TECHNICAL REPORT

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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

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Foreword

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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is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

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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.

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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]

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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]