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Medical electrical equipment — Deployment, implementation and operational guidelines for identifying febrile humans using a screening thermograph

Équipement électrique médical — Déploiement, mise en oeuvre et lignes directrices opérationnelles pour l'identification d'êtres humains fébriles en utilisant un thermographe de criblage

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment,* and Technical Committee IEC/TC 62, *Electrical equipment in medical practice*, Subcommittee SC D, *Electromedical equipment*.

This second edition cancels and replaces the first edition (ISO/TR 13154:2009), which has been technically revised.

Introduction

The purpose of this document is to provide guidance on the implementation of IEC 80601-2-59[1] to minimize the spread of infectious diseases. The first edition of this document was derived, in part, from SPRING Technical Reference 15.[2] The SPRING Technical Reference was created as result of the Singapore experiences during the SARS epidemic.[3][4][5][6][7] The scale of the global problem has increased in recent years, with emergence of infectious disease with pandemic potential as a threat to public health. Pandemics of infectious diseases (e.g. influenza) have swept the world from time to time throughout history and have caused widespread illness, large numbers of deaths, notably among children and young adults, and huge societal disruption. New pandemic sources emerge with serious consequences, with potential to affect a quarter of the world population over one or more cycles.[5][8]

The prime objectives of pandemic planning are to save lives, reduce the health impact of a pandemic and minimize disruption to health and other essential services, while maintaining business continuity as far as is possible and reducing the general disruption to society that is likely to ensue, serious though this will be. Strong leadership, organization and co-ordination, and clear lines of accountability and communication are key to preparing for and responding to a pandemic.[9][10][11][12]

The ability to limit the spread of a pandemic disease, direct public health interventions, and limit the unintended consequences of these actions is greatly enhanced by the widespread availability of cost-effective screening methods for infectious diseases such as rapid diagnostic tests.[13][14] Early outbreak detection with continued surveillance of travellers and the institution of appropriate measures, including social distancing, isolation of infected individuals, isolation/quarantine of suspected cases or treatment with appropriate medication, can help delay or limit the spread of a disease once a case has been identified. Well-coordinated international implementation of entry and exit restrictions is an important component of an effective global response to contain cases and prevent a pandemic. All countries should prepare to implement steps to limit the spread, including local, regional and national entry and exit restrictions based on veterinary and health monitoring, screening and surveillance for humans, animals, and animal products[15][16][17], and information sharing and cooperation to manage borders.[9][10]

Pandemic disease includes, but is not limited to, such infections as influenza[9][11][18][19][20], SARS[5][6][7], tuberculosis[21], Middle East Respiratory Syndrome (MERS)[22][23][24][25][26], haemorrhagic fevers (e.g. Ebola)[13][27][28][29][30] and other biological or bacterial agents.[31][32][33] Table 1 contains examples of infectious diseases characterized by fever for which thermographic fever screening can be useful. On the other hand, pandemic diseases such as Zika virus are not necessarily accompanied by high fever and are therefore not suitable for thermographic fever screening.[34][35] The sources of such diseases can be naturally occurring, accidental releases or the result of subversive activities or terrorism.

Individual screening of all persons entering a country, for infectious illness and exposure factors for infection with a pandemic strain, helps minimize the likelihood of transmission.[27][36] However, such screening is challenged by a lack of sensitivity (e.g. asymptomatic infected individuals might not be detected) and specificity (e.g. many individuals exhibiting symptoms might not be infected with a pandemic strain). For example, the typical incubation period for influenza is two days, and infected persons with influenza can be contagious for 24 h prior to the onset of symptoms. Other possible pandemic diseases have varying periods of latency or incubation.[37][38] Since some asymptomatic travellers who are incubating a disease can become symptomatic *en route*, overall screening effectiveness can be improved by adopting layered pre-departure, *en route* and arrival screening measures. The policy of layered screening measures should apply to all in-bound travellers from affected areas, but the characteristics of the outbreak, including the rapidity of spread, can make it necessary to implement this screening at all international airports from which passengers originate. In addition, development of rapid diagnostic tests can dramatically change our ability to screen effectively.[9][13][14][38]

Table 1 — Examples of infectious diseases characterized by fever, identifiable by thermographic fever screening

Infectious disease	Pathogen	Transmission mode	References
Ebola virus disease (EVD)	Ebola virus	Blood, body fluids	[12][28][29][30][37][39][40]
Influenza	Influenza viruses	Airborne or contact with infected humans, birds or animals, or their remains	[9][10][11][14][16][18][19][41][42]
Middle East Respiratory Syndrome-coronavirus (MERS)	MERS coronavirus (CoV)	Contact with virally contaminated surfaces	[22][23][24][25][26]
Severe acute respiratory syndrome (SARS)	SARS virus (coronavirus)	Airborne	[5][6][7]
Tuberculosis	*Myobacterium tuberculosis*	Airborne; multiple	[21]

During the outbreaks of pandemics, internationally agreed measures designed to restrict the movement of possibly infected people were instituted and were assessed by WHO to have greatly contributed to bringing the disease under control.

Possible measures to delay or slow the transmission of infectious diseases include:

— providing travel advice on travel to and from affected countries;

— providing health information for exiting and returning travellers;

— providing health screening at ports of entry and exit.[11][12][18][20][27][28][29][30][31][32][37][40][41][42][43][44][45]

In a severe pandemic, absenteeism attributable to illness, the need to care for ill family members and fear of infection can reach 40 % during the peak weeks of a community outbreak, with lower rates of absenteeism during the weeks before and after the peak. Certain public health measures (closing schools, quarantining household contacts of infected individuals) are likely to increase rates of absence from the workplace. Actions that reduce the likelihood of disease exposure and limit transmission, assure the public of the ability to maintain domestic safety and security, advise the public to curtail non-essential travel and communal activities while preparing for implementation of community disease containment measures as the epidemic spreads, are important public policy objectives.[9][10][11] To support the objective of pandemic prevention, a SCREENING THERMOGRAPH with appropriate follow-up of febrile persons can be useful to separate potentially infectious individuals from others in locations such as:[20]

— entrances to hospitals and clinics, including emergency rooms;

— entrances to critical infrastructure facilities;

— entrances to workplaces;

— entrances to schools;

— entrances to government buildings, including police and fire stations;

— entrances to other communal locations;

— public transportation.

