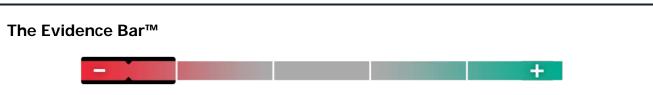


Infrared Temperature Screening to Identify Potentially Infected Staff or Visitors Presenting to Healthcare Facilities during Infectious Disease Outbreaks

Editorial note: Updated September 9, 2020. One diagnostic cohort study added; guidelines section updated.

Temperature monitoring during infectious disease outbreaks has become commonplace, and various monitoring approaches have been taken at public entry points, such as at health systems and airports. A common monitoring approach has been the use of external infrared (IR) temperature screening devices with or without questionnaires for visitors and staff entering healthcare facilities to identify those who may have potentially infectious disease and prevent their entry into the facility. This report focuses on the accuracy of these systems for identifying infected visitors or staff.



Evidence is unfavorable

Temperature screening programs using IR alone or with a questionnaire for mass screening are ineffective for detecting infected individuals, based on our review of evidence from 1 large systematic review (SR), 1 health technology assessment (HTA), 3 simulation studies, 7 diagnostic cohort studies, 3 case-control studies, and 2 case series not included in the SR or HTA. In best-case scenarios, simulation studies suggest such screening will miss more than half of infected individuals. Such programs are ineffective because of the low number of infected individuals with fever when screened, inconsistent operator technique, and the fact that >40% of individuals with SARS-CoV-2 are asymptomatic but infectious. Adding questionnaires does not increase screening accuracy due to environmental temperatures, false answers to questionnaires, and use of fever-reducing drugs. FDA guidance states, "Temperaturebased screening, such as thermal imaging, is not effective at determining if someone definitively has COVID-19... A diagnostic test must be performed to determine if someone has COVID-19." Temperature screening to reduce infection transmission risk from visitors and staff entering healthcare facilities could provide a false sense of safety. Evidence limitations and strengths: The evidence base is large and current. The effectiveness of airport screening with IR devices has been examined in a recent SR of 27 studies, and the effectiveness of IR device screening has been examined in an SR of 20 studies. Of the 15 additional studies we identified, most were conducted outside the United States, but 2 of the newest diagnostic cohort studies were conducted in the United States. Variations across studies are due primarily to variations in the devices used both for noncontact IR measurements and standard reference temperature measurements.

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Executive Summary

Findings

We assessed 1 SR, 1 HTA, and 15 additional studies that examined use of IR technology to screen temperature at airports or healthcare facilities.

- 1 SR (Mouchtouri et al. 2019) examined exit and entry screening at airports, ports, and border crossings and reported very low infection detection rates.
- 1 HTA (Canadian Agency for Drugs and Technologies in Health [CADTH], 2014) examined the effectiveness of noncontact thermometers in hospital settings and reported that evidence for the accuracy of handheld IR skin thermometers is mixed (favored by 3 studies and not favored by 3 studies).
- Sensitivity for detecting fever: Three simulation studies of airport screening programs (Gostic et al. 2020, Quilty et al. 2020, Gostic et al. 2015) assumed IR thermal scanner sensitivity (ability to detect fever) was 70%, 86%, and 70%, respectively, and reported detection rates were 30%, 54%, and 25% to 50%, respectively. Seven diagnostic cohort studies reported IR skin thermometer sensitivities (Chen et al. 2020, Fong et al. 2020, Hogan et al. 2015, Tay et al. 2015, Hausfater et al. 2008) of 93%, 3.7%, 24%, 29%, and 76%, respectively, and IR camera sensitivities (Tay et al. 2015, Nguyen et al. 2010, Chiang et al. 2008) of 90%, 91%, and 57%, respectively. Three case-control studies (Bardou et al. 2017, Sun et al. 2016) reported IR camera sensitivities of 93%, 88%, and 96%, respectively.
- Distance and accuracy: Two case series (Sun et al. 2017, Suzuki et al. 2010) reported decreased accuracy as distance from subject increased and in colder environmental temperatures.

Evidence

Search dates: January 1, 2008, through August 25, 2020. We reviewed full text of 1 SR and 1 HTA and 15 additional studies not included the SR or HTA and reporting on nearly 10,000 people.

- We identified and included 2 SRs, 3 simulation studies, 7 cohort studies, 3 case-control studies, and 2 case series. We
 excluded studies of pediatric patients and studies already included in the SRs (which primarily assessed airport
 screening).
- 1 SR (Mouchtouri et al. 2019, 27 studies) and 1 HTA (CADTH 2014, 16 studies and 4 SRs) assessed entry and exit airport screening programs and noncontact thermometers for detecting fever in a hospital setting and reported effectiveness.
- 3 simulation studies (Gostic et al. 2020, Quilty et al. 2020, Gostic et al. 2015) assessed effectiveness of screening programs using noncontact thermometers.
- 7 diagnostic cohort studies (Chen et al. 2020, n = 528; Fong et al. 2020, n = 1,576; Hogan et al. 2015, n = 548; Tay et al. 2015, n = 430; Nguyen et al. 2010, n = 2,873; Chiang et al. 2008, n = 1,032; Hausfater et al. 2008, n = 2,026) in which patients entered a medical center for health reasons were examined with a noncontact device and a more traditional contact body temperature measurement device and reported sensitivity and specificity.
- 3 case-control studies (Bardou et al. 2017, n = 625; Sun et al. 2017, n = 38; Sun et al. 2016, n = 87) in which ill and healthy patients were compared using 1 or more temperature measurement devices and reported sensitivity and specificity.
- 2 case series (Sun et al. 2014, n = 155; Suzuki et al. 2010, n = 50) examined thermography and effects of distance and environmental temperature and reported sensitivity and specificity.

Guidelines

We searched PubMed, EMBASE, and ECRI Guidelines Trust® (EGT) for guidelines published from January 1, 2015, through August 25, 2020. We identified 10 relevant documents.

 Of these 10 documents, only an FDA document provides specific guidance about using noncontact IR temperature devices for COVID-19 detection: FDA states the technology is ineffective for COVID-19 detection.



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Background

Fever Detection and Infrared Devices

The body's response to infectious disease organisms often results in a core body temperature increase. Normal internal body temperature is 98.6°F (37°C) and ranges from 96°F to 100.8°F (see the eMedicineHealth article <u>Fever</u> in <u>Adults</u> and the Medscape article <u>Fever of Unknown Origin</u>). A core body temperature of 100.4°F (38°C) or above, preferably measured in the rectum, is considered a fever. Some authors have proposed slightly higher temperatures (100.8°F, 38.2°C) (see <u>Walter et al. 2016</u>).

Traditional temperature-measurement devices (glass/mercury and electronic thermometers) come in contact with the patient's body (under the tongue, in the rectum, or under the arm). Handheld IR thermometers may substitute for contact thermometers by measuring a patient's emitted thermal radiation from the ear canal (still using skin contact) or a noncontact device measuring the forehead skin (see ECRI report <u>Thermometers, Electronic, Infrared</u>). IR thermometers have an IR probe, electronic circuitry, a microprocessor, and a display. Probe covers are needed when measuring the ear canal. Temperatures are displayed in fewer than five seconds. Inaccurate and inconsistent measurements are commonly reported problems with these devices, especially the noncontact devices, and are usually due to inconsistent technique by healthcare workers. Patient movement and cold weather affect skin thermometers. For a list of handheld IR thermometers, see the ECRI report <u>Thermometers, Electronic, Infrared</u>.

IR cameras (IR thermography) may also be used as a noncontact means of measuring a person's temperature (see <u>The Use of Thermography in Elevated Body Temperature Screening</u>). These devices produce a thermal image on a video monitor and calculate body temperatures based on skin temperatures. Human error, environmental conditions, and equipment variables can affect IR camera accuracy. Temperatures too warm or too cold will affect IR cameras. Optimal environmental temperatures are 18°C to 24°C (64°F to 75°F). The International Organization for Standardization has set technical guidelines for using IR cameras (see Guidelines section below).

IR devices allow real-time body temperature assessment, which may then allow for early quarantine of infected individuals and prevent them from entering a healthcare facility. Mass screening with IR devices (handheld IR thermometers and IR cameras) have been used during outbreaks of infectious disease pandemics, such as Ebola virus disease, severe acute respiratory syndrome (SARS), and COVID-19.(1) Shortly after diagnosing COVID-19 in its first patient, Kaohsiung Chang Gung Memorial Hospital in Taiwan introduced IR cameras at hospital entrances and the emergency department to scan staff and visitors.(2) Those identified by the scan were confirmed with a tympanic thermometer.

