TECHNICAL REPORT

ISO/TR 13154

First edition
2009-04-01

Medical electrical equipment — Deployment, implementation and operational guidelines for indentifying 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

Reference number
ISO/TR 13154:2009(E)

PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. The ISO Central Secretariat accepts no liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies. In the unlikely event that a problem relating to it is found, please inform the Central Secretariat at the address given below.

COPYRIGHT PROTECTED DOCUMENT

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In exceptional circumstances, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example), it may decide by a simple majority vote of its participating members to publish a Technical Report. A Technical Report is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

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.

ISO/TR 13154 was prepared by Technical Committee 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*.

Introduction

This Technical Report was derived, in part, from SPRING Technical Reference 15.[1] [2] The SPRING Technical Reference was created as result of the Singapore experiences during the SARS epidemic.[6] [7] [10] [12] [13] [16]

Pandemics of influenza have swept the world from time to time throughout history, including three times in the last century. They caused widespread illness, large numbers of deaths, notably among children and young adults, and huge societal disruption, concentrated in just a few weeks. There is currently rising concern that a new influenza virus with pandemic potential will emerge and spread, and a further pandemic can be expected. It is not known when that will be but the consequences, whenever it occurs, will be serious, with around a quarter of the population possibly affected. This could be over one or more cycles, each lasting around three months. See Reference [10]. It should be noted that current estimates indicate that it will take approximately five months to develop, produce and distribute a pandemic vaccine following the declaration of a pandemic and isolation of the pandemic virus. See Reference [12].

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 will be key to preparing for, and responding to, a pandemic.

The ability to limit the spread of a pandemic disease, target public health interventions, and limit the unintended consequences of these actions will be greatly enhanced by the widespread availability of cost-effective screening tools for influenza viruses such as rapid diagnostic tests. Early outbreak detection with continued surveillance of travellers and the institution of appropriate measures, including social distancing, isolation of infected individuals, quarantine of suspected cases or treatment with antiviral medication, can help delay or limit the spread of a virus once a case occurs. 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 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, and information-sharing and cooperation to manage borders. See Reference [5].

Influenza is not the only possible pandemic disease. SARS, tuberculosis, anthrax, MRSA and other biological or bacterial agents can cause a widespread pandemic. The sources of such diseases can be naturally occurring, accidental releases or the result of subversive activities.

Individual screening of all persons entering a country, for influenza-like illness and risk factors for infection with a pandemic strain, will help minimize the likelihood of transmission. However, such screening is challenged by a lack of sensitivity (e.g. asymptomatic infected individuals may not be detected) and specificity (e.g. many individuals with influenza-like illness will not be infected with a pandemic strain). The typical incubation period for influenza is two days, and infected persons with influenza may be contagious for 24 h prior to the onset of symptoms. Other possible pandemic diseases have longer incubation periods. Since some asymptomatic travellers who are incubating a disease may 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, may 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. See Reference [5].

During the outbreaks of severe acute respiratory syndrome (SARS) in 2003, internationally agreed measures designed to restrict the movement of people possibly infected with SARS were instituted and were assessed by WHO to have greatly contributed to bringing the disease under control.

Influenza is more infectious than SARS, is most infectious early in the course of the disease (and possibly even before symptoms begin), and has a much shorter incubation period (one to three days). These important differences make it unlikely that similar interventions will do more than delay or slow the transmission of pandemic influenza at best, but this may still be deemed useful. Possible measures 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; see Reference [15].

In a severe pandemic, absenteeism attributable to illness, the need to care for ill family members and fear of infection may 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 absenteeism. 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 epidemic spreads, are important public policy objectives. See Reference [5]. To support these objectives, a screening thermograph can be useful to separate potentially infectious individuals from others in pandemic situations in locations such as:

— 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;

— 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 is a non-contact, accurate and repeatable means of quickly screening individuals for fever when proper procedures are followed.

NOTE The requirements for a screening thermograph are found in IEC 80601-2-59.

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

IMPORTANT — The colours represented in the electronic file of this document are considered as important colours for a correct understanding and use of this document but are not considered as mandatory precise colours. ISO strongly recommends to print this electronic file on a colour printer.

1 Scope

This Technical Report provides general guidelines for the deployment, implementation and operation of a screening thermograph intended to be used for individual non-invasive febrile temperature screening of humans 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

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 80601-2-56, *Medical electrical equipment — Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement*

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

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

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

[IEC 60601-1:2005, definition 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**

[IEC 60601-1:2005, definition 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

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**

[IEC 60601-1:2005, definition 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

[IEC 80601-2-59:2008, definition 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 The **measuring site** can be the same as the **reference body site**.

[ISO 80601-2-56:—[1)], definition 201.3.206]

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

NOTE 2 An ideal blackbody is described by Planck's Law.

[IEC 80601-2-59:2008, definition 201.3.204]

3.8
essential performance
performance necessary to achieve freedom from unacceptable risk

NOTE **Essential performance** is most easily understood by considering whether its absence or degradation would result in an unacceptable **risk**.

