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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

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.

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is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

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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 coordination, 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 80601-2-69.

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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]