Deficiencies of Mass Screening for COVID-19

Several authors have noted specific deficiencies with mass screening using IR devices. The primary problem with mass screening is many infected subjects will not have a temperature.(3-5) Bwire and Paulo (2020) have cautioned:

[B]ody temperature might not be an adequate screening as it can potentially miss travelers incubating the disease or travelers concealing fever during travel and contribute to the importation of the virus to the countries of destination. Therefore, travel restrictions to and from high risk areas and/or 14-day quarantine of people coming from high risk areas are recommended to prevent possible importation of COVID-19.(5)

Several recent publications have provided further evidence of the extent of asymptomatic individuals infected with SARS-CoV-2 virus. Oran and Topol (2020) estimated that asymptomatic individuals account for approximately 40% to 45% of SARS-CoV-2 infections and may transmit the virus for up to 14 days.(6) Their findings are based on a systematic literature search, review, and analysis of 16 cohorts testing for SARS-CoV-2 infection using real-time reverse transcriptase polymerase chain reaction and nasopharyngeal swab samples. The cohorts varied from Iceland, to cities in Europe and the United States, cruise line passengers, and naval vessels. Due to the high risk of virus spread from asymptomatic individuals, the authors believe "it is imperative that testing programs include those without symptoms." A report based on data collected through January 2020 from 552 hospitals throughout China (1,099 patients with laboratory-confirmed COVID-19) indicated that only 43.8% had a fever on admission.(7) Fever



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did develop in 88.7% during hospitalization. The authors noted the lack of fever in many patients complicates the diagnosis. Bielecki et al. alerted readers of Travel Medicine and Infectious Disease to the futility of body temperature screening at airports and border entry points.(8) In their study, 83% of 84 patients with COVID-19 (mostly young male recruits in military basic training) never developed a fever (measured with a tympanic thermometer).

Gostic et al. (2020) describe the impact of possible screening programs for COVID-19.(3) In their best-case simulation of mass screening "nearly two-thirds of infected travelers will not be detectable," and "in a growing epidemic, the majority of travelers will have been recently infected and hence will not yet have progressed to exhibit any symptoms." The authors also asserted that the low proportion of cases that would self-report truthfully on a screening questionnaire would decrease the effectiveness of screening programs. Aw (2020) has also commented on the reliability of handheld IR thermometers and noted measurement inaccuracies and low sensitivity.(4) Sun et al. (2014) noted that "some of the patients [in their study] were misdiagnosed as normal because they were taking medication to reduce fever."(9). Tay et al. (2015) have noted difficulties in using IR detection systems for fever-screening in tropical conditions (see below).(10) Other research has found that commonly used cosmetic products interfere with accurate IR camera reading.(11)

The <u>Centre for Evidence-Based Medicine</u> (Nuffield Department of Primary Care Health Sciences, Oxford, UK), matching ECRI's assessment, has warned against using IR thermometers to screen for COVID-19, citing the lack of a detectable fever in many SARS-CoV-2 infected individuals. In its assessment, the center states: "Temperature screening is not reliable and should therefore not be used."

An editorial by Howell et al. (2020) notes that IR thermal imaging cameras are not being used according to ISO guidelines (see below).(12) Equipment intended for industrial and not medical use has been used for mass screening. Individuals, not groups, should be assessed facing the camera with the face unobscured by masks, eyeglasses, and headwear. The authors note: "It is far from certain that thermography could ever be useful as a rapid mass-screening tool for fever detection, we will never know the answer to this unless measurements are performed to rigorous standards, and the outcomes - that is to say positive and negative predictive values - recorded and published for scientific scrutiny."

See also <u>"Thermometer Guns" on Coronavirus Front Lines are "Notoriously Not Accurate"</u> and <u>Why Airport Screening</u> <u>Won't Stop the Spread of Coronavirus</u>.

<u>Ghassemi et al. (2018)</u> describe how commercial IR devices are tested and evaluated for stability and drift, image uniformity, minimum resolvable temperature difference, and radiometric temperature laboratory accuracy.(1) The authors used laboratory test methods based on International Electrotechnical Commission recommendations for standardized, objective, and quantitative assessment of IR performance. The authors note that environmental temperature and humidity can affect device accuracy.

Clinical Guidelines, Position and Consensus Statements

Searches of PubMed, EMBASE, <u>EGT</u>, and other web-based resources identified 10 guidelines and guidance documents relevant to fever screening published between January 1, 2014, and August 25, 2020. Only FDA provides specific guidance for using noncontact IR temperature devices and states it is ineffective for detecting COVID-19. Please review the full guideline or document for information on the level of recommendation and the strength of evidence supporting each guideline's recommendations.

FDA

<u>Thermal Imaging Systems (Infrared Thermographic Systems / Thermal Imaging Cameras)</u>. May 2020. In this document, FDA discusses the benefits and limitations of thermal imaging systems and proper use of these systems. FDA states the following regarding fever detection:

When used correctly, thermal imaging systems generally have been shown to accurately measure someone's surface skin temperature without being physically close to the person being evaluated. Thermal imaging systems offer certain benefits in that other methods need a closer proximity or



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contact to measure temperature (for example, non-contact infrared thermometers or oral thermometers).

Temperature-based screening, such as thermal imaging, is not effective at determining if someone definitively has COVID-19 because, among other things, a person with COVID-19 may not have a fever. A diagnostic test must be performed to determine if someone has COVID-19.

FDA also addresses questions about using thermal imaging systems during COVID:

Q: Are thermal imaging systems effective for screening people for fevers in places like nursing homes, airports, and hospital emergency rooms?

A: When using a thermal imaging system, it is important to assess whether the system will provide the intended results in high throughput areas. We understand that these devices are being used for initial temperature assessment and triage of individuals for elevated temperatures in medical and non-medical environments. They should not be used for measuring temperatures of many people at the same time in crowded areas, in other words "mass fever screening" is not recommended.

Based on where the system will be used, there may be more appropriate methods to initially assess and triage people, especially if there is a risk that infected people would not be identified right away. For example:

In a nursing home, inaccurate temperature measurement or a missed contagious person without a fever could spread infection among nursing home residents. So, in this case, other assessment options and following infection control practices may be more effective.

In airports, workplaces, grocery stores, concert venues, or other areas where you are trying to screen large groups of people for mass fever screening, diagnostic testing may be too difficult because of the time and costs needed to screen and get results. These systems will likely miss most individuals with COVID-19 who are contagious. Thermal imaging systems could be considered as one method for initial temperature assessment in these types of settings when used as part of a larger approach to risk management.

In a hospital emergency room, a thermal imaging system may help to quickly assess temperature and triage patients to determine who needs more evaluation or isolation.

Enforcement Policy for Telethermographic Systems during the Coronavirus Disease 2019 (COVID-19) Public Health <u>Emergency. Guidance for Industry and Food and Drug Administration Staff</u>. April 2020. FDA issued this guidance document "to provide a policy to help expand the availability of telethermographic systems used for body temperature measurements for triage use for the duration of the public health emergency declared by the Secretary of Health and Human Services (HHS) on January 31, 2020." In addition, "FDA is taking steps to help expand the availability of telethermographic systems and believes the policy set forth in this guidance may help address the urgent public health concerns raised by shortages of temperature measurement products such as thermometers and telethermographic systems by taking a risk-based approach and clarifying the policies that FDA intends to apply to telethermographic systems during the COVID-19 pandemic."

In our clinical evidence assessment, we refer to telethermographic devices as thermography. The guidance describes FDA's current thinking and should be viewed as recommendations and not required actions with regard to these devices. The guidance provides information on performance and labeling (e.g., performance specifications, calibration methods, environmental and set up factors, appropriate imaging distances). The labeling references should be consistent with the guidelines in ISO/TR 13154:2017 (see below). The guidance does not provide any recommendations for a temperature threshold for determining when an individual has a fever.

The guidance states the following regarding telethermographic systems:

The advantage of using telethermographic systems for initial temperature assessment for triage use is the potential use in high throughput areas (e.g., airports, businesses, warehouses, factories)



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and in settings where other temperature assessment products may be in short supply. The available scientific literature supports the use of telethermographic systems in the context of initial human temperature measurement during such a triage process.

Telethermographic systems are devices when they meet the definition of a device set forth in section 201(h) of the FD&C Act (21 U.S.C. 321(h)). Under section 201(h) of the FD&C Act (21 U.S.C. 321(h)), these products are devices when they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease.

The labeling includes a prominent notice that the measurement should not be solely or primarily relied upon to diagnose or exclude a diagnosis of COVID-19, or any other disease; ... Elevated body temperature in the context of use should be confirmed with secondary evaluation methods (e.g., an NCIT [non-contact infrared thermometer] or clinical grade contact thermometer).

