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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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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.

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).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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]