[IEC 60601-1:2005, definition 3.27]

1) To be published.

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 The **external temperature reference source** is normally imaged in each thermogram or prior to each thermogram.

[IEC 80601-2-59:2008, definition 201.3.205]

3.10
face
anterior cranial face of the **patient** being measured

[IEC 80601-2-59:2008, definition 201.3.206]

3.11
functional connection
connection, electrical or otherwise, including those intended to transfer signals, data, power or substances

NOTE 1 Connection to a fixed **supply mains** socket-outlet, whether single or multiple, is not considered to result in a **functional connection**.

[IEC 60601-1:2005, definition 3.33]

NOTE 2 A **network/data coupling** is a **functional connection**.

3.12
harm
physical injury or damage to the health of people or animals, or damage to property or the environment

[IEC 60601-1:2005, definition 3.38]

3.13
hazard
potential source of **harm**

[IEC 60601-1:2005, definition 3.39]

3.14
intended use
use of a product, process or service in accordance with the specifications, instructions and information provided by the **manufacturer**

NOTE **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, service, transport, etc.

[IEC 60601-1:2005, definition 3.44]

3.15
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 ISO 13485 [17] 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 Technical Report, that material is described as markings and **accompanying documents**.

NOTE 2 "Adapting" includes making substantial modifications to **me equipment** or an **me system** already in use.

NOTE 3 In some jurisdictions, the **responsible organization** can be considered a **manufacturer** when involved in the activities described.

NOTE 4 Adapted from ISO 14971:2007, definition 2.8.

[IEC 60601-1:2005, definition 3.55]

3.16
measuring site
part of a **patient** where the temperature is measured

EXAMPLES Pulmonary artery, distal esophagus, sublingual cavity in the mouth, rectum, ear canal, axilla (armpit), forehead skin.

[ISO 80601-2-56:—, definition 201.3.212]

3.17
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**;

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 **Me equipment** includes those **accessories**, as defined by the **manufacturer**, which are necessary to enable the normal use of the **me equipment**.

NOTE 2 Not all electrical equipment used in medical practice falls within this definition (e.g. some *in vitro* diagnostic equipment).

NOTE 3 The implantable parts of active implantable medical devices can fall within this definition, but they are excluded from the scope of this Technical Report by appropriate wording in Clause 1.

[IEC 60601-1:2005, definition 3.63]

3.18
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 Equipment, when mentioned in this Technical Report, includes **me equipment**.

[IEC 60601-1:2005, definition 3.64]

3.19
multiple socket-outlet
one or more socket-outlets intended to be connected to, or integral with, flexible cables or cords or **me equipment** for **supply mains** or equivalent voltage

NOTE A **multiple socket-outlet** can be a separate item or an integral part of the equipment.

[IEC 60601-1:2005, definition 3.67]

3.20
network/data coupling
any means to transmit or receive information to or from other equipment in accordance with the **manufacturer's** specifications

NOTE A **network/data coupling** is a **functional connection**.

[IEC 60601-1:2005, definition 3.68]

3.21
normal condition
condition in which all means provided for protection against **hazards** are intact

[IEC 60601-1:2005, definition 3.70]

3.22
normal use
operation, including routine inspection and adjustments by any **operator**, and stand-by, according to the instructions for use

NOTE **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 also maintenance, service, transport, etc.

[IEC 60601-1:2005, definition 3.71]

3.23
objective evidence
information that can be proven true, based on facts obtained through observation, measurement, test or other means

[IEC 60601-1:2005, definition 3.72]

3.24
operator
person handling equipment

[IEC 60601-1:2005, definition 3.73]

3.25
output temperature
temperature indicated by a thermometer

NOTE Methods of indication can include: printed, spoken, displayed and displayed remotely.

[ISO 80601-2-56:—, definition 201.3.215]

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

NOTE In the context of this Technical Report, an individual being screened is a **patient**.

[IEC 60601-1:2005, definition 3.76]

3.27
record
document that furnishes **objective evidence** of activities performed or results achieved

[IEC 60601-1:2005, definition 3.98]

3.28
reference body site
part of a **patient** to which the **output temperature** refers

[ISO 80601-2-56:—, definition 201.3.219]

3.29
responsible organization
entity accountable for the use and maintenance of an **me equipment** or an **me system**

NOTE 1 The accountable entity can be, for example, a hospital, an individual clinician or a layperson. In home use applications; the **patient**, **operator** and **responsible organization** can be one and the same person.

NOTE 2 Education and training is included in "use".

[IEC 60601-1:2005, definition 3.101]

3.30
risk
combination of the probability of occurrence of **harm** and the **severity** of that **harm**

[IEC 60601-1:2005, definition 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 A **screening thermograph** is non-contact, non-invasive temperature screening **me equipment** used to measure the **face** temperature and indicate the screened region with a different colour if the temperature is above the **threshold temperature** setting.