Centers for Disease Control and Prevention (CDC)

- <u>CDC Activities and Initiatives Supporting the COVID-19 Response and the President's Plan for Opening America</u> <u>Up Again</u>. May 2020. "This document briefly summarizes CDC's initiatives, activities, and tools in support of the Whole-of-Government response to COVID-19. The document states the following about temperature screening:
 - Under Interim Guidance for Child Care Programs / Monitoring and Preparing / Check for signs and symptoms (Steps 1–3)
 - Screen children upon arrival, if possible. Establish routine, daily health checks on arrival, such as temperature screening of both staff and children. Options for daily health check screenings for children are provided in CDC's supplemental Guidance for Child Care Programs that Remain Open and in CDC's General Business FAQs for screening staff.
 - Implement health checks (e.g. temperature checks and symptom screening) screenings safely and respectfully, and with measures in place to ensure confidentiality as well as in accordance with any applicable privacy laws or regulations. Confidentiality should be maintained.
 - o Under Interim Guidance for Schools and Day Camps / Check for signs and symptoms
 - If feasible, conduct daily health checks (e.g. temperature screening and/or symptoms checking) of staff and students safely, respectfully, as well as in accordance with any applicable privacy laws or regulations. Confidentiality should be maintained.
 - Under Interim Guidance for Employers with Worker at High Risk / Monitoring and Preparing / Check for signs and symptoms (Steps 1–3)
 - Consider conducting routine, daily health checks (e.g., temperature and symptom screening) of all employees.
 - Under Interim Guidance for Restaurants and Bars / Monitoring and Preparing / Check for signs and symptoms (Steps 1–3)
 - Consider conducting routine, daily health checks (e.g., temperature and symptom screening) of all employees.
 - Under Interim Guidance for Mass Transit Administrators / Monitoring and Preparing / Check for signs and symptoms (Steps 1–3)
 - Consider conducting routine, daily health checks (e.g., temperature and symptom screening) of all employees.
- <u>Interim U.S. Guidance for Risk Assessment and Work Restrictions for Healthcare Personnel with Potential</u> <u>Exposure to COVID-19</u>. Updated 2020 Jun 18. This document recommends the following for healthcare professionals (HCPs):
 - HCP who had prolonged close contact with a patient, visitor, or HCP with confirmed COVID-19.



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- Advise HCP to monitor themselves for fever or symptoms consistent with COVID-19.
- Any HCP who develop fever or symptoms consistent with COVID-19 should immediately contact their established point of contact (e.g., occupational health program) to arrange for medical evaluation and testing.
- HCP other than those with exposure risk described above.
 - Follow all recommended infection prevention and control practices, including wearing a facemask for source control while at work, monitoring themselves for fever or symptoms consistent with COVID-19 and not reporting to work when ill, and undergoing active screening for fever or symptoms consistent with COVID-19 at the beginning of their shift.
 - Any HCP who develop fever or symptoms consistent with COVID-19 should immediately self-isolate and contact their established point of contact (e.g., occupational health program) to arrange for medical evaluation and testing.

For the purpose of this guidance, fever is defined as subjective fever (feeling feverish) or a measured temperature of 100.0°F (37.8°C) or higher. Note that fever may be intermittent or may not be present in some people, such as those who are elderly, immunocompromised, or taking certain fever-reducing medications (e.g., nonsteroidal anti-inflammatory drugs).

- Preparing for COVID-19 in Nursing Homes. updated June 25, 2020. This document recommends screening of healthcare workers, residents, and visitors for fever and respiratory symptoms.
- <u>Steps Healthcare Facilities Can Take Now to Prepare for Coronavirus Disease 2019 (COVID-19)</u>. [cited 2020 Aug 25]. This document recommends that healthcare facilities "screen patients and visitors for symptoms of acute respiratory illness (e.g., fever, cough, difficulty breathing) before entering your healthcare facility."</u>
- <u>Infection Prevention and Control Recommendations for Hospitalized Patients Under Investigation (PUIs) for</u> <u>Ebola Virus Disease (EVD) in U.S. Hospitals</u>. 2018. The guidance is intended for healthcare personnel in any healthcare setting and is most relevant for hospital staff caring for a patient under investigation or patient with confirmed Ebola virus disease (EVD). The guidance states:

Visits should be scheduled and controlled to allow for:

Screening for EVD (fever and other symptoms) before entering or upon arrival to the hospital.

Evaluating risk to the health of the visitor and ability to comply with precautions.

Providing instruction, before entry into the patient care area on hand hygiene, limiting surfaces touched, and use of [personnel protective equipment] according to the current facility policy while in the patient's room.

Visitor movement within the facility should be restricted to the patient care area and an immediately adjacent waiting area.

Other Guidelines and Standards

— ISO. <u>ISO/TR 13154:2017 Medical Electrical Equipment — Deployment, Implementation and Operational</u> <u>Guidelines for Identifying Febrile Humans Using a Screening Thermograph</u>. 2017 Mar. 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." The document states the following:

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. 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



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possible pandemic diseases have varying periods of latency or incubation. Since some asymptomatic travelers 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 travelers 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.

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:

- 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 is a non-contact, non-invasive, non-ionizing temperature screening me equipment used to measure the face temperature and indicate the screened region with a different color if the temperature is above the threshold temperature setting. Such a device is commonly referred to as an infrared camera.

— World Health Organization (WHO). <u>Management of III Travelers at Points of Entry – International Airports, Ports and Ground Crossings – in the Context of COVID-19 Outbreak</u>. Interim guidance. 2020 Feb 16. "This document aims to provide advice on detecting and managing ill travelers with suspected COVID-19 infection who arrive at international airports, ports and ground crossings, including those arriving in conveyances." The document recommends the following related to temperature screening:

If travelers will be screened for fever, handheld no-touch thermometers or thermal imaging cameras should be used to ascertain a traveler's temperature. Manual thermometers that require contact with skin or mucous membranes should not be used.

Signs or symptoms of illness suggesting respiratory infection should be evaluated, including fever >38° C or the traveler mentioning feeling feverish; cough; breathing difficulties.

 WHO. <u>Updated WHO Advice for International Traffic in Relation to the Outbreak of the Novel Coronavirus 2019-</u> <u>nCoV</u>. 2020 Jan 24. The document recommends the following:

Advice for exit screening in countries or areas with ongoing transmission of the novel coronavirus 2019-nCoV (currently People's Republic of China).

 Conduct exit screening at international airports and ports in the affected areas, with the aims early detection of symptomatic travelers for further evaluation and treatment, and thus prevent exportation of the disease, while minimizing interference with international traffic.



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 Exit screening includes checking for signs and symptoms (fever above 38°, cough), interview of passengers with respiratory infection symptoms leaving the affected areas with regards to potential exposure to high-risk contacts or to the presumed animal source, directing symptomatic travelers to further medical examination, followed by testing for 2019-nCoV, and keeping confirmed cases under isolation and treatment.

Advice for entry screening in countries/areas without transmission of the novel coronavirus 2019-nCoV.

 Evidence shows that temperature screening to detect potential suspect cases at entry may miss travelers incubating the disease or travelers concealing fever during travel and may require substantial investments. However, during the current outbreak with the novel coronavirus 2019-nCoV, the majority of exported cases were detected through entry screening. The risk of importation of the disease may be reduced if temperature screening at entry is associated with early detection of symptomatic passengers and their referral for medical follow up.

Clinical Literature

We searched PubMed, EMBASE, CINAHL, and selected web-based resources for documents relevant to this topic and published between January 1, 2008, and August 25, 2020. Our search strategies included the following keywords: fever/diagnosis; body temperature; thermometers; thermography. We identified and included one SR, one HTA, two simulation studies, and one cohort studies. We did not include studies of pediatric patients. We excluded studies already included in the SRs, which were primarily studies of airport screening.

The evidence to support use of a screening or diagnostic test can be broadly classified into three categories: analytic validity, clinical validity, and clinical utility, described as follows:

- Analytic validity refers to a test's ability to accurately and reliably measure the properties or characteristics it is intended to measure. Analytic validity is a function of many factors, including analytic accuracy, precision, reproducibility, uncertainty, traceability, robustness, analytic sensitivity, and analytic specificity. Analytic validity is generally established in controlled situations with laboratory reference standards.
- Clinical validity refers to the accuracy with which a test predicts the presence or absence of a clinical condition
 or predisposition. Clinical validity is usually described in terms of clinical sensitivity, clinical specificity, and
 positive and negative predictive values.
- Clinical utility refers to the test's usefulness and the information's value to medical practice. Clinical utility
 represents a balance between health-related benefits and the harms that can ensue from using the information
 that a test provides.

The most commonly used study design to evaluate a diagnostic test's accuracy is the diagnostic cohort study. All enrolled patients are examined with both the diagnostic test and the accepted reference standard test. Outcomes of interest are sensitivity, specificity, and positive and negative predictive values. Another commonly used study design for evaluating diagnostic tests is the case-control study. Patients known to have the disease, and patients known to not have the disease (healthy controls), are enrolled and evaluated with the diagnostic test of interest. A variant of the case-control study is the diagnostic case series, a study that enrolls only patients known to have the disease. Case-control/diagnostic case series generally overestimate the accuracy of diagnostic tests.

We review full text of articles available through open access or our library subscriptions and abstracts of the remaining articles. We identified and included one SR, one HTA, three simulation studies, seven cohort studies, three case-control studies, and two case series. We excluded studies of pediatric patients and studies already included in the SRs (which primarily assessed airport screening).