A SCREENING THERMOGRAPH should be an element of the layered screening process for those diseases specifically associated with elevated fever. It can also play an important epidemiological role in defining

the geographical boundaries of an outbreak. A SCREENING THERMOGRAPH complying with IEC 80601-2-59 is a non-contact, accurate and repeatable means of quickly screening individuals for fever when proper procedures are followed.

International experience has demonstrated numerous instances of noncompliance with the International Standard and the recommendations of the first edition of this document, as well as Internet postings documenting inappropriate use of radiometry and infrared cameras. It should emphasized that the efficacy and utility of this technology is contingent on the use of both equipment and protocols meeting the recommendations of these committees.[45]

NOTE The requirements for a SCREENING THERMOGRAPH are found in IEC 80601–2-59.

In this document, the following print types are used:

— Text and definitions: roman 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 OR AS NOTED: SMALL CAPITALS.

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.

Medical electrical equipment — Deployment, implementation and operational guidelines for identifying febrile humans using a screening thermograph

1 Scope

This document provides general guidelines for the deployment, implementation and operation of a SCREENING THERMOGRAPH intended to be used for non-invasive febrile temperature screening of individuals under indoor environmental conditions to prevent the spread of infection.

NOTE The equipment standard for SCREENING THERMOGRAPHS is found in IEC 80601-2-59.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions 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 For convenience, an alphabetized index of defined terms used in this document is given in Annex C.

3.1
ACCESSORY
additional part for use with equipment in order to

— achieve the INTENDED USE;

— adapt it to some special use;

— facilitate its use;

— enhance its performance;

— enable its functions to be integrated with those of other equipment.

[SOURCE: IEC 60601-1:2005, 3.3]

3.2
ACCOMPANYING DOCUMENT
document accompanying ME EQUIPMENT, an ME SYSTEM, equipment or an ACCESSORY and containing information for the RESPONSIBLE ORGANIZATION or OPERATOR, particularly regarding BASIC SAFETY and ESSENTIAL PERFORMANCE

[SOURCE: IEC 60601-1:2005, 3.4]

3.3
APPLIED PART
part of ME EQUIPMENT that in NORMAL USE necessarily comes into physical contact with the PATIENT for ME EQUIPMENT or an ME SYSTEM to perform its function

[SOURCE: IEC 60601-1:2005, 3.8, modified - deleted Notes 1, 2 and 3]

3.4
BASIC SAFETY
freedom from unacceptable RISK directly caused by physical HAZARDS when ME EQUIPMENT is used under NORMAL CONDITION and SINGLE FAULT CONDITION

[SOURCE: IEC 60601-1:2005, 3.10]

3.5
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

[SOURCE: IEC 80601-2-59:—, 201.3.201]

3.6
CLINICAL THERMOMETER
ME EQUIPMENT used for measuring at the MEASURING SITE and indicating the temperature at the REFERENCE BODY SITE

Note 1 to entry: The MEASURING SITE can be the same as the REFERENCE BODY SITE.

[SOURCE: ISO 80601-2-56:—, 201.3.207]

3.7
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 an 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.[47][48]

Note 2 to entry: An ideal blackbody is described in Planck's Law.

[SOURCE: IEC 80601-2-59:—, 201.3.204]

3.8
ESSENTIAL PERFORMANCE
performance of a clinical function, other than that related to BASIC SAFETY, where loss or degradation beyond the limits specified by the MANUFACTURER results in an unacceptable RISK

Note 1 to entry: ESSENTIAL PERFORMANCE is most easily understood by considering whether its absence or degradation would result in an unacceptable RISK.

[SOURCE: IEC 60601-1:2005 + AMD1:2012, 3.27]

3.9
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.

[SOURCE: IEC 80601-2-59:—, 201.3.205]

3.10
FACE
anterior cranial FACE of the PATIENT being measured

[SOURCE: IEC 80601-2-59:—, 201.3.206]

3.11
FIXED
term meaning fastened or otherwise secured at a specific location either permanently or so that it can only be detached by means of a TOOL

[SOURCE: IEC 60601-1:2005 + AMD1:2012, 3.30, modified - deleted Note 1 and the examples]

3.12
FUNCTIONAL CONNECTION
connection, electrical or otherwise, including those intended to transfer signals, data, power or substances

Note 1 to entry: Connection to a FIXED SUPPLY MAINS socket-outlet, whether single or multiple, is not considered to result in a FUNCTIONAL CONNECTION.

Note 2 to entry: A NETWORK/DATA COUPLING is a FUNCTIONAL CONNECTION.

[SOURCE: IEC 60601-1:2005, 3.33, modified - added Note 2]

3.13
HARM
physical injury or damage to the health of people or animals, or damage to property or the environment

[SOURCE: IEC 60601-1:2005 + AMD1:2012, 3.38]

3.14
HAZARD
potential source of HARM

[SOURCE: IEC 60601-1:2005 + AMD1:2012, 3.39]

3.15
INTENDED USE
use for which a product, process or service is intended according to the specifications, instructions and information provided by the MANUFACTURER

Note 1 to entry: INTENDED USE should not be confused with NORMAL USE. While both include the concept of use as intended by the MANUFACTURER, INTENDED USE focuses on the medical purpose while NORMAL USE incorporates not only the medical purpose, but also maintenance, transport, etc.

[SOURCE: IEC 60601-1:2005 + AMD1:2012, 3.44]

3.16
MANUFACTURER
natural or legal person with responsibility for the design, manufacture, packaging, or labelling of ME EQUIPMENT, assembling an ME SYSTEM, or adapting ME EQUIPMENT or an ME SYSTEM, regardless of whether these operations are performed by that person or on that person's behalf by a third party

Note 1 to entry: ISO 13485[49] defines "labelling" as written, printed or graphic matter:

— affixed to a medical device or any of its containers or wrappers, or

— accompanying a medical device,

related to identification, technical description, and use of the medical device, but excluding shipping documents. In this document, that material is described as markings and ACCOMPANYING DOCUMENTS.