NOTE 2 A **screening thermograph** has to identify the **target** from the thermogram to obtain the **target** temperature reading.

[IEC 80601-2-59:2008, definition 201.3.209]

3.32
severity
measure of the possible consequences of a **hazard**

[IEC 60601-1:2005, definition 3.114]

3.33
single fault condition
condition in which a single means for reducing a **risk** is defective or a single abnormal condition is present

[IEC 60601-1:2005, definition 3.116]

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

[IEC 80601-2-59:2008, definition 201.3.211]

3.35
supply mains
source of electrical energy not forming part of **me equipment** or **me system**

NOTE This also includes battery systems and converter systems in ambulances and the like.

[IEC 60601-1:2005, definition 3.120]

3.36
target
region of the **face** selected for **threshold temperature** comparison

[IEC 80601-2-59:2008, definition 201.3.212]

3.37
target plane
in-focus plane perpendicular to the line of sight of a **screening thermograph**

[IEC 80601-2-59:2008, definition 201.3.213]

3.38
training
application-specific **operator**-oriented instruction or exercises required for the safe and effective use of the **me equipment**

[IEC 60601-1-6:2006, definition 3.8]

3.39
threshold temperature
temperature setting above which the **screening thermograph** indicates that the **target** is potentially febrile

NOTE This is typically indicated in degrees centigrade.

[IEC 80601-2-59:2008, definition 201.3.214]

3.40
workable target plane
region of the **target plane** which meets the specified performance requirements

NOTE The workable **target plane** can be the whole or a part of the **target plane**.

[IEC 80601-2-59:2008, definition 201.3.215]

4 General considerations

This Technical Report 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 individual non-invasive febrile temperature screening of humans 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 divert airflow from blowing directly on to 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 temperature. 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 Reference [1]. 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 will occur. 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 fixed 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 will 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.

Since the screening thermograph is a medical device for screening (i.e. potentially identifying) febrile individuals, the responsible organization should 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.

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. It is therefore 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 inner canthus and not the body core temperature; there is a small difference in temperature between these two sites. 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.

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 facial temperature distribution one at a time. Measuring individuals one at a time facilitates the capture of the reliable thermogram and allows the identification of the individual 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 line of sight between the screening thermograph and its external temperature reference source is not obstructed 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 the 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. The screening thermograph is intended to detect a human face with elevated skin temperature. A raised temperature needs to be confirmed by temperature measurement using a clinical thermometer. 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 will not obstruct the mainstream traffic flow.

In some events and functions, when the screening thermograph is to be used together with other screening devices such as a metal detection device, 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 these devices appropriately.

6.3 Interpretation of screening results

Obtaining meaningful temperature measures for the human body requires identifying a body site that will provide 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 inner canthus of the eye has been demonstrated to be a robust measurement site and is supplied by the internal carotid artery. See References [4], [6] and [9]. It is for this reason that a screening thermograph utilizes 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 identification of suspected febrile individuals. Hence it is important that they are sufficiently trained in the following areas.

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

b) They 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) They should be familiar with the work flow, safety issues and protocol of the responsible organization.

d) They 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:

a) the evaluation and purchase of the screening thermograph;

b) the number, proper location and installation of each screening thermograph and the secondary screening station.

NOTE 1 Screening protocols should be optimized in consideration of the incubation times of various diseases.

EXAMPLE 1 In the transportation environment, screening should be considered both before and after travel for long journeys.

c) protocol development:

— 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,

EXAMPLE 3 Supply mains failure or equipment failure.

— process for handling an individual who is suspected of being febrile (individual who exceeds the threshold temperature),

— process for secondary screening an individual who is suspected of being febrile,

— procedure for referral to the public health authority,

— 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 2 The minimum service interval for a screening thermograph that complies with IEC 80601-2-59 is 14 d. Longer service intervals are possible.

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. The information can include a visible light image. Collecting the data, managing them and promptly reporting them to the public health authorities 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.

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 should be maintained.

Annex A
(informative)

Deployment considerations

The successful application of a screening thermograph is dependant 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: 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.

— Secondary screening area: the secondary screening area is a patient care area that needs to be 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 planeload 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 screening thermograph should be provided with a data connection for its network/data coupling. This provides the responsible organization with a means of sending data to the public health authorities when required. Additionally, the screening thermograph area should be provided with telephone connections for alerting the public health authorities, as necessary.

— 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 the 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 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 on the temperature reading, of elevated humidity and ambient temperature caused by sweating.

NOTE 3 The measurements provided by a screening thermograph 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. See Reference [3].

— Significant convective air flow 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 camera of the screening thermograph should be positioned perpendicular, both horizontally and vertically, to the face of the individual being screened so that both 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, high emissivity (non-reflective in the IR spectrum) and light in colour (visible spectrum).

— The operator should be positioned with a clear visual field of the individual being screened and the display of the screening thermograph. The operator may 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.