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Systematic Review and Health Technology Assessment

- 1 SR (27 studies, n = not reported) assessed entry and exit airport screening programs and reported effectiveness.(13)
- 1 HTA (16 studies, 4 SRs) assessed effectiveness of noncontact thermometers for detecting fever in a hospital setting. (14)

Simulation Studies

- 2 studies simulated the effectiveness of screening programs during the COVID pandemic.(3,15)
- 1 study simulated the effectiveness of screening programs in 2015.(16)

Clinical Cohort Studies

- 7 diagnostic cohort studies (n = 430, n = 1,576, n = 528, n = 548, n = 2,873, n = 1,032, n = 2,026) in which patients enter a medical center for health reasons are examined with a noncontact device and a more traditional contact body temperature measurement device and reported sensitivity and specificity.(10,17-22)
- 3 case-control studies (n = 625, n = 38, n = 87) compared ill and healthy patients using 1 or more temperature measurement devices and reported sensitivity and specificity.(23-25)
- 2 case series (155 patients with the seasonal flu, 50 healthy subjects) examined thermography and effects of distance and environmental temperature and reported sensitivity and specificity.(9,26)

Table 1 provides summaries of the SR and HTA. Table 2 provides summaries of the simulation studies. Table 3 provides summaries of the clinical cohort studies.

Evidence limitations and strengths: The evidence base is fairly large and up to date. The effectiveness of airport screening with IR devices has been examined in a recent SR of 27 studies, and the effectiveness of IR device screening has been examined in an HTA of 16 studies and 4 SRs. Of the 15 additional studies identified in our searches, most were conducted outside the United States, but 2 of the newest diagnostic cohort studies were conducted in the United States. Variations across studies are due primarily to variations in the devices used both for noncontact IR measurements and standard reference temperature measurements.

	J			
	Systematic	Resources		Conclusions
	Review	Searched and		Reported
Reference	Purpose	Inclusion Criteria	Findings	in the Abstract
Mouchtouri et al. 2019(13) systematic review Reviewed full text, subscription required	To analyze published evidence on worldwide practices, guidelines, and experiences in entry and exit screening during the past 15 years	Searched grey literature, PubMed, and Scopus for the past 15 years. Included "articles or reports or other documents published in peer-reviewed journals or national and international organizations' publications, from 2003 until May 2018 that report practices, implementation of guidelines, experiences, structures, processes, evaluation results about national	"Most of the available data identified through the systematic literature review concerned entry screening measures at airports. Little evidence is available about entry and exit screening measure implementation and effectiveness at ports and ground crossings. Exit screening was part of the World Health Organization's (WHO) temporary recommendations for implementation in certain points of entry, for specific time periods. Exit screening measures for Ebola Virus Disease (EVD) in the three most affected West African	"Exit screening measures in affected areas are important and should be applied jointly with other measures including information strategies, epidemiological investigation, contact tracing, vaccination, and quarantine to achieve a comprehensive outbreak management response. Based on review results, an algorithm about decision-making for entry/exit screening was developed." "Evidence from this review suggests that entry screening

Table 1. Systematic Review and Technology Assessment



Reference	Systematic Review Purpose	Resources Searched and Inclusion Criteria	Findings	Conclusions Reported in the Abstract
		routine or ad hoc entry or exit screening activities referring to travelers at ports or airports or ground crossings, worldwide, performed during serious cross- border health events." Included 27 studies.	countries did not identify any cases and showed zero sensitivity and very low specificity. The percentages of confirmed cases identified out of the total numbers of travelers that passed through entry screening measures in various countries worldwide for Influenza Pandemic (H1N1) and EVD in West Africa were zero or extremely low. Entry screening measures for Severe Acute Respiratory Syndrome (SARS) did not detect any confirmed SARS cases in Australia, Canada, and Singapore. Despite the ineffectiveness of entry and exit screening measures, authors reported several important concomitant positive effects that their impact is difficult to assess, including discouraging travel of ill persons, raising awareness, and educating the traveling public and maintaining operation of flights from/to the affected areas." "Training of staff is an important component and should address recognizing the signs and symptoms of the disease, screening procedures and documentation, and appropriate use of personal protective equipment and technology for measuring body temperature."	measures alone are not effective in detecting imported cases at borders, but may allow opportunities for raising awareness and educating the traveling public. The current review further suggests that there are difficulties in assessing the impact of border screening measures. Statistical data demonstrate very low detection rates of cases in both entry and exit screening. The decision about the implementation of screening measures should be examined on a case-by-case basis, after considering the disease and outbreak characteristics, the country situation, and the available resources, which can be compared to the cost and effectiveness of other alternative measures. Screening measures have important concomitant effects when implemented in combination with health education and informative strategies for travelers, the decision- making process should take those effects into consideration."
Canadian Agency for Drugs and Technologies in Health(14) 2014 Health	To determine the effectiveness and accuracy of noncontact thermometers for detecting febrile	Searched PubMed, the Cochrane Library (2014, Issue 10), University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major	Key Findings: "Evidence retrieved from sixteen non- randomized studies and four systematic reviews (SRs) supports the accuracy of tympanic thermometers and, more cautiously, of thermal scanners. Evidence for the	"The accuracy of handheld infrared skin thermometers were favored by three studies but also unfavored by three studies. Four studies expressed conclusions in favor of



Reference	Systematic Review Purpose	Resources Searched and Inclusion Criteria	Findings	Conclusions Reported in the Abstract
Technology Assessment Reviewed <u>full text</u>	individuals	international health technology agencies, as well as a focused Internet search limited to English- language documents published between January 1, 2004, and October 15, 2014. The intervention was tympanic thermometers, handheld infrared thermometers, and thermal scanners. Outcome was diagnostic accuracy (true/false positives/negatives, agreement with reference standard). 20 publications met the inclusion criteria and were included in this report. Of the studies included, 4 are systematic reviews and 16 are nonrandomized studies. The studies are from hospital settings.	accuracy of infrared skin thermometers is equivocal and requires more research. However, the generalizability of the evidence found is questionable." "The [SR] from Bitar et al. reported sensitivities ranging from 4.0 to 89.6%, specificities ranging from 75.4 to 99.6%, positive likelihood ratios ranging from 0.9 to 76.0%, negative likelihood ratios ranging from 86.1 to 99.7%, correlation coefficients ranging from 0.25 to 0.71, and AUROC ranging from 0.86 to 0.96 when comparing infrared non- contact thermometers (including both skin thermometers and cameras) with tympanic thermometry. The authors of this SR highlighted the poor scientific evidence available for the utilization of infrared skin thermometers and thermal scanners for mass screening." "The most common limitation across studies is that they all used, at least in part, non-blinded investigators for the assessment of temperature, but given the objective nature of temperature measurement, this should not be considered a major biasing limitation. Moreover, for many studies it is not clear if they were powered to find a difference between their devices. Also, many studies failed to reveal the percentage of eligible participants who were actually enrolled. This is of importance since it is not clear if the samples were	the utilization of thermal scanners for fever detection, whereas one study stated that this type of device is unsuitable for this purpose. The conclusions of a SR, although of low quality, highlighted the poor scientific evidence available for the utilization of infrared skin thermometers and thermal scanners for mass screening. Evidence for the accuracy of infrared skin thermometers is equivocal whereas it is somehow in favor of the accuracy of thermal scanners." "Depending on the context of utilization (hospital vs border), the volume of measurements to be done and the age of the person to be measured, it might be imperative to use infrared thermometers over more accurate and/or more invasive thermometers. Therefore, tympanic thermometers and thermal scanners might be the only effective and accurate tools to detect fever under certain circumstances. However, one has to keep in mind that screening for a virus are two different issues."



Reference	Systematic Review Purpose	Resources Searched and Inclusion Criteria	Findings	Conclusions Reported in the Abstract
			representative of the population. The profile of people who refused to participate to the studies has not been described. Therefore, it is plausible that feverish or very ill people might be underestimated in those studies. Across studies, many potential confounders of body temperature have been mentioned such as sweat, gender, age, the range of temperature, the rater, physical activity, the use of antipyretic drugs and the emotional state, but the list is not exhaustive. It has to be kept in mind that those factors can bias the results of the study reviewed, especially when using non- contact infrared (including tympanic, skin or scanners) thermometers."	



Infrared Temperature Screening to Identify Potentially Infected Staff or Visitors Presenting to Healthcare Facilities during Infectious Disease Outbreaks

Table 2. Simulation Studies

Reference	Number of Patients	Treatment	Results	Conclusions Presented in the Abstract
Gostic et al. 2020(3) Reviewed <u>full text</u>	Simulation study to "estimate the impact of different screening programs given current knowledge of key COVID-19 life history and epidemiological parameters."	Sensitivity of infrared thermal scanners for fever was set at 70% with a range of 60% to 90%. "Most studies estimated sensitivity between 60–88%. But a handful of studies estimated very low sensitivity (4– 30%). In general, sensitivity depended on the device used, body area targeted and ambient temperature." Percent of case with no fever or cough: Best-case scenario 5%. Middle-case scenario 25%. Worst-case scenario 50%. Mean incubation period of 5.5 days, range of 4.5 to 6.5 days.	"Even under best-case assumptions, we estimate that screening will miss more than half of infected people. Breaking down the factors leading to screening successes and failures, we find that most cases missed by screening are fundamentally undetectable, because they have not yet developed symptoms and are unaware they were exposed." "The probability that an infected person is detectable in a screening program depends on: the incubation period (the time from exposure to onset of detectable symptoms); the proportion of subclinical cases (mild cases that lack fever or cough); the sensitivity of thermal scanners used to detect fever; the fraction of cases aware they have high exposure risk; and the fraction of those cases who would self-report truthfully on a screening questionnaire. Further, the distribution of individual times since exposure affects the probability that any single infected traveler has progressed to the symptomatic stage. If the source epidemic is still growing, the majority of infected cases will have been recently exposed, and will not yet show symptoms. If the source epidemic is no longer growing (stable), times since exposure will be more evenly distributed, meaning that more infected travelers will have progressed through incubation and will show detectable symptoms." "The striking finding is that in a growing epidemic, even under the best-case assumptions, with just one infection in twenty	"Our work underscores the need for measures to limit transmission by individuals who become ill after being missed by a screening program. These findings can support evidence- based policy to combat the spread of COVID-19, and prospective planning to mitigate future emerging pathogens." "The international expansion of COVID- 19 cases has led to widespread adoption of symptom and risk screening measures, in travel-associated and other contexts, and programs may still be adopted or expanded as source epidemics of COVID- 19 emerge in new geographic areas. Using a mathematical model of screening effectiveness, with preliminary estimates of COVID-19 epidemiology and natural history, we estimate that screening will detect less than half of infected travelers in a growing epidemic, and that screening effectiveness will increase marginally as growth of the source epidemic decelerates. We found that two main