Note 2 to entry: "Adapting" includes making substantial modifications to ME EQUIPMENT or an ME SYSTEM already in use.

Note 3 to entry: In some jurisdictions, the RESPONSIBLE ORGANIZATION can be considered a MANUFACTURER when involved in the activities described.

Note 4 to entry: Adapted from ISO 14971:2007, 2.8[50].

[SOURCE: IEC 60601-1:2005 + AMD1:2012, 3.55, modified - replaced "standard" with "document" in Note 1]

3.17
MEASURING SITE
part of a PATIENT where the temperature is measured

EXAMPLE Pulmonary artery, distal oesophagus, sublingual space in the mouth, rectum, ear canal, axilla (armpit), forehead skin.

Note 1 to entry: This definition refers to sites measured by the thermometry.

[SOURCE: ISO 80601-2-56:—, 201.3.213, modified - added Note 1]

3.18
MEDICAL ELECTRICAL EQUIPMENT
ME EQUIPMENT
electrical equipment having an APPLIED PART or transferring energy to or from the PATIENT or detecting such energy transfer to or from the PATIENT and which is:

a) provided with not more than one connection to a particular SUPPLY MAINS; and

b) intended by its MANUFACTURER to be used:

1) in the diagnosis, treatment or monitoring of a PATIENT or

2) for compensation or alleviation of disease, injury or disability

Note 1 to entry: ME EQUIPMENT includes those ACCESSORIES, as defined by the MANUFACTURER, which are necessary to enable the NORMAL USE of the ME EQUIPMENT.

Note 2 to entry: Not all electrical equipment used in medical practice falls within this definition (e.g. some in vitro diagnostic equipment).

Note 3 to entry: The implantable parts of active implantable medical devices can fall within this definition, but they are excluded from the scope of this document by appropriate wording in Clause 1.

[SOURCE: IEC 60601-1:2005 + AMD1:2012, 3.63, modified - replaced "standard" by "document" in Note 3 and deleted Notes 4 and 5]

3.19
MEDICAL ELECTRICAL SYSTEM
ME SYSTEM
combination, as specified by its MANUFACTURER, of items of equipment, at least one of which is ME EQUIPMENT to be inter-connected by a FUNCTIONAL CONNECTION or by use of a MULTIPLE SOCKET-OUTLET

Note 1 to entry: Equipment, when mentioned in this document, includes ME EQUIPMENT.

[SOURCE: IEC 60601-1:2005 + AMD1:2012, 3.64, modified - replaced "standard" by "document" in Note 1]

3.20
MULTIPLE SOCKET-OUTLET
one or more socket-outlets intended to be connected to, or integral with, flexible cables, cords or ME EQUIPMENT providing SUPPLY MAINS or equivalent voltage

Note 1 to entry: A MULTIPLE SOCKET-OUTLET can be a separate item or an integral part of the equipment.

[SOURCE: IEC 60601-1:2005 + AMD1:2012, 3.67]

3.21
NETWORK/DATA COUPLING
any means to transmit or receive information to or from other equipment in accordance with the MANUFACTURER'S specifications

Note 1 to entry: A NETWORK/DATA COUPLING is a FUNCTIONAL CONNECTION.

[SOURCE: IEC 60601-1:2005, 3.68, modified - added Note 1]

3.22
NORMAL CONDITION
condition in which all means provided for protection against HAZARDS are intact

[SOURCE: IEC 60601-1:2005, 3.70]

3.23
NORMAL USE
operation, including routine inspection and adjustments by any OPERATOR, and stand-by, according to the instructions for use

Note 1 to entry: NORMAL USE should not be confused with INTENDED USE. While both include the concept of use as intended by the MANUFACTURER, INTENDED USE focuses on the medical purpose while NORMAL USE incorporates not only the medical purpose, but maintenance, transport, etc.

[SOURCE: IEC 60601-1:2005 + AMD1:2012, 3.71]

3.24
OPERATOR
person handling equipment

[SOURCE: IEC 60601-1:2005 + AMD1:2012, 3.73, modified - deleted note]

3.25
OUTPUT TEMPERATURE
temperature indicated by a thermometer

Note 1 to entry: Methods of indication can include printed, spoken, displayed and displayed remotely.

[SOURCE: ISO 80601-2-56:—, 201.3.216]

3.26
PATIENT
living being (person or animal) undergoing a medical, surgical or dental procedure

[SOURCE: IEC 60601-1:2005 + AMD1:2012, 3.76, modifed - deleted note]

3.27
RECORD
document stating results achieved or providing evidence of activities performed

[SOURCE: IEC 60601-1:2005 + AMD1:2012, 3.98]

3.28
REFERENCE BODY SITE
part of a PATIENT to which the OUTPUT TEMPERATURE refers

EXAMPLE Pulmonary artery, distal oesophagus, sublingual space in the mouth, rectum, ear canal, axilla (armpit), forehead skin

[SOURCE: ISO 80601-2-56:—, 201.3.220]

3.29
RESPONSIBLE ORGANIZATION
entity accountable for the use and maintenance of an ME EQUIPMENT or an ME SYSTEM

Note 1 to entry: The accountable entity can be, for example, a hospital, an individual clinician or a lay person. In home use applications; the PATIENT, OPERATOR and RESPONSIBLE ORGANIZATION can be one and the same person.

Note 2 to entry: Education and training is included in "use".

[SOURCE: IEC 60601-1:2005, 3.101]

3.30
RISK
combination of the probability of occurrence of HARM and the SEVERITY of that HARM

[SOURCE: IEC 60601-1:2005 + AMD1:2012, 3.102]

3.31
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;

— 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.

