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INTERNATIONAL STANDARD

NORME INTERNATIONALE

Withdrawn

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 80601-2-59:2008

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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

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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.

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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.

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.

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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]

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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.

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 International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of SCREENING THERMOGRAPHS intended to be used for the individual non-invasive febrile temperature screening of humans under indoor environmental conditions, hereafter referred to as ME EQUIPMENT. This International Standard sets laboratory characterization test limits for the SCREENING THERMOGRAPH.

NOTE A SCREENING THERMOGRAPH is intended for screening and detection of human subjects with SKIN TEMPERATURES elevated above normal. An elevated SKIN TEMPERATURE needs to be followed up by a subsequent temperature measurement using a clinical thermometer (see IEC 80601-2-56).

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

IEC 60601-1-3 does not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

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

2) The general standard is IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*.

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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 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of sections, clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this standard 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 particular standard addresses the content of Clause 4 of the 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the 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 particular standard.

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

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

Subclauses or figures 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 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

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Subclauses or figures 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 standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, 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 particular standard.

201.2 Normative references

NOTE Informative references are listed in the bibliography beginning on page 29.

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

Addition:

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

ASTM E1213-97:2002[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 given in IEC 60601-1:2005 and IEC 60601-1-8:2006 apply, except as follows:

NOTE An index of defined terms is found beginning on page 34.

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

[ISO Guide 99, definition 2.39, modified]

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 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 The EMISSIVITY of dry human skin is accepted to be 0,98.

NOTE 2 An ideal blackbody is 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 The EXTERNAL TEMPERATURE REFERENCE SOURCE is normally imaged in each thermogram or prior to each thermogram.

201.3.206
FACE
anterior cranial face of the PATIENT being measured

3) ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA, 19428-2959 USA

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201.3.207
IMAGE PIXEL
individual infrared thermal detections from the DETECTOR

NOTE 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 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 A SCREENING THERMOGRAPH is a non-contact, non-invasive 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.

NOTE 2 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

NOTE An uncooled microbolometer DETECTOR can be subject to significant drift in its measurements over time.

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

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 The EMISSIVITY of dry human skin is accepted to be 0,98.

201.3.212
TARGET
region of the FACE selected for THRESHOLD TEMPERATURE comparison

201.3.213
TARGET PLANE
in-focus plane perpendicular to the line of sight of a SCREENING THERMOGRAPH

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

NOTE This is typically indicated in degrees Celsius.

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

NOTE 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:

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 – 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 of ME EQUIPMENT

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

201.5.3 Ambient temperature, humidity, atmospheric pressure

a) *Addition:*

* 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 %.

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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:

Additional subclauses:

201.7.9.2.101 SCREENING THERMOGRAPH

The instructions for use shall:

a) instruct the OPERATOR to ensure that the FACE is unobstructed by hair, eyeglasses, and other objects because their presence will interfere with the ability of a SCREENING THERMOGRAPH to detect a febrile condition.

b) disclose the recommended position of the FACE required to obtain the TARGET relative to the optical pathway of the SCREENING THERMOGRAPH;

EXAMPLE Position of the FACE relative to the lens of the infrared camera.

c) recommend secondary screening with a clinical thermometer of any individual that the SCREENING THERMOGRAPH indicates is possibly febrile .

201.7.9.3.101 SCREENING THERMOGRAPH

The technical description shall include:

a) a reference to ISO/TR 13154, *Medical electrical equipment — Deployment, implementation and operational guidelines for identifying febrile humans using a screening thermograph*, (the guidance document for the application of SCREENING THERMOGRAPHS), upon its publication;

b) a recommendation that the relative humidity in the area of screening should be maintained below 50 % and temperature below 24 °C to achieve the INTENDED USE and an explanation of the effects of elevated humidity and ambient temperature on the temperature reading caused by sweating.

NOTE 1 The measurements provided by a SCREENING THERMOGRAPH in INTENDED USE can be influenced when the PATIENT is sweating. Sweating thresholds can vary, according to a person's fitness level, environment of residence, length of adaptation and the relative humidity. [16]

c) an explanation of the effects due to environmental infrared sources such as sunlight, nearby electrical sources and lighting, and instructions that these should be minimized;

NOTE 2 The RESPONSIBLE ORGANIZATION needs to be aware of the type of lighting used at the screening area. Lighting such as incandescent, halogen, quartz tungsten halogen and other type of lamps that produce significant interference (heat) should be avoided.