Reference	Number of Patients	Treatment	Results	Conclusions Presented in the Abstract
			being subclinical and all travelers passing through departure and arrival screening, the median fraction of infected travelers detected is only 0.30, with 95% interval extending from 0.10 up to 0.53. The total fraction detected is lower for programs with only one layer of screening, with arrival screening preferable to departure screening owing to the possibility of symptom onset during travel. Considering higher proportions of subclinical cases, the overall effectiveness of screening programs is further degraded, with a median of just one in ten infected travelers detected by departure screening in the worst-case scenario. The key driver of these poor outcomes is that even in the best-case scenario, nearly two thirds of infected travelers will not be detectable. There are three drivers of this outcome: (1) in a growing epidemic, the majority of travelers will have been recently infected and hence will not yet have progressed to exhibit any symptoms; (2) we assume that a fraction of cases never develop detectable symptoms; and (3) we assume that few people are aware of their exposure risk. As above, the dominant contributor to successful detections is fever screening."	factors influenced the effectiveness of screening. First, symptom screening depends on the natural history of an infection: individuals are increasingly likely to show detectable symptoms with increasing time since exposure. A fundamental shortcoming of screening is the difficulty of detecting infected individuals during their incubation period, or early after the onset of symptoms, at which point they still feel healthy enough to undertake normal activities or travel. This difficulty is amplified when the incubation period is longer; infected individuals have a longer window in which they may mix socially or travel with low probability of detection."
Quilty et al. 2020(15) Reviewed <u>full text</u>	Simulation study of 100 2019-nCoV- infected travelers planning to board a flight who would pose a risk for seeding transmission in	"We assumed that infected individuals will develop symptoms, including fever, at the end of their incubation period (mean 5.2 days) and progress to more severe symptoms after a	"In our baseline scenario, we estimated that 46% (95% confidence interval: 36 to 58) of infected travelers would not be detected, depending on incubation period, sensitivity of exit and entry screening, and proportion of asymptomatic cases." "For the baseline scenario we estimated that 44 (95% CI: 33–	"Airport screening is unlikely to detect a sufficient proportion of 2019-nCoV infected travelers to avoid entry of infected travelers." "We estimate that the key goal of syndromic screening at airports - to prevent infected



Reference	Number of Patients	Treatment	Results	Conclusions Presented in the Abstract
	a new region	few days, resulting in hospitalization and isolation. We also took into account that individuals may have asymptomatic (subclinical) infection that would not be detected by thermal scanning or cause them to seek medical care, although these individuals may be infectious, and that infected travelers may exhibit severe symptoms during their travel and be hospitalized upon arrival without undergoing entry screening." Assumed the sensitivity of infrared thermal image scanners for exit and entry screening was 86% (based on a single study by Priest et al. (2011)(27) included in the systematic reviews summarized above.	56) of 100 infected travelers would be detected by exit screening, no case (95% CI: 0– 3) would develop severe symptoms during travel, nine (95% CI: 2–16) additional cases would be detected by entry screening, and the remaining 46 (95% CI: 36–58) would not be detected."	travelers from entering countries or regions with little or no ongoing transmission is only achievable if the rate of asymptomatic infections that are transmissible is negligible, screening sensitivity is almost perfect, and the incubation period is short." "Due to the duration of the incubation period of 2019-nCoV infection, we find that exit or entry screening at airports for initial symptoms, via thermal scanners or similar, is unlikely to prevent passage of infected travelers into new countries or regions where they may seed local transmission."
Gostic et al. 2015(16) Reviewed <u>full text</u>	"Efforts to prevent the spread of SARS, Ebola and other disease outbreaks have included screening air passengers for infection prior to boarding, or immediately after arrival. In these situations, infrared	"A review of studies of non- contact infrared thermometer efficacy, when applied to forehead (as is typical for airport screening), suggested that the scanners had an average efficacy of 70% (Bitar et al., 2009). In our main analysis, we therefore assumed	"Overall screening effectiveness was greater in stable than growing epidemics. These gains were driven by increased potential for fever detection in stable epidemics, where cases are less likely to be recently exposed and asymptomatic. In contrast, exposure risk detection does not vary with epidemic phase because exposure risk awareness does not depend on the infection age distribution. Regardless of epidemic phase, the full	"Screening policies have been implemented during several recent epidemics and will likely continue to be discussed in response to future disease outbreaks. Certain aspects of screening, particularly fever screening at arrival, have been criticized as having little scientific justification



Reference	Number of Patients	Treatment	Results	Conclusions Presented in the Abstract
	thermometers are often used to check for symptoms of fever and passengers may be asked to fill out questionnaires to assess their risk of exposure to the disease." "To understand how departure and arrival screening combine with pathogen natural history, epidemiological knowledge, efficacy of screening methodology, and human behavioral factors to determine overall screening outcomes, we developed a general modelling framework for the screening process."	that the probability that febrile travelers would be detected by fever screening was 70%. This is an optimistic estimate, ignoring possible challenges in implementation in outbreak-affected regions and oversights made by device operators in arrival sites where risk may seem remote."	screening program fails to detect at least 25% of infected travelers, despite our optimistic assumptions. Focusing on the contribution made by screening at point of arrival, our projections suggest that arrival screening will still miss half to three-quarters of infected travelers that manage to complete their flights. For pathogens with short incubation periods (i.e., influenza virus) fever detection was responsible for the majority of case identification in all epidemic phases. However, for pathogens with longer incubation periods (i.e., Ebola, Marburg, and SARS-CoV), exposure risk screening was responsible for half or more of case detection in growing epidemics. For these pathogens, fever detection was dominant only in stable epidemics."	but political leaders and health policy makers are likely to consider implementing screening programs when public pressure becomes intense. Thus there is a need to characterize the potential contributions of screening programs when implemented at different times, in different pathogens; ultimately a quantitative understanding will be needed, to factor into cost-benefit calculations. In this study we begin to address these issues by demonstrating that screening outcomes depend strongly on pathogen natural history and epidemiological features, as well as human factors in implementation and compliance. Our results emphasize the need to characterize basic properties of emerging pathogens, as this knowledge can enhance disease control measures."



Table 3. Clinical Studies -	· Hospital Screening
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Reference	Number of Patients	Treatment	Results	Conclusions Presented in the Abstract
Chen et al. 2020(18) China (Ningbo First Hospital, Ningbo, Zhejiang Province) Reviewed full text, subscription required	Single-center cohort study of 528 adults (261 from an indoor fever clinic and emergency department and 267 outdoor participants) conducted in February 2020 during the COVID-19 epidemic	Tympanic temperature was measured using infrared tympanic temperature (Braun ThermoScan PRO 6000). Wrist and forehead temperature were measured using noncontact infrared thermometer (type not reported).	"We enrolled a total of 528 participants including 261 indoor and 267 outdoor participants. We divided outdoor participants into four types according to their means of transportation to the hospital as walk, bicycle, electric vehicle, car, and inside the car. Under different circumstance, the mean difference ranged from -1.72 to -0.56°C in different groups for the forehead measurements, and -0.96 to -0.61°C for the wrist measurements. Both measurements had high fever screening abilities in inpatients (wrist: AUC 0.790; 95% CI: 0.725- 0.854, P <0.001; forehead: AUC 0.816; 95% CI: 0.757- 0.876, P <0.001). The cut- off value of wrist measurement for detecting tympanic temperature \geq 37.3°C was 36.2°C with a 86.4% sensitivity and a 67.0% specificity, and the best threshold of forehead measurement was also 36.2°C with a 93.2% sensitivity and a 60.0% specificity."	"Wrist measurement is more stable than forehead measurement under different circumstance. Both measurements have great fever screening abilities for indoor patients. The cut-off value of both measurements was 36.2°C."



