IEC 80601-2-59

Edition 2.1 2023-01
CONSOLIDATED VERSION

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+AMD1:2023-01 CSV(en-fr)



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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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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This consolidated version of the official IEC Standard and its amendment has been prepared for user convenience.

IEC 80601-2-59 edition 2.1 contains the second edition (2017-09) [documents 62D/1501/FDIS and 62D/1515/RVD] and its amendment 1 (2023-01) [documents 62D/1892/CDV and 62D/1938A/RVC].

In this Redline version, a vertical line in the margin shows where the technical content is modified by amendment 1. Additions are in green text, deletions are in strikethrough red text. A separate Final version with all changes accepted is available in this publication.

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 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.

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 the base publication and its amendment will remain unchanged until the stability date indicated on the IEC web site under 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

INTRODUCTION to Amendment 1

At the October 2019 meeting of IEC SC 62D in Shanghai, China, the subcommittee discussed the need for administrative/technical changes to most 62D standards after completion of the amendment projects within the IEC 60601-1 series. Those projects were all completed and the amendments published in 2020.

The full list of IEC SC 62D documents that will be amended or revised can be found within the IEC document 62D/1792/DC. The results and comments on the DC can be found within 62D/1808/INF. The review report for this amendment is 62D/1888/RR.

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 60601-1-2:2014/AMD1:2020, IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013 and IEC 60601-1-6:2010/AMD2:2020 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.

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2 The general standard is IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, *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, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020 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~~ 3.154, 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 60601-1-2:2014/AMD1:2020

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 60601-1-6:2010/AMD2:2020

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
IEC 60601-1-8:2006/AMD2:2020

Addition:

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012
IEC 60601-1:2005/AMD2:2020

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, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020, IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020, 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 41.

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

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

by a material measure or a reference material and the corresponding values realized by standards

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;

201.7.9.1 General

Replacement of the first dash by:

– 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;

201.7.9.2.9 * Operating instructions

Addition at the end of the subclause:

The instructions for use shall include the following.

a) * Instruction to 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. 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.

b) Recommendation to the OPERATOR to perform a secondary screening with a clinical thermometer of any individual that the SCREENING THERMOGRAPH indicates is possibly febrile.

201.7.9.3.1 * General

Addition to the first dash:

A recommendation that the relative humidity in the area of screening should be maintained below 50 % and the 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 101 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. [33]

Addition as the last four dashes:

– a reference to ISO/TR 13154 including its title.

– 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.

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

– a description of the TARGET.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard applies.

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 of ME EQUIPMENT

Additional subclauses:

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.

201.12.2.103 * WORKABLE TARGET PLANE

The minimum display of the WORKABLE TARGET PLANE shall be 320 IMAGE PIXELS by 240 IMAGE PIXELS. In NORMAL USE, the thermogram of the FACE shall fill at least 240 IMAGE PIXELS by 180 IMAGE PIXELS. The WORKABLE TARGET PLANE should be parallel to the FACE to improve performance. [34] 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. [34]

NOTE 240 IMAGE PIXELS by 180 IMAGE PIXELS is 56 % 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 for ME EQUIPMENT

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 PEMS intended to be incorporated into an IT-NETWORK

Additional subclause:

201.14.13.101 * NETWORK/DATA COUPLING to other equipment

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

The SCREENING THERMOGRAPH shall be capable of communicating the data to appropriate authorities.

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.

Additional clauses:

201.101 LABORATORY ACCURACY of a SCREENING THERMOGRAPH

201.101.1 * TARGET

The measuring site of the TARGET shall be the region medially adjacent to the inner canthus of each eye.

Compliance is checked by inspection.

201.101.2 Thermogram of the FACE

201.101.2.1 * Minimum temperature imaging range of the FACE

The SCREENING THERMOGRAPH shall be capable of creating a thermogram of the FACE over at least the range of 30 °C to 40 °C.

Compliance is checked by functional testing.

201.101.2.2 * Minimum radiometric temperature LABORATORY ACCURACY

The temperature LABORATORY ACCURACY of a SCREENING THERMOGRAPH, including the measurement uncertainty, shall be less than or equal to an offset error of ± 0,5 °C over the range of at least 34 °C to 39 °C. An automated service test mode may be utilized to perform these measurements to allow for the substitution of the CALIBRATION SOURCE for a FACE.