[SOURCE: IEC 80601-2-59:—, 201.3.209]

3.32
SEVERITY
measure of the possible consequences of a HAZARD

[SOURCE: IEC 60601-1:2005 + AMD1:2012, 3.114]

3.33
SINGLE FAULT CONDITION
condition of ME EQUIPMENT in which a single means for reducing a RISK is defective or a single abnormal condition is present

[SOURCE: IEC 60601-1:2005 + AMD1:2012, 3.116, modified - deleted Note]

3.34
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.[47][48]

[SOURCE: IEC 80601-2-59:—, 201.3.211]

3.35
SUPPLY MAINS
source of electrical energy not forming part of ME EQUIPMENT or ME SYSTEM

Note 1 to entry: This also includes battery systems and converter systems in ambulances and the like.

[SOURCE: IEC 60601-1:2005, 3.120]

3.36
TARGET
region of the FACE selected for THRESHOLD TEMPERATURE comparison

[SOURCE: IEC 80601-2-59:—, 201.3.212]

3.37
TARGET PLANE
in-focus plane perpendicular to the central axis of the field of view of the infrared camera of a SCREENING THERMOGRAPH

[SOURCE: IEC 80601-2-59:—, 201.3.213]

3.38
TOOL
extra-corporeal object that can be used to secure or release fasteners or to make adjustments

Note 1 to entry: Coins and keys are considered TOOLS within the context of this document.

[SOURCE: IEC 60601-1:2005, 3.127 — modified: replaced “standard” by “document” in Note 1]

3.39
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.

[SOURCE: IEC 80601-2-59:—, 201.3.214]

3.40
WORKABLE TARGET PLANE
region of the TARGET PLANE which meets the specified performance requirements

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

[SOURCE: IEC 80601-2-59:—, 201.3.215]

4 General considerations

This document is concerned with the aspects of the practical use of SCREENING THERMOGRAPHS used to detect a febrile condition in various cohorts of humans, the INTENDED USE of a SCREENING THERMOGRAPH.

Deployment provides guidelines on the appropriate physical positioning and use of SCREENING THERMOGRAPHS in:

— international and national points-of-entry and points-of-exit;

— hospital and clinic entrances;

— points-of-entry to buildings designated by an authority with jurisdiction;

— points-of-entry to buildings used by the general public;

— points-of-entry to and points-of-exit from workplaces.

Implementation requirements should consider the information that can be obtained by such screening and its further value in maintaining appropriate public health standards.

The operational demands of a SCREENING THERMOGRAPH are influenced by environmental conditions for the long-term operation and function of the equipment as well as the training needed for the OPERATOR, protocols of use, and the need for secondary screening.

This document is based upon the assumption that any SCREENING THERMOGRAPH used for non-invasive febrile temperature screening of individuals under indoor environmental conditions complies with IEC 80601-2-59.

5 Planning for deployment

5.1 General

Each implementation of temperature screening requires careful consideration and examination of the proposed installation site and the deployment conditions. Problems with and restrictions of the site can affect the sensitivity and specificity of the temperature screening process. The deployment, implementation, operational setup and appropriate selection of the SCREENING THERMOGRAPH achieve the best results when such problems are considered by the RESPONSIBLE ORGANIZATION.

5.2 Condition of screening site

A SCREENING THERMOGRAPH measures SKIN TEMPERATURES by the detection of infrared radiation emitted from the FACE and provides the OPERATOR with an image of the SKIN TEMPERATURE distribution of the FACE. As a result, the environment can affect both the SCREENING THERMOGRAPH and the individual being screened. Therefore, these factors need to be considered by the RESPONSIBLE ORGANIZATION in the planning for deployment.

The operating area where the individual being screened is located should be free from significant natural and forced convective airflow. Forced convective airflow, e.g. from air conditioning ducts, should be baffled or diffused to prevent the airflow from blowing directly onto the individual being screened and the camera and EXTERNAL TEMPERATURE REFERENCE SOURCE of the SCREENING THERMOGRAPH.

The area chosen for screening should have a non-reflective background and minimal reflected infrared radiation from the surroundings. Reflective background such as glass panels should be avoided or covered with opaque materials. Unwanted sources of infrared radiation such as sunlight, heaters, electrical sources, and strong lighting (e.g. incandescent, halogen, quartz tungsten halogen) should be avoided at the screening area, particularly within the field of view of the camera of the SCREENING THERMOGRAPH.

The environment in which the individual is being screened can affect the SKIN TEMPERATURES. The temperatures measured by a SCREENING THERMOGRAPH can be influenced when the individual being screened is sweating. Sweating thresholds can vary according to a person's fitness level, environment of residence, length of adaptation and the relative humidity (see References [3], [51], [52], [53] and [54]). When humidity is controlled, these effects are minimized. To produce consistent and reliable results of the temperature screening process, it is imperative that the SCREENING THERMOGRAPH be situated in a

stable indoor environment with a temperature range of 20 °C to 24 °C and relative humidity range from 10 % to 50 %.

These conditions can best be achieved by creating a local, controlled environment.

EXAMPLE A walk-through booth.

5.3 Design of screening operation

The number of individuals and their rate of presentation need to be considered by the RESPONSIBLE ORGANIZATION when selecting and designing the placement of the SCREENING THERMOGRAPH.

The cost-effective design of a screening process should be based on the number and rate at which individuals need to be screened. In very high volume situations, multiple SCREENING THERMOGRAPHS can be required. Because each individual being screened has to pause, one at a time, in a position in front of the camera of the SCREENING THERMOGRAPH, a disruption to the flow of moving people occurs. To minimize disruption in high volume situations, the response time and throughput of the SCREENING THERMOGRAPH should be capable of operating in near real time for rapid and effective screening. This can necessitate that the SCREENING THERMOGRAPH be highly automated.

Alternatively, when the response time and throughput is not as demanding, the temperature screening operation can require the individual to stand still at a set location in front of the camera of the SCREENING THERMOGRAPH while the temperature is being screened. This could permit the SCREENING THERMOGRAPH to utilize a skilled OPERATOR to perform more of the operations.