Reference	Number of Patients	Treatment	Results	Conclusions Presented in the Abstract
Fong et al. 2020(17) Singapore Reviewed <u>full text</u>	Diagnostic cohort study of 1,576 consecutive visitors to Singapore General Hospital	Microlife NC150 thermometer was used for forehead and temporal region temperature readings. Covidien Genius 2 or 3 was used for tympanic temperatures. For temporal temperature readings, the thermometer was aimed at the temple area (about 1 cm above the eyebrow) at 3 to 5 cm. Forehead temperature readings were obtained from the center of the forehead at no more than 5 cm. All 3 thermometers utilized infrared technology to measure temperature. Temperature readings of 37.5°C or above were considered a fever.	"Of all the visitors, 27 (1.7%) had fever. Moderate positive correlation was found between temporal and forehead temperature readings (r=0.602, mean difference (temporal – forehead), (95% limits of agreement) = 0.1 (-0.8 , 0.7)), and there was very weak positive correlation between tympanic and temporal temperature readings (r=0.177, mean difference (temporal – tympanic), (95% limits of agreement) = $-0.3 (-1.7,$ 1.1)). Sensitivity for temporal temperature readings (\geq 37.5°C) to detect febrile visitors was 3.7%, specificity was 99.6%, positive predictive value was 14.3% and negative predictive value was 98.3%."	"Our results demonstrate that tympanic temperature readings should be used for fever screening instead of temporal or forehead readings."



Reference	Number of Patients	Treatment	Results	Conclusions Presented in the Abstract
Bardou et al. 2017(23) France Reviewed full text, subscription required	Diagnostic case-control study of 246 in-patients and out-patients and 379 healthcare workers	Mobotix® M15D infrared thermal camera (Mobotix, Germany) and Genius™ 2 Tympanic Thermometer (Medtronic). Fever threshold set at ≥38.5°C (101.3°F). Devices were adjusted to room temperature.	"We identified 14 cases (2.24%) of fever in our study. Five febrile cases detected by the tympanic thermometer and infrared thermal camera had an upper respiratory infection. Thirteen febrile cases were detected both with the tympanic thermometer and infrared thermal camera (true positive).Two cases were detected only by the infrared thermal camera, which were confirmed to be false positive cases. One febrile case was not detected with the infrared thermal camera (false negative: 38.5 °C). Six- hundred and nine cases were afebrile, i.e. fever was not detected by both techniques (true negative: n = 609 cases)." "The sensitivity of the infrared thermal camera in detecting febrile cases was identified as 0.9286 (95%CI: 0.6613 to 0.9982); and the specificity of the infrared thermal camera in detecting febrile cases was identified as 0.9286 (95%CI: 0.5954 to 0.9834). The negative predictive value was identified as 0.9984 (95%CI: 0.9909 to 1)."	"We believed that rapid fever detection using infrared thermal cameras, followed by rapid clinical intervention remains the most effective way of controlling infection. Mass screening for fever using infrared thermal cameras will be included at an early stage in the reception of patients as part of the rapid and efficient control of infection. Infrared thermal cameras are a rapid and reliable way to detect fever in infected persons in clinical settings. This modern approach should be included in the management of infection. Prior calibration of the thermal sensitivity of infrared thermal cameras according to ambient temperature is required to obtain greater accuracy."



Reference	Number of Patients	Treatment	Results	Conclusions Presented in the Abstract
Sun et al. 2017(24) Japan Reviewed <u>full text</u>	Single-center case-control study of 16 patients with influenza-like illness who visited the Takasaka Clinic in Fukushima in Japan and 22 control patients from Tokyo Metropolitan University, Japan.	Infrared thermography (IRT) system that produced visible and thermal images was used for image acquisition and neart rate measurement. Axillary temperature was obtained. "A CMOS [complementary metal oxide Semiconductor] camera-equipped IRT system was used which is the same system used in the quarantine station at Narita International Airport in Japan. The system integrates CMOS camera with thermography to capture visible and thermal images, respectively. The image acquisition and processing programs were written in LabVIEW software. Subjects were seated in front of the IRT system at a distance of approximately 0.5 m. The IRT system displays the 'Infection' or 'Healthy' result within 10 s using the logistic regression discriminant function, which bases the output on the heart rate, respiration rate, and facial skin temperature."	"The vital-sign-based IRT screening system had a sensitivity of 87.5% and a negative predictive value of 91.7%; these values are higher than those of conventional fever-based screening approaches." III patients: "The average axillary temperature of the patient group was 37.2 °C (range <36.2– < 39.0 °C), and their average age was 36 years." Control patients: The average axillary temperature of the control group was 36.3 °C (range <35.4– < 37.0 °C), and their average age was 35 years." "The sensitivity, specificity, NPV [negative predictive value], and PPV [positive predictive value] were 87.5%, 100%, 91.7%, and 100%, respectively. The fever-based screening, for which the cut-off value for the axillary temperature was set at 37.0 °C, did not detect five influenza patients (false-negative). The sensitivity of the fever- based screening was 68.7%."	"Multiple vital-sign-based screening efficiently detected patients with suspected infectious diseases. It offers a promising alternative to conventional fever-based screening." "In summary, the feasibility of using IRT to remotely sense multiple vital signs and to rapidly and accurately screen patients who are suspected of carrying infectious diseases has been demonstrated, and it appears that this is a very promising approach that will provide an alternative to conventional fever-based screening."



Reference	Number of Patients	Treatment	Results	Conclusions Presented in the Abstract
Sun et al. 2016(25) Japan Reviewed full text, subscription required	Case-control study of 54 patients admitted with fever at Narita International Airport Clinic and 33 normal patients with no symptoms from Hino Campus of Tokyo Metropolitan University.	Noncontact infection screening radar system that monitors facial skin temperature, heart rate, and respiration rate compared with axillary temperature.	Airport clinic patients' axillary temperature averaged $37.9 \pm 0.6^{\circ}$ C (body temperature ranged from 36.3° C to 39.3° C. Control patients axillary temperature averaged $36.3 \pm 0.4^{\circ}$ C (body temperature ranged from 35.4° C to 37.0° C). "The corresponding sensitivity, specificity, positive predictive value, and negative predictive value were 96.3° , 81.8° , 89.6° , and 93.1° , respectively. The correctly identified patients tended to have increased vital signs, where the heart rate, respiration rate, and facial skin temperature averaged 96 beats per minute, 18 breaths per minute, and 36.5° C, respectively."	"To conclude, in the present study, we further evaluated the performance of our infection screening system on completely random outpatients with different ages and body morphologies, as well as different common infectious diseases. The system performed as expected in this clinical evaluation, which indicated that it can be used as a helpful tool for the rapid screening and isolation of suspected infectious disease patients, thereby reducing the risk of secondary infection."



Reference	Number of Patients	Treatment	Results	Conclusions Presented in the Abstract
Hogan et al. 2015(19) United States Reviewed full text, subscription required	Single-center cohort study of 548 patients entering an emergency department for care	Cutaneous infrared thermometry (CIT) measured with Westward® Infrared Thermometer Model #1VEP6 and standard oral temperature using Welch Allyn® SureTemp Plus Model 690. Fever defined as oral temperature ≥38°C.	"There are 548 cases comprising 224 males, 324 females, with mean age 26 years. The mean temperature difference is 12.95°C, (13.18-9.08°C) $p \le 0.0001$. Bland-Altman demonstrates bias at 8.680 (-9.084 to -8.275) $p \le 0.0001$ with upper and lower level bias values of 18.124 (18.819-17.435) and 0.768 (0.076-1.459), respectively. Based on Receiver Operator Characteristics analysis, detection of hyperpyrexia at a CIT of 35.3°C provided sensitivity of 0.236 (0.143- 0.359), specificity 0.977 (0.959-0.989), positive predictive value 0.589 (0.325-0.810), negative predictive value 0.904 (0.891-0.919), and accuracy of 0.888 (0.861-0.913)."	"The use of a readily available CIT measurement device predicted hyperpyrexia about 59 percent of the time and the absence of hyperpyrexia about 90 percent of the time. This is consistent with previous reports of more complex infrared measurement devices. Although commonly used in mass fever screening, the current performance characteristics of CIT are limited and may add little to detection of target diseases in a mass screening context." "This study demonstrates that use of a simple hand-held infrared device for CIT measurement similar to the method commonly used globally during recent contagious outbreaks – has insufficient performance characteristics to be relied on as a primary screening tool. Additionally, the performance characteristics of the simple inexpensive tool used in this study are comparable to most reports for more complex and expensive devices that have been used for CIT. The overall utility of CIT in mass screening processes for target disease is at best unclear."