The uncertainty of the SCREENING THERMOGRAPH, u_{ST}, shall be calculated. The calculation shall include all relevant components of standard uncertainty according to Formula (1). The terms included in the calculation of uncertainty of the SCREENING THERMOGRAPH shall be disclosed in the technical description.

$$u_{ST}^2 = u_D^2 + u_S^2 + u_U^2 + u_{ER}^2 + u_{MRTD}^2 + \text{all other relevant terms} \quad (1)$$

where

u_D is the standard uncertainty of the measurement drift (see 201.101.4),

u_S is the standard uncertainty of the measurement stability (see 201.101.4),

u_U is the standard uncertainty of the measurement uniformity of the WORKABLE TARGET PLANE (see 201.101.6),

u_{ER} is the standard uncertainty of the EXTERNAL TEMPERATURE REFERENCE SOURCE temperature (see 201.101.3.1),

u_{MRTD} is the standard uncertainty caused by the MRTD (see 201.101.5).

The total uncertainty of the LABORATORY ACCURACY (i.e. the measured temperature difference) shall be calculated using Formula (2).

$$u^2 = u_{CS}^2 + u_{ST}^2 \quad (2)$$

where

u_{CS} is the standard uncertainty of the CALIBRATION SOURCE used in CALIBRATION of the SCREENING THERMOGRAPH.

The measured radiometric temperature LABORATORY ACCURACY shall meet the criterion of Formula (3) to fulfil the requirements of this subclause.

$$\left| t_{ST} - t_{CS} \right| + \left| u \right| \leq 0{,}5 \quad (3)$$

where

t_{ST} is the temperature of the CALIBRATION SOURCE measured by the SCREENING THERMOGRAPH,

t_{CS} is the temperature of the CALIBRATION SOURCE.

Compliance is checked by the following test:

a) *Set up the SCREENING THERMOGRAPH according to the ACCOMPANYING DOCUMENT.*

b) *Wait until the stabilization period TECHNICAL ALARM CONDITION disappears.*

NOTE 1 Additional information is found in 201.102.1.

c) *Select a CALIBRATION SOURCE temperature approximately equal to the bottom of the operating range.*

d) *Measure the CALIBRATION SOURCE temperature 5 times.*

NOTE 2 The CALIBRATION SOURCE has a different EMISSIVITY than a PATIENT.

e) *Ensure that the temperature measurement of the CALIBRATION SOURCE uses the algorithm used to determine the THRESHOLD TEMPERATURE from the IMAGE PIXELS in the field of a TARGET (see 201.102.2).*

f) *Calculate the mean of the five measurements.*

g) *Confirm that the SCREENING THERMOGRAPH complies with Formula (3).*

h) *Repeat d) to g) with CALIBRATION SOURCE temperature approximately equal to the top of the operating range and three different points within the range.*

201.101.2.3 THRESHOLD TEMPERATURE

The THRESHOLD TEMPERATURE shall be adjustable over at least the range 34 °C to 39 °C with increments not greater than 0,1 °C.

Compliance is checked by functional testing.

201.101.3 * EXTERNAL TEMPERATURE REFERENCE SOURCE

201.101.3.1 * Performance

The EXTERNAL TEMPERATURE REFERENCE SOURCE shall have a known radiance temperature over the range of 33 °C to 40 °C with an expanded uncertainty of ± 0,3 °C and a combined stability and drift of ± 0,1 °C over the interval for measurement drift specified in 201.101.4.

Compliance is checked by functional testing.

201.101.3.2 * Size

The EXTERNAL TEMPERATURE REFERENCE SOURCE shall be capable of being imaged by the thermal imager of the SCREENING THERMOGRAPH. The size of EXTERNAL TEMPERATURE REFERENCE SOURCE shall be greater than or equal to 20 IMAGE PIXELS by 20 IMAGE PIXELS. For a SCREENING THERMOGRAPH, which sequentially measures the EXTERNAL TEMPERATURE REFERENCE SOURCE and the WORKABLE TARGET PLANE, the EXTERNAL TEMPERATURE REFERENCE SOURCE should be imaged by the same IMAGE PIXELS as the TARGET to minimize the effect of non-uniformity across the WORKABLE TARGET PLANE.

Compliance is checked by functional testing.