The design of the screening process and the selection of the SCREENING THERMOGRAPH affect the installation cost and the operational cost of the temperature screening operation.

5.4 Selection of screening thermograph

The choice of SCREENING THERMOGRAPH requires careful examination of the proposed installation site and properly taking into consideration the intended deployment situation.

IEC 80601-2-59 provides the set of BASIC SAFETY and ESSENTIAL PERFORMANCE requirements and test methods which both MANUFACTURERS and RESPONSIBLE ORGANIZATIONS can apply to SCREENING THERMOGRAPHS for the intended application. These requirements for a SCREENING THERMOGRAPH are intended for general temperature screening operations for the individual non-invasive febrile temperature screening of humans under indoor environmental conditions. IEC 80601-2-59 provides recommendations on the types of temperature screening operations and relevant performance requirements for RESPONSIBLE ORGANIZATIONS to adopt for their intended operation.[55][56][57][58][59][60][61]

Since the SCREENING THERMOGRAPH is a medical device for screening (i.e. potentially identifying) febrile individuals, the RESPONSIBLE ORGANIZATION needs to consult homeland security agencies, biomedical engineers, infectious disease experts and other authorities with jurisdiction for additional guidance in the proper selection of a SCREENING THERMOGRAPH for the particular application. The inappropriate selection and operation of a SCREENING THERMOGRAPH could lead to a failure to control a wider spread or larger outbreak of serious infectious diseases.

The most suitable type of thermographic camera for continuous imaging is one using an uncooled detector system, which can be used in conjunction with an EXTERNAL TEMPERATURE REFERENCE SOURCE.

6 Operation

6.1 System setup

MANUFACTURERS should provide specific recommendations in the ACCOMPANYING DOCUMENT for the RESPONSIBLE ORGANIZATION to ensure that the performance of their products meets the stated specification. The RESPONSIBLE ORGANIZATION should consult their medical advisor on the setting of

the THRESHOLD TEMPERATURE. Therefore, it is important that the RESPONSIBLE ORGANIZATION be fully aware of these operation requirements, restrictions and special features prior to operating the SCREENING THERMOGRAPH.

NOTE 1 The SCREENING THERMOGRAPH measures the SKIN TEMPERATURE of the region medially adjacent to the inner canthus and not a body core temperature; there is a small difference in temperature between these two sites.[62] This difference should be accounted for in the selection of the THRESHOLD TEMPERATURE.

NOTE 2 The critical setting for the SCREENING THERMOGRAPH is the THRESHOLD TEMPERATURE setting.

NOTE 3 Where automated passport recognition systems are in use, there is the possibility of integration with the SCREENING THERMOGRAPH.

6.2 Screening protocol

The individuals to be screened are channelled into single file and caused to stop or pause so that the SCREENING THERMOGRAPH can capture the region medially adjacent to the inner canthi temperature distribution one individual at a time. Measuring individuals one at a time facilitates the capture of a reliable thermogram and allows the determination of potentially febrile individuals requiring secondary screening.

The field of view of the SCREENING THERMOGRAPH has to be adjusted such that both the EXTERNAL TEMPERATURE REFERENCE SOURCE and the FACE of the individual being screened can be captured by the SCREENING THERMOGRAPH. The setup also has to be arranged to ensure that the EXTERNAL TEMPERATURE REFERENCE SOURCE is not obstructed from the field of view of the infrared camera of the SCREENING THERMOGRAPH during screening. For example, this can be done by barricading the path between the SCREENING THERMOGRAPH and the EXTERNAL TEMPERATURE REFERENCE SOURCE. The distance between the camera of the SCREENING THERMOGRAPH and both the EXTERNAL TEMPERATURE REFERENCE SOURCE and the FACE of the individual being screened has to be controlled as indicated in the ACCOMPANYING DOCUMENT. Failure to ensure that either the EXTERNAL TEMPERATURE REFERENCE SOURCE or the FACE of the individual being screened adequately fills the WORKABLE TARGET PLANE can cause inaccurate temperature measurement.

To facilitate an effective screening operation, trained OPERATORS are stationed near the SCREENING THERMOGRAPH'S display monitor to observe the thermogram of the individual being screened.[63] The SCREENING THERMOGRAPH is intended to detect a human FACE with elevated SKIN TEMPERATURE. A raised temperature should confirmed by temperature measurement using a CLINICAL THERMOMETER compliant with ISO 80601-2-56. Any confirmed case of raised temperature should be handled according to established medical protocols.

The workflow has to be designed in a manner that allows ease of extraction of suspected febrile individuals for further temperature measurements so that they do not obstruct the mainstream traffic flow.

In some events and functions, when the SCREENING THERMOGRAPH is to be used together with other screening equipment such as a metal detection equipment, it is worthwhile to consider these screening systems in totality when managing the workflow and space constraints. It is important to recognise areas of bottlenecks and deploy this equipment appropriately.

6.3 Interpretation of screening results

Obtaining meaningful temperature measures for the human body requires identifying a body site that provides reliable data across a large cross-section of the population. It is important to understand that SKIN TEMPERATURE does not solely depend on body-core temperature and can be affected by other physiological and environmental factors. 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 (see References [3], [52], [53], [59], [60], [64] and [65]). It is for this reason that a SCREENING THERMOGRAPH utilizes the region medially adjacent to the inner canthus for determining the body temperature.

Annex B shows examples illustrating the facial temperature distributions of individuals (as detected by a SCREENING THERMOGRAPH) with different body temperatures ranging from normal to elevated body temperatures. It is advisable to send individuals being screened whose temperature profiles are indeterminable for more definitive body temperature measurements.

6.4 Requirements of the operator

OPERATORS play a key role in the determination as to whether an individual is febrile. Hence, it is important that they are sufficiently trained in the following areas.[63]

a) OPERATORS should be proficient in recognising the proper alignment and positioning of a person in the thermogram.

b) OPERATORS should be able to operate the SCREENING THERMOGRAPH. They need to be able to recognize common system problems or faults and know when to alert the RESPONSIBLE ORGANIZATION.

c) OPERATORS should be familiar with the workflow, safety issues and protocol of the RESPONSIBLE ORGANIZATION.

d) OPERATORS should respond in an appropriate manner (follow protocol) as determined by the RESPONSIBLE ORGANIZATION when the SCREENING THERMOGRAPH indicates that an individual is suspected of being febrile.