Reference	Number of Patients	Treatment	Results	Conclusions Presented in the Abstract
Tay et al. 2015(10) Singapore Reviewed full text, subscription required	Single-center cohort study of 430 Singapore military personnel seeking medical care at a high-volume primary healthcare center	3 infrared thermal detection systems (ITDS), the <u>STE Infrared</u> <u>Fever Screening System</u> (IFSS; Singapore Technologies Electronics, Singapore), the <u>Omnisense Sentry MKIII</u> (Omnisense Systems Ptd. Ltd, Singapore; Omnisense Systems USA, Inc., Fort Lauderdale, FL, USA), and the handheld Quick Shot Infrared Thermoscope HT-F03B (Shenzhen WTYD Technology Limited, Guangdong, China), were evaluated. "All the ITDS were calibrated to detect core body temperature based on adjusted skin temperatures, with a calibrated setpoint of 37.5 °C core body temperature being a positive result. The gold standard of oral temperature was measured by clinical staff (Digital Thermometer KT-DT4B; Hong Kong Capital International Electronics Co. Ltd, Guangdong, China), as per the healthcare centre's established protocol."	"There were 430 subjects screened, of whom 34 participants (7.9%) had confirmed fever, determined by oral thermometer measurement. The handheld infrared thermoscope had a very low sensitivity (29.4%), but a high specificity (96.8%). The STE ITDS had a moderate sensitivity (44.1%), but a very high specificity (99.1%). Self- reported fevers showed good sensitivity (88.2%) and specificity (93.9%). The sensitivity of the Omnisense ITDS (89.7%) was the highest among the three methods with good specificity (92.0%)."	"The new generation Omnisense ITDS displayed a relatively high sensitivity and specificity for fever. Though it has a lower sensitivity, the old generation STE ITDS system showed a very high specificity. Self- reporting of fever was reliable. The handheld thermograph should not be used as a fever- screening tool under tropical conditions."



Reference	Number of Patients	Treatment	Results	Conclusions Presented in the Abstract
Sun et al. 2014(9) Japan Reviewed full text, subscription required	Single-center diagnostic case series of 155 inpatients with a diagnosis of seasonal flu	Thermopile array (Chino Corp., Tokyo, Japan) compared to axillary temperature.	"The maximum facial temperature, measured by the array at 0.3 m from the subject, exhibited a positive correlation with axillary temperature measured using a contact-type thermometer (r = 0.71, p < 0.01). The sensitivity and specificity of the thermopile array in identifying the febrile subjects were 80.5% and 93.3%, respectively, setting the threshold cut-off of maximum facial temperature at an appropriate value." Threshold cut-off for fever was 36.5°C.	"Our cost-effective thermopile array appears promising for future close-range fever screening of patients with infectious diseases at primary care doctor clinics, health care centers, and quarantine stations in developing and developed countries." "The main limitation of our thermopile array is that the operational distance between the thermopile array and the subject is ≤0.5 m, as opposed to approximately 1.0–3.0 m for some high-resolution commercial thermography systems. Therefore, this thermopile array will be more suitable for close- range fever screening of patients with infectious diseases at primary care doctor offices, health care centers, and quarantine stations in developing and developed countries.



Reference	Number of Patients	Treatment	Results	Conclusions Presented in the Abstract
Nguyen et al. 2010(20) United States Reviewed <u>full text</u>	Multicenter diagnostic cohort study of 2,873 adult patients who sought care at the emergency room	"Compared temperature measurements for 3 ITDS (FLIR ThermoVision A20M [FLIR Systems Inc., Boston, MA, USA], OptoTherm Thermoscreen [OptoTherm Thermal Imaging Systems and Infrared Cameras Inc., Sewickley, PA, USA], and Wahl Fever Alert Imager HSI2000S [Wahl Instruments Inc., Asheville, NC, USA]) with oral temperatures (>/= 100 degrees F = confirmed fever) and self-reported fever."	"Of 2,873 patients enrolled, 476 (16.6%) reported a fever, and 64 (2.2%) had a confirmed fever. Self- reported fever had a sensitivity of 75.0%, specificity 84.7%, and positive predictive value 10.1%. At optimal cutoff values for detecting fever, temperature measurements by OptoTherm and FLIR had greater sensitivity (91.0% and 90.0%, respectively) and specificity (86.0% and 80.0%, respectively) than did self-reports. Correlations between ITDS and oral temperatures were similar for OptoTherm (rho = 0.43) and FLIR (rho = 0.42) but significantly lower for Wahl (rho = 0.14; p < 0.001). When compared with oral temperatures, 2 systems (OptoTherm and FLIR) were reasonably accurate for detecting fever and predicted fever better than self-reports."	"Maximizing accuracy by choosing the optimal cutoff with the highest sensitivity and specificity may not be practical in a real-world setting, considering the relative costs of false-positive and false-negative results. In settings where secondary evaluation is available or during a pandemic with high illness severity, ITDS temperature can be set at a lower cutoff to ensure fewer false negatives, each of which represents a potential public health threat. However, setting the cutoff to achieve very high sensitivity can result in many false positives, which could have adverse consequences to the population being screened (e.g., unnecessary travel delays, missed work) and increase the workload of staff who are conducting the screening. In settings where confirmatory testing may not be feasible or high costs may be associated with a false-positive result, a higher ITDS temperature cutoff may be preferable."



Reference	Number of Patients	Treatment	Results	Conclusions Presented in the Abstract
Suzuki et al. 2010(26) Japan Reviewed full text, subscription required	Diagnostic case series of 50 healthy participants to test effect of environmental temperature on thermography	Body temperature was measured with 3 devices: Axillary thermometer used as the reference standard: Terumo Corp., C202, Tokyo, Japan. Ear thermometer: Terumo, EM-30CPLB, Tokyo, Japan. Thermography: NEC Avio Infrared Technologies Co., Ltd., TH5108ME, Tokyo, Japan. Used 2 meters from craniofacial region. Participates waited outdoors for 20 minutes at 12.6°C before measurement indoors and for 20 minutes at 20.0°C before measurement indoors.	"The body temperature obtained with an axillary thermometer was used as a reference; receiver operating characteristic (ROC) analysis was conducted to determine the validity of temperatures obtained by measurement with an ear thermometer and thermography at 36.7 degrees C (median of the axillary body temperature). The area under the ROC curve (AUC) indicates the validity of measurements. The AUC for ear thermometers in a warm environment (mean temperature: 20.0 degrees C) showed a fair accuracy (AUC: 0.74 [95% CI: 0.64- 0.83]), while that (AUC: 0.62 [95% CI: 0.51-0.72]) in a cold environment (mean temperature: 12.6 degrees C) and measurements with thermography used in both environments (AUC: 0.57 [95% CI: 0.45-0.68] in a warm environment and AUC: 0.65 [95% CI: 0.54- 0.76] in a cold environment) showed a low accuracy." "The simple correlation coefficients between measured in cold and warm environments were 0.68 for axillary temperature (P <0.01), 0.77 for ear temperature (P <0.01), and 0.32 for facial temperature (P =0.01)." "Facial temperature taken in the cold environment showed a significant difference of -4°C from axillary temperature (P <0.01).	"When ear and facial temperatures are compared with the reference axillary temperatures under an ambient temperature of 20.0°C, ear temperatures, which are relatively free from the effects of ambient temperature, are more accurate than facial temperature." "In conclusion, measurement with an ear thermometer in a warm environment, but not a cold environment, has a fair validity. Further technological development is required for mass body temperature screening."
Chiang et al. 2008(21)	Single-center diagnostic	Digital infrared thermal imaging (DITI)	"Different distances and ambient temperature	"The temperature readings obtained by IRT



Reference	Number of Patients	Treatment	Results	Conclusions Presented in the Abstract
Taiwan Reviewed full text, subscription required	cohort study of 1,032 subjects who entered Wan Fang Medical Center, Taipei, Taiwan	(Spectrum 9000MB Medical Thermal Imaging System; Telesis Technologies, Inc., Kaohsiung, Taiwan), Thermoguard (device was not described and source not reported), and ear drum IRT. "In Spectrum 9000MB fever test mode, the alarm sounds when thermographic temperature is > 37.5°C, as expected in a febrile patient. When a subject was found to have thermographic temperature >37.5°C, the ear drum temperature was measured to confirm whether the patient had a fever (38°C). When the ear drum temperature was ≥ 38°C, the patient was immediately isolated for further examination." Measurements were made at various distances from the entry door.	discrepancy had a significant influence on thermoguard, and lateral and frontal view DITI. By ICC [intraclass correlation coefficient] analysis, a significant difference was found at 10 m distance between ear drum IRT and thermoguard (r = 0.45), lateral view DITI (r = 0.37), and frontal view DITI (r = 0.44). With ROC analysis, the optimal preset cut-off temperatures for the different imagers were: 36.05 degrees C for thermoguard (area under the curve [AUC], 0.716), 36.25 degrees C for lateral view DITI (AUC, 0.801), and 36.25 degrees C for frontal view DITI (AUC, 0.812)." "Sensitivity of ear drum and thermoguard at 0 m was 13%, specificity was 95%, and positive predictive value was 44%. At a distance of 5 m, the sensitivity of ear drum and thermoguard was 45%, specificity was 70% and [PPV] was 29%. At a distance of 10 m, the sensitivity of ear drum and thermoguard was 57%, specificity was 85% and positive predictive value was 39%." "At a distance of 0 m, the sensitivity of ear drum and DITI in lateral view was 32%, specificity was 89% and positive predictive value was 32%, specificity was 77% and [PPV] was 33%. At a distance of 10 m, the sensitivity of ear drum and DITI was 24%, specificity was 93% and positive predictive value was 36%."	may be used as a proxy for core temperature. An effective IRT system with a strict operating protocol can be rapidly implemented at the entrance of a hospital during SARS or avian influenza epidemics." "This study suggests that temperature readings obtained by remote- sensing IRT could be used as a proxy for core temperature. The optimal distance for IRT is at 10 m from the entrance. The preset threshold cut-off alarm temperature should be set at 37.5°C for ear drum IRT, 36.25°C for lateral view DITI, 36.25°C for frontal view DITI, and 36.05°C for thermoguard. To prepare for future SARS or avian influenza epidemics, an effective IRT system with a strict operating protocol to detect febrile individuals needs be rapidly implemented at hospital entrances."