201.101.4 * Measurement of drift and stability

The sum of the permissible drift and stability of a SCREENING THERMOGRAPH shall be less than or equal to 0,2 °C over an interval of 14 days or the CALIBRATION interval specified in the technical description, whichever is longer. A SCREENING THERMOGRAPH may use SELF-

CORRECTIONS to maintain the drift within acceptable limits. An automated service test mode may be utilized to perform these measurements to allow for the substitution of the CALIBRATION SOURCE for a FACE.

NOTE A low drift and stability ensures that the LABORATORY ACCURACY of the SCREENING THERMOGRAPH is maintained. Although the drift can be reduced if a SELF-CORRECTION is performed more regularly, SELF-CORRECTION performed too often creates interruptions in the ability to screen individuals with the SCREENING THERMOGRAPH.

Compliance is checked with the following test:

a) *Set up the SCREENING THERMOGRAPH according to the ACCOMPANYING DOCUMENT.*

b) *Wait until the stabilization period TECHNICAL ALARM CONDITION disappears.*

c) *Measure the CALIBRATION SOURCE every 5 s to 15 s for 8 h.*

d) *Ensure the temperature measurement of the CALIBRATION SOURCE uses the algorithm used to determine the temperature compared to the THRESHOLD TEMPERATURE from the IMAGE PIXELS in the field of a TARGET (see 201.102.2).*

e) *Calculate the mean and standard deviation of the mean of the 8 h of measurements.*

f) *Evaluate stability by ensuring that 3 times the standard deviation is less than 0,1 °C.*

g) *Repeat b) through f) consecutively for either 14 days or the CALIBRATION interval, whichever is longer.*

h) *Determine the smallest and largest mean value as values calculated in e).*

i) *Evaluate drift by ensuring that the difference of the values in h) is less than ± 0,1 °C. under achievable conditions.*

201.101.5 * Minimum resolvable temperature difference (MRTD)

The MRTD shall be less than or equal to 0,1 °C.

NOTE The minimum resolvable temperature difference reflects the smallest temperature (or equivalent temperature) difference that the SCREENING THERMOGRAPH can consistently detect within the WORKABLE TARGET PLANE.

Compliance is checked using the method specified in ASTM E1213-14.

201.101.6 * Uniformity of WORKABLE TARGET PLANE

The maximum permissible temperature (or equivalent temperature) difference measured at various locations distributed across the WORKABLE TARGET PLANE shall be 0,2 °C. Uniformity should not be obtained by utilizing IMAGE PIXEL averaging algorithms. An automated service test mode may be utilized to perform these measurements to allow for the substitution of the CALIBRATION SOURCE for a FACE.

Good uniformity within the TARGET PLANE allows flexibility of deployment of the SCREENING THERMOGRAPH for screening the FACE.

Compliance is checked by using the following test.

a) *Set up the SCREENING THERMOGRAPH according to the ACCOMPANYING DOCUMENT.*

b) *Wait until the stabilization period TECHNICAL ALARM CONDITION disappears.*

c) *Position a CALIBRATION SOURCE, complying with the requirements of Annex BB, maintained at a fixed temperature and at the nominal distance between the TARGET and the SCREENING THERMOGRAPH for optimal performance of the DETECTOR and lens at each of the four corners and the centre of the WORKABLE TARGET PLANE. Choose at least 24 additional points, randomly distributed throughout the WORKABLE TARGET PLANE.*

d) *Measure the CALIBRATION SOURCE at each of these points.*

e) *Ensure the temperature measurement of the CALIBRATION SOURCE uses the algorithm used to determine the THRESHOLD TEMPERATURE from the IMAGE PIXELS in the field of a TARGET (see 201.102.2).*

f) *Determine the minimum and maximum measurements.*

g) *Ensure that the maximum difference between the minimum and maximum measurements of temperature in the WORKABLE TARGET PLANE is 0,2 °C.*

201.101.7 * FACE position

The WORKABLE TARGET PLANE of the SCREENING THERMOGRAPH shall accommodate a FACE that is positioned 0,75 m to 2,2 m above the floor. This requirement may be met by moving the infrared camera. The plane of the lens of the infrared camera also should be parallel to the FACE and in line with the TARGET.

Compliance is checked by functional testing.