Refresher courses should be conducted periodically to maintain the proficiency level of the OPERATOR. The RESPONSIBLE ORGANIZATION should maintain RECORDS of OPERATOR training and performance.

6.5 Requirements of the responsible organization

The RESPONSIBLE ORGANIZATION plays a key role in the use of a SCREENING THERMOGRAPH, including the following.

a) The evaluation and purchase of the SCREENING THERMOGRAPH and its periodic quality assurance and CALIBRATION.

b) The number, proper location and installation of each SCREENING THERMOGRAPH and the secondary screening station.

NOTE 1 Screening protocols are dependent upon the incubation times of various diseases.

EXAMPLE 1 In the transportation environment, screening should be considered both before and after travel for long journeys.[12][20][29][30][39][40][42]

c) Protocol development, including the following.

— Fitness for use determination (operational readiness check) of the SCREENING THERMOGRAPH.

EXAMPLE 2 Daily check or per shift check.

— NORMAL USE operating procedure for the OPERATOR.

— Failure management procedures, including immediate availability of additional SCREENING THERMOGRAPHS. When possible, parallel screening sites would eliminate delays should equipment failure occur, and facilitate rapid movement of individuals through the screening process. The SCREENING THERMOGRAPHS should have a reliable back-up power supply or battery source.

NOTE 2 Current systems now provide reliable technology and operational longevity.

EXAMPLE 3 Supply mains failure

— Process for handling an individual who is suspected of being febrile (individual who exceeds the THRESHOLD TEMPERATURE).

— Process for secondary screening of an individual who is suspected of being febrile, including completion of a questionnaire attesting to the accuracy of their recent travel experiences.[40]

— Procedure for referral to medical personnel and/or facilities and the appropriate public health, authorities and other organizations ensuring protection of public safety.

— OPERATOR training and performance evaluation, including maintenance of RECORDS of these events.

— Periodic review of OPERATOR training and performance, including maintenance of RECORDS of these events.

— System maintenance procedures that are consistent with the recommendations of the MANUFACTURER, including maintenance of RECORDS of these events.

NOTE 3 IEC 80601–2-59 requires the calibration interval to be disclosed in the accompanying documents.

7 Data storage and security

The RESPONSIBLE ORGANIZATION should collect the information from the NETWORK/DATA COUPLING of the SCREENING THERMOGRAPH. This information includes radiometric thermal images, the THRESHOLD TEMPERATURE and results of the comparison of the TARGET to this THRESHOLD TEMPERATURE. Collecting the data, managing them and promptly reporting them to the public health authorities and other organizations ensuring protection of public safety is necessary in the response and management of public health emergencies and pandemic disease.

The RESPONSIBLE ORGANIZATION should retain this information for at least one month (normal maximum incubation time for known infectious diseases). The RESPONSIBLE ORGANIZATION should be prepared to maintain the data for longer periods when deemed necessary by the public health authorities and other organizations ensuring protection of public safety.

The collected data are electronic health information and thus subject to privacy and security laws in many jurisdictions. As such, access to the collected data should be restricted and access RECORDS and all metadata should be maintained according to local law.

Annex A
(informative)

Deployment considerations

The successful application of a SCREENING THERMOGRAPH is dependent on a number of factors. The basic requirements for operation include the facility, the environment and the equipment. These requirements are all interrelated.

a) Factors to consider in the application and installation of a SCREENING THERMOGRAPH in a facility should include the following.

— **Preventing cross-contamination:**

  — **Location**: The SCREENING THERMOGRAPH area should be positioned near the entrance of the facility. The secondary screening area should be at a tangent to the SCREENING THERMOGRAPH area, but removed from the general traffic flow. Screening near the entrance of the facility prevents comingling.

  — **Secondary screening area**: The secondary screening area is a care area that should equipped with a CLINICAL THERMOMETER and ACCESSORIES that comply with ISO 80601-2-56 and should be staffed by qualified medical personnel. The secondary screening area should be equipped with sanitation supplies, e.g. masks, wipes, disinfectants. To prevent cross-contamination, the secondary screening area should be positioned to allow PATIENT removal from the facility or to quarantine with reasonable privacy and with minimum exposure to others (maintaining cross-contamination prevention).

NOTE 1 Quarantine regulations vary by authority with jurisdiction. The RESPONSIBLE ORGANIZATION should be aware of local regulations.

NOTE 2 In a pandemic situation when groups of individuals who have travelled together are being screened (e.g. a plane load of passengers), the RESPONSIBLE ORGANIZATION should be prepared to segregate the entire group until all have been screened. Furthermore, the RESPONSIBLE ORGANIZATION should be prepared to quarantine the entire group.

— **Communication capability**: The primary screening data in cases of suspected febrile temperatures is sent to the secondary screening area, which should be provided with a NETWORK/DATA COUPLING for communication to the authority having jurisdiction. This provides the RESPONSIBLE ORGANIZATION with a means of sending copies of data to the public health authorities when required. The secondary screening area should have telephone and electronic communications connections in case of emergency.

— **Adequate source of SUPPLY MAINS**: Since a SCREENING THERMOGRAPH can have a prolonged stabilization period prior to being ready for use, consideration should be given to a means of providing a reliable source of SUPPLY MAINS. Even a short transient loss of SUPPLY MAINS or start-up can cause a 30 min to 40 min delay in the availability of use. Such delays can cause a significant disruption in the flow of traffic.

— **Lighting**: There are several significant issues that should be considered. The ambient visual light level should be adequate for the OPERATOR to determine that the individual being screened is properly positioned and free from obstruction. The lighting source should not produce significant IR emissions, as those can interfere with the thermal image. If visual imaging is provided, the light level should be adequate for image quality.