NOTE 3 The area chosen for screening should have a non-reflective background and minimal reflected infrared radiation from the surroundings.

d) an explanation of the effects due to airflow, and instructions that this should be minimized.

NOTE 4 Drafts from air conditioning ducts can cause forced cooling or heating of the FACE and should be baffled or diffused to prevent airflow from blowing directly onto the PATIENT.

e) a description of the TARGET.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard applies.

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201.9 Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of the general standard applies.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of the general standard applies.

201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 of the general standard applies.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 of the general standard applies, except as follows:

201.12.2 Usability

Additional subclauses:

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201.12.2.101 Display

201.12.2.101.1 * Display colour scale

The SCREENING THERMOGRAPH shall be provided with an isothermal colour display for visual interpretation and rapid identification of the thermogram of the WORKABLE TARGET PLANE. The indication of temperature range, with colour code/temperature scale, shall be displayed. The SCREENING THERMOGRAPH shall be provided with at least one colour mapping mode where the colours follow the order of the visible spectrum (e.g., rainbow scale) such that blue is cooler and red is hotter.

Compliance is checked by inspection.

201.12.2.101.2 Display temperature resolution

The temperature increment displayed in a thermal image of the SCREENING THERMOGRAPH should not exceed 0,1 °C.

NOTE This is typically indicated in degrees Celsius.

Compliance is checked by inspection.

201.12.2.102 * Response time and throughput

The SCREENING THERMOGRAPH should be capable of operating in near real-time for rapid and effective screening of a mass population. The MANUFACTURER shall estimate the throughput (time between measurements) in NORMAL USE of the SCREENING THERMOGRAPH. The average time required by a SCREENING THERMOGRAPH to measure, process and display the temperature of the FACE and throughput of the SCREENING THERMOGRAPH shall be disclosed in the technical description.

Compliance is checked by functional testing and inspection of the instructions for use.

Withdrawn

201.12.2.103 * WORKABLE TARGET PLANE

The minimum display of the WORKABLE TARGET PLANE shall be 240 IMAGE PIXELS by 180 IMAGE PIXELS. In NORMAL USE, the thermogram of the FACE shall fill at least 180 IMAGE PIXELS by 135 IMAGE PIXELS. The WORKABLE TARGET PLANE should be perpendicular to the FACE to improve performance. [42] If the SCREENING THERMOGRAPH requires that the OPERATOR frame the thermogram of the FACE in the WORKABLE TARGET PLANE, a guide or mask shall be provided in the image of the WORKABLE TARGET PLANE on the display. [42]

NOTE 180 IMAGE PIXELS by 135 IMAGE PIXELS is 75 % of the minimum display of the WORKABLE TARGET PLANE.

The size or coordinates of the WORKABLE TARGET PLANE, if it is smaller than the SCREENING THERMOGRAPH'S TARGET PLANE, shall be disclosed in the instructions for use.

Compliance is checked by functional testing and inspection of the instructions for use.

201.13 HAZARDOUS SITUATIONS and fault conditions

Clause 13 of the general standard applies.

201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)

Clause 14 of the general standard applies, except as follows:

201.14.13 * Connection of PEMS by NETWORK/DATA COUPLING to other equipment

Addition:

The SCREENING THERMOGRAPH shall be equipped with a NETWORK/DATA COUPLING that can communicate the following:

a) radiometric thermal image of the FACE including an indication of temperature range, with colour code/temperature scale (see 201.12.2.101);

b) date and time that the image was acquired;

c) THRESHOLD TEMPERATURE;

d) results of the comparison of the TARGET to this THRESHOLD TEMPERATURE.

The SCREENING THERMOGRAPH should be capable of communicating a visible light image of the FACE.

Compliance is checked by inspection.

201.15 Construction of ME EQUIPMENT

Clause 15 of the general standard applies.

201.16 ME SYSTEMS

Clause 16 of the general standard applies.

201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS

Clause 17 of the general standard applies.

Withdrawn
IEC 80601-2-59:2008
https://standards.iteh.ai/catalog/standards/sist/a8e28b7a-cb21-4acc-a8cc-6aeae3ca6e92/iec-80601-2-59-2008