201.101.8 * SCREENING THERMOGRAPH start-up

The SCREENING THERMOGRAPH shall inhibit operation during the period of stabilization following start-up until it is capable of performing to the drift specification of 201.101.4. The maximum duration of this start-up period shall be disclosed in the instructions for use.

NOTE Additional information is found in 201.102.1.

Compliance is checked by inspection and the tests of 201.101.4.

201.101.9 * Spatial resolution

The horizontal and vertical spatial resolution of an IMAGE PIXEL when imaging the TARGET in NORMAL USE shall be ≤ 1 mm and the value shall be disclosed in the technical description.

Compliance is checked by functional testing.

201.101.10 * EMISSIVITY setting

An EMISSIVITY of 0,98 shall be used in the calculation of SKIN TEMPERATURE by the SCREENING THERMOGRAPH. [31] [32] [35]

Compliance is checked by inspection.

201.102 SCREENING THERMOGRAPH ALARM CONDITIONS

201.102.1 * Start-up ALARM CONDITION

A SCREENING THERMOGRAPH shall be provided with an ALARM SYSTEM that includes a TECHNICAL ALARM CONDITION of at least LOW PRIORITY during the period of stabilization following start-up until the SCREENING THERMOGRAPH is capable of performing to specification.

NOTE Additional information is found in 201.101.8.

Compliance is checked by functional testing.

201.102.2 * Exceeding the THRESHOLD TEMPERATURE ALARM CONDITION

A SCREENING THERMOGRAPH shall be provided with an ALARM SYSTEM that includes a PHYSIOLOGICAL ALARM CONDITION of at least MEDIUM PRIORITY that indicates when the THRESHOLD TEMPERATURE has been exceeded inside of the TARGET. The technical description

shall include a description of the algorithm used to determine the THRESHOLD TEMPERATURE from the IMAGE PIXELS in the field of the TARGET.

Compliance is checked by inspection of the technical description and functional testing.

202 Electromagnetic disturbances – Requirements and tests

IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020 appli~~es~~y, except as follows:

202.4.3.1 Configurations

Addition after the last dash of 4.3.1:

– if applicable, attachment of ACCESSORIES as necessary to achieve the BASIC SAFETY and ESSENTIAL PERFORMANCE of the SCREENING THERMOGRAPH.

202.5.2.2.1 Requirements applicable to all ME EQUIPMENT and ME SYSTEMS

Addition of the note to list element b):

NOTE 101 The requirements of this document are not considered deviations or allowances.

202.8.1 General

Additional subclause:

202.8.1.101 Additional general requirements

The following degradations, if associated with BASIC SAFETY or ESSENTIAL PERFORMANCE, shall not be allowed:

– component failures;
– changes in programmable parameters or settings;
– reset to default settings;
– change of operating mode; and
– change in LABORATORY ACCURACY at any point in the measurement range greater than permitted in 201.101.2 without the generation of either a TECHNICAL ALARM CONDITION or an indication of abnormal operation.

The SCREENING THERMOGRAPH may exhibit temporary degradation of performance (e.g. deviation from the performance indicated for use during IMMUNITY testing), which does not require OPERATOR intervention, and does not affect BASIC SAFETY or ESSENTIAL PERFORMANCE.

In the event of disruption during IMMUNITY tests, the SCREENING THERMOGRAPH shall recover from any disruption within 30 s.

206 USABILITY

IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013 and IEC 60601-1-6:2010/AMD2:2020 apply except as follows:

For a SCREENING THERMOGRAPH, the following shall be considered PRIMARY OPERATING FUNCTIONS:

a) observing the radiometric thermal image;
b) observing the determination as to whether the PATIENT is febrile;

c) properly positioning the SCREENING THERMOGRAPH in relation to the PATIENT;

d) starting the SCREENING THERMOGRAPH from power off;

e) turning off the SCREENING THERMOGRAPH; and

f) performing a basic pre-use functional check of the SCREENING THERMOGRAPH.

The following functions, if available, also shall be considered PRIMARY OPERATING FUNCTIONS:

g) performing a basic pre-use functional check of the ALARM SIGNALS;

h) configuring the ACCESSORIES including connection of the detachable parts to the SCREENING THERMOGRAPH; and

i) setting the OPERATOR-adjustable controls, including
   – setting SCREENING THERMOGRAPH control parameters,
   – setting ALARM LIMITS, and
   – inactivating ALARM SIGNALS.