— **IR sources**: Thermal sources, either hot or cold, need to be avoided in the area around the SCREENING THERMOGRAPH. Sun-facing windows, radiant heaters or sources of cold (cold windows or outside walls) can interfere with the SCREENING THERMOGRAPH.

  — The traffic layout should be designed to channel the traffic into a single file prior to entering each SCREENING THERMOGRAPH area.

  — Toilets should not be proximal to the SCREENING THERMOGRAPH area. This is to both inhibit potential cross-infection and to prevent facial washing (alteration of the thermal profile) immediately prior to entering the SCREENING THERMOGRAPH area.

b) Factors to consider in the environment of a SCREENING THERMOGRAPH should include the following.

— **Humidity and temperature**: the area leading to the SCREENING THERMOGRAPH and the immediate area around the SCREENING THERMOGRAPH should be maintained at a humidity level below 50 % and a temperature below 24 °C to minimize the effects, of elevated humidity and ambient temperature, which can produce sweating. See References [51], [53] and [54].

— Significant convective airflow should be avoided in the SCREENING THERMOGRAPH area.

c) Factors to consider in the set-up of a SCREENING THERMOGRAPH should include the following.

— The infrared camera of the SCREENING THERMOGRAPH should be positioned perpendicular, both horizontally and vertically, to the FACE of the individual being screened so that both regions medially adjacent to the inner canthi can be imaged.

— The individual being screened and the EXTERNAL TEMPERATURE REFERENCE SOURCE should be in the correct position and orientation relative to the camera for proper focal distance, depth of field and image capture. There should be a means of ensuring that the individual being screened is in this proper position, e.g. a stool, marks on the floor. Consideration should be given to individuals in wheelchairs.

— The backdrop behind the individual being screened and, where utilized, side screens should be

  — thermally uniform,

  — non-reflective in the IR spectrum, and

  — not dark in colour in the visible spectrum (closer to white than black).

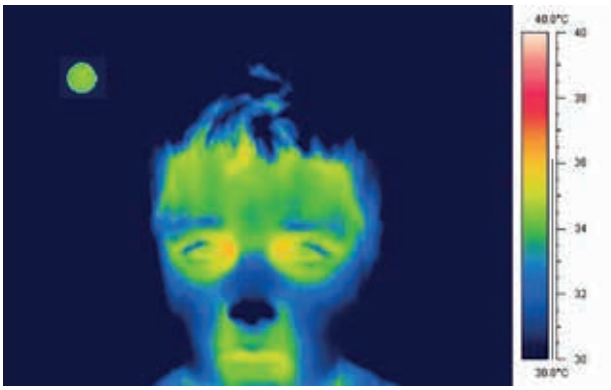
— The OPERATOR should be positioned with a clear visual field of the individual being screened and the display of the SCREENING THERMOGRAPH. The OPERATOR can need to intervene to correct the individual's position. The OPERATOR should also be positioned in such a way as to divert individuals to the secondary screening area when required.

— OPERATORS should be assessed as to their ability to discern the colours of the rainbow scale of the SCREENING THERMOGRAPH.

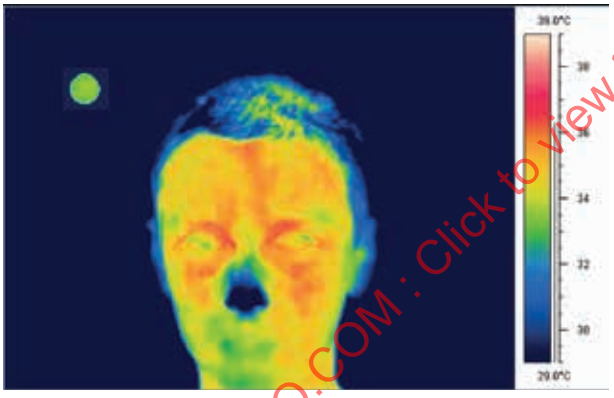
Annex B
(informative)

Example facial thermograms

Figures B.1 to B.3 show example thermograms from a SCREENING THERMOGRAPH.



a)



b)

c)

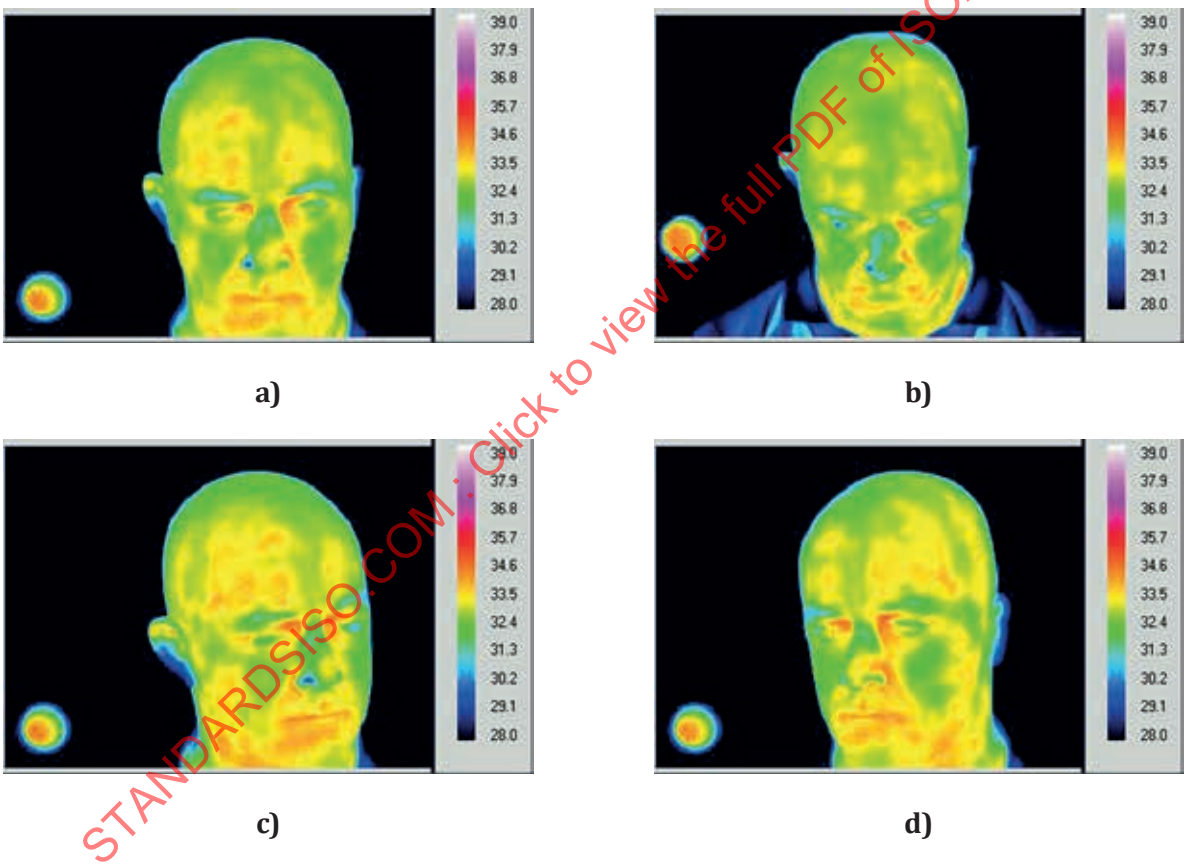
a) Normal afebrile male individual with a mean region medially adjacent to the inner canthi temperature of 36,6 °C and an EXTERNAL TEMPERATURE REFERENCE SOURCE temperature of 35,0 °C.

