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BSI Standards Publication

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

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National foreword

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TECHNICAL REPORT

ISO/TR 13154

Second edition
2017-03

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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Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
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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.

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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]

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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

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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.

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TECHNICAL REPORT ISO/TR 13154:2017(E)

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]

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