH) and the true value of the measurand

Note 1 to entry: LABORATORY ACCURACY is a qualitative concept. For a quantitative description, the term 'uncertainty' should be used.

201.3.209
SCREENING THERMOGRAPH
ME EQUIPMENT or ME SYSTEM that:

– detects infrared radiation emitted from the FACE from which a thermogram is obtained from the TARGET;

– detects infrared radiation emitted from an EXTERNAL TEMPERATURE REFERENCE SOURCE;

– displays a radiometric thermal image;

– obtains a temperature reading from the TARGET; and

– compares that temperature reading to the THRESHOLD TEMPERATURE to determine if the PATIENT is febrile

Note 1 to entry: A SCREENING THERMOGRAPH is a non-contact, non-invasive, non-ionizing temperature screening ME EQUIPMENT used to measure the FACE temperature and indicate the screened region with a different colour if the temperature is above the THRESHOLD TEMPERATURE setting. Such a device is commonly referred to as an infrared camera.

Note 2 to entry: A SCREENING THERMOGRAPH has to identify the TARGET from the thermogram to obtain the TARGET temperature reading.

201.3.210
SELF-CORRECTION
automatic process carried out to compensate for DETECTOR drift

EXAMPLE To reduce the error caused by possible drift, the SCREENING THERMOGRAPH carries out a SELF-CORRECTION.

Note 1 to entry: An uncooled microbolometer DETECTOR can be subject to significant drift in its measurements over time.

201.3.211
SKIN TEMPERATURE
skin surface temperature as measured from the WORKABLE TARGET PLANE of a SCREENING THERMOGRAPH, with an appropriate adjustment for skin EMISSIVITY

Note 1 to entry: The EMISSIVITY of wet or dry human skin is accepted to be 0,98. [31] [32]

201.3.212
TARGET
region of the FACE selected for THRESHOLD TEMPERATURE comparison

201.3.213
TARGET PLANE
in-focus plane perpendicular to the central axis of the field of view of the infrared camera of a SCREENING THERMOGRAPH

201.3.214
THRESHOLD TEMPERATURE
temperature setting, above which the SCREENING THERMOGRAPH indicates that the TARGET is potentially febrile

Note 1 to entry: This is typically indicated in degrees Celsius.

201.3.215
WORKABLE TARGET PLANE
region of TARGET PLANE that meets the specified performance requirements

Note 1 to entry: The WORKABLE TARGET PLANE can be the whole or part of the TARGET PLANE.

201.4 General requirements

Clause 4 of the general standard applies, except as follows:

201.4.1 Conditions for application to ME EQUIPMENT or ME SYSTEMS

Addition at the end of the subclause:

When applying this document to a SCREENING THERMOGRAPH, definitions and requirements that use the term PATIENT shall be considered as applying to the person being screened for a febrile state.

201.4.3 ESSENTIAL PERFORMANCE

Addition:

Table 201.101 summarizes the ESSENTIAL PERFORMANCE requirements of this document.

Table 201.101 – Distributed ESSENTIAL PERFORMANCE requirements

Requirement	Subclause
Minimum radiometric temperature LABORATORY ACCURACY of the SCREENING THERMOGRAPH	201.101.2.2
THRESHOLD TEMPERATURE and the resulting ALARM CONDITION	201.101.2.3 201.102.2
Start-up TECHNICAL ALARM CONDITION	201.102.1
NOTE Failure to indicate that the SCREENING THERMOGRAPH is not capable of performing to specification is considered a loss of ESSENTIAL PERFORMANCE.	

201.5 General requirements for testing ME EQUIPMENT

Clause 5 of the general standard applies, except as follows:

201.5.3 * Ambient temperature, humidity, atmospheric pressure

Addition at end of a):

The range of environmental conditions for NORMAL USE shall include:

– a temperature range of 18 °C to 24 °C;

– a relative humidity range of 10 % to 75 %.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard applies, except as follows:

201.7.2.2 Identification

Replacement of the first dash by:

– the name or trade name and address of the following:

- the MANUFACTURER;
- where the MANUFACTURER does not have an address within the locale, an authorized representative within the locale,

to which the RESPONSIBLE ORGANIZATION can refer;