b) Female individual with an abnormal thermal pattern due to sinusitis. The regions medially adjacent to the inner canthi are within normal range at 36,7 °C. The display scale has been adjusted by 1 °C at each end (to 29 °C and 39 °C) to demonstrate the thermal pattern more clearly.

c) Febrile male individual with regions medially adjacent to the inner canthi temperatures of 37,9 °C (left eye), 38,4 °C (right eye) and an EXTERNAL TEMPERATURE REFERENCE SOURCE temperature of 35,0 °C.

NOTE These thermograms were acquired under optimal conditions as described in IEC 80601–2-59. Each individual is facing the camera lens at the correct level and position to avoid rotation or vertical misalignment. This ensures that both regions medially adjacent to the inner canthi of the eyes are equal in size and are optimally imaged for temperature measurement.

Figure B.1 — Examples of properly positioned individuals



a) Normal afebrile male individual properly positioned. The regions medially adjacent to the inner canthi temperatures are 34,3 °C (left eye), 34,4 °C (right eye) and the EXTERNAL TEMPERATURE REFERENCE SOURCE temperature is 35,0 °C. The display scale is adjusted to 28 °C and 39 °C to demonstrate the thermal pattern more clearly.

b) Same individual as in a), looking down. The regions medially adjacent to the inner canthi temperatures are 33,9 °C (left eye), 33,4 °C (right eye) and the EXTERNAL TEMPERATURE REFERENCE SOURCE temperature is 35,0 °C. The display scale is adjusted to 28 °C and 39 °C to demonstrate the thermal pattern more clearly.

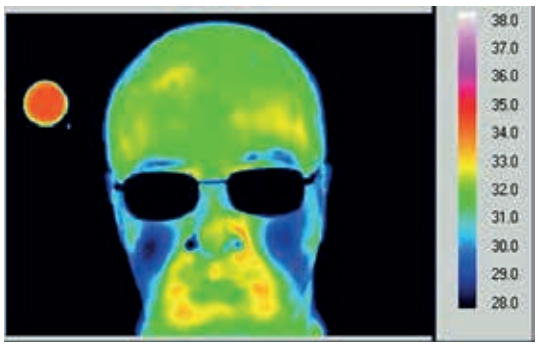
c) Same individual as in a), looking left. The regions medially adjacent to the inner canthi temperatures are 33,8 °C (left eye), 34,0 °C (right eye) and the EXTERNAL TEMPERATURE REFERENCE SOURCE temperature is 35,0 °C. The display scale is adjusted to 28 °C and 39 °C to demonstrate the thermal pattern more clearly.

d) Same individual as in a), looking right. The regions medially adjacent to the inner canthi temperatures are 33,9 °C (left eye), 33,3 °C (right eye) and the EXTERNAL TEMPERATURE REFERENCE SOURCE temperature is 35,0 °C. The display scale is adjusted to 28 °C and 39 °C to demonstrate the thermal pattern more clearly.

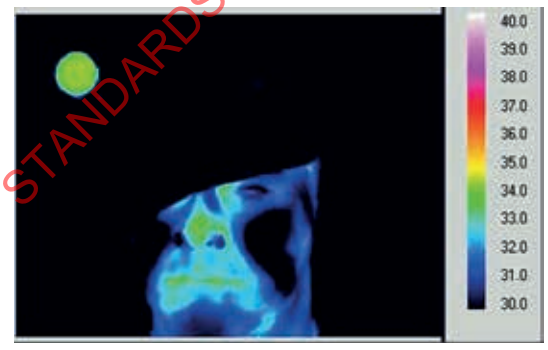
NOTE Unless the FACE and camera lens are correctly aligned, errors of up to 1 °C can be introduced. Such errors usually lower the temperature value measured.

Figure B.2 — Examples of effects of improperly positioned individuals

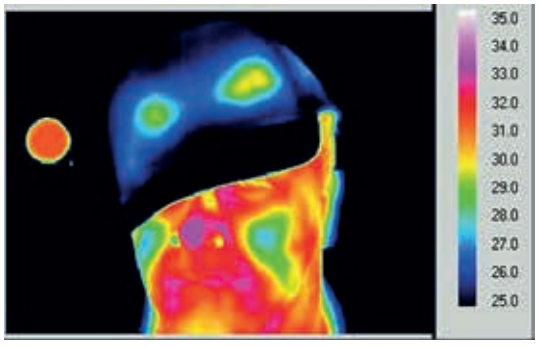
a)



b)



c)



d)