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Reference	Number of Patients	Treatment	Results	Conclusions Presented in the Abstract
Hausfater et al. 2008(22) France Reviewed <u>full text</u>	Single-center cohort study of 2,026 patients in an emergency department	Tympanic temperature was measured using an infrared tympanic thermometer (Pro 4000; Welch Allyn, Skaneateles Falls, NY, USA). Systolic and diastolic arterial blood pressure and heart rate were also measured. "Cutaneous temperature was measured on the forehead by using an infrared thermometer (Raynger MX; Raytek, Berlin, Germany)." Study was intended "to assess diagnostic accuracy of infrared thermometry for detecting patients with fever, defined as a tympanic temperature > 38.0°C."	Diagnostic performance: Hyperthermia threshold ≥37.5°C, sensitivity 0.76 (95% CI: 0.69 to 0.82), specificity 0.65 (0.63 to 0.67), PPV 0.16 (0.14 to 0.19), NPV 0.97 (0.96 to 0.98).	"In conclusion, we observed that cutaneous temperature measurement by using infrared thermometry does not provide a reliable basis for screening outpatients who are febrile because the gradient between cutaneous and core temperatures is markedly influenced by patient's age and environmental characteristics. Mass detection of febrile patients by using this technique cannot be envisaged without accepting a high rate of false-positive results."

Selected Resources and References

Search Summaries

The following databases were used to identify the literature and related materials.

ECRI Resources [searched January 1, 2015, through March 13, 2020]. Available from <u>http://www.ecri.org</u>. Subscription required.

Search Strategy: thermography; thermometers; disease outbreaks

Universal Medical Device Nomenclature System (UMDNS) Codes:

17887 (thermometers, electronic, infrared, ear); 34712 (thermographs, infrared, patient)

Results: We identified two related reports and no records in the Health Devices Alerts database.

- <u>Thermometers, electronic, infrared</u>. [Healthcare Product Comparison System]. 2018 Sep 1.
- Is your hospital prepared for the next Ebola outbreak? Risk Management News. 2018 Oct 31.
- Outbreak preparedness and response: The essentials. [Evaluations & Guidance]. 2020 Mar.
- Professional organizations release updated guidelines in response to the COVID-19 outbreak In Washington State. [Aging Services Risk, Quality & Safety Guidance]. 2020 Mar 9.
- Protecting against infectious disease transmission during equipment maintenance: Lessons from the 2003 SARS outbreak. [Evaluations & Guidance]. 2020 Feb 18.
- <u>Temperature screening to prevent COVID-19 transmission: Creating false security</u>. [Position paper]. 2020 Apr 27.



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PubMed. Bethesda (MD): National Library of Medicine [searched January 1, 2008, through August 25, 2020]. Available from: <u>http://www.pubmed.gov.</u>

Search Strategy:

- #1 body temperature[mj] OR fever/diagnosis[mj] OR thermometers[mj] OR thermography[mj] OR febrile[ti] OR temperature[ti] OR "infrared thermal detection"[ti] OR thermometer[ti] OR thermography[ti]
- -#2 communicable diseases[mj] OR disease outbreaks[mj] OR "influenza a virus"[mj] OR mass screening[mj] OR screen*[ti] OR endemic*[ti] OR epidemic*[ti] OR influenza*[ti] OR outbreak*[ti] OR pandemic[ti] OR respiratory[ti] OR coronavirus*[ti] OR covid19[ti] OR covid-19[ti]

-#3 #1 AND #3

Results: We identified 53 records.

EMBASE. Amsterdam (The Netherlands): Elsevier B.V. [searched January 1, 2008, through August 25, 2020]. Available from: <u>www.embase.com</u>. Subscription required.

Search Strategy:

- #1 'body temperature'/exp/mj OR fever/mj OR 'temperature measurement'/exp/mj OR thermometer/exp/mj OR febrile:ti OR temperature:ti OR 'infrared thermal detection':ti OR thermometer:ti OR thermography:ti
- -#2 'communicable disease'/mj OR epidemic/mj OR influenza/exp/mj OR pandemic/exp/mj OR screening/mj OR screen*:ti OR endemic*:ti OR epidemic*:ti OR influenza*:ti OR outbreak*:ti OR pandemic:ti OR respiratory:ti OR coronavirus*:ti OR covid19:ti OR covid-19:ti
- -#3 #1 AND #2

Results: We identified one unique records.

Guidelines and Standards [searched January 1, 2015, through August 25, 2020].

Search Strategy: temperature screening; mass screening; thermography; infectious disease; visitors

Results: We identified eight documents.

- Centers for Disease Control and Prevention (CDC). [cited 2020 Aug 25].
 - Implementation of mitigation strategies for communities with local COVID-19 transmission. 2019.
 - Infection prevention and control recommendations for hospitalized patients under investigation (PUIs) for ebola virus disease (EVD) in U.S. hospitals. 2018.
 - Interim U.S. guidance for risk assessment and public health management of healthcare personnel with potential exposure in a healthcare setting to patients with coronavirus disease (COVID-19). [updated 2020 May 29 and 2020 Jun 18].
 - Preparing for COVID-19 in nursing homes. [updated 2020 Jun 25].
 - <u>Steps healthcare facilities can take now to prepare for coronavirus disease 2019 (COVID-19)</u>. [updated 2020 Mar 20].
- International Organization for Standardization (ISO). <u>ISO/TR 13154:2017 Medical electrical equipment</u> <u>Deployment, implementation and operational guidelines for identifying febrile humans using a screening thermograph</u>. 2017 Mar.
- World Health Organization (WHO). <u>Management of ill travelers at points of entry international airports, ports</u> and ground crossings – in the context of the COVID-19 outbreak. Interim guidance. 2020 Feb 16. See section 2.1.2 Equipment.
- World Health Organization (WHO). <u>Updated WHO advice for international traffic in relation to the outbreak of</u> <u>the novel coronavirus 2019-nCoV</u>. 2020 Jan 24.

FDA website. U.S. Department of Health and Human Services. Available from: <u>http://www.fda.gov</u>.

Search Strategy: infrared temperature; thermography; temperature screening



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Results: We identified three documents.

- FDA. <u>Thermal imaging systems (infrared thermographic systems / thermal imaging cameras)</u>. [cited 2020 Aug 25]. Note: overview page.
- FDA. <u>Enforcement policy for telethermographic systems during the coronavirus disease 2019 (COVID-19) public</u> <u>health emergency. Guidance for industry and Food and Drug Administration staff.</u> April 2020.
- Non-contact temperature assessment devices during the COVID-19 pandemic. [cited 2020 Aug 25].

Selected Web Resources. [searched March 13, 2020].

Manufacturers of Handheld Infrared Thermometers

- See the ECRI Healthcare Product Comparison System report listed under ECRI Resources above.

Manufacturers of Remote-sensing Infrared Thermography Systems

- FLIR Systems, Inc. [cited 2020 Aug 25].
 - Handheld thermal cameras. [cited 2020 Aug 25].
 - Fixed thermal cameras. [cited 2020 Aug 25].
 - Photonics Media. Riley R. <u>Demand for FLIR temperature screening devices rises along with number of coronavirus cases</u>. Vision Spectra. 2020 Mar.
 - Rapid Tech Equipment. <u>Minimizing the spread coronavirus infections with fever detection</u>. [cited 2020 Aug 25].
- Infrared Cameras, Inc (ICI). [cited 2020 Aug 25].
 - Infrared for medical use. [cited 2020 Aug 25]. Note: includes some devices that are used for diagnostic use rather than screening.
 - Screening thermography. Supplemental user label. COVID-19 public health emergency manual. 2020 Aug.
 - How infrared cameras can help prevent the spread of COVID-19. 2020 Mar 24.
- <u>Omnisense Systems, Inc</u>. [cited 2020 Aug 25].
 - Sentry MK4 mass fever screening and pandemic control system. [cited 2020 Aug 25].
 - <u>News</u>. [cited 2020 Aug 25].

Other Selected Web Resources

- Canadian Agency for Drugs and Technologies and Health (CADTH). [cited 2020 Aug 25].
 - Infrared thermometers for detecting fever: Clinical effectiveness. 2014 Oct 17.
 - <u>Mass thermography screening for infection and prevention: A review of the clinical effectiveness</u>. 2014 Nov 19.
 - <u>Non-contact thermometers for detecting fever: A review of clinical effectiveness</u>. 2014 Nov 20.
 - <u>Non-contact infrared thermometers for pediatric patients: Clinical evidence and guidelines</u>. 2014 Oct 9.
- The Centre for Evidence-Based Medicine (CEBM). <u>More Marketing than medical evidence: infrared</u> <u>thermometers to screen for COVID-19</u>. 2020 Aug 3.
- Chopra V et al. <u>How should U.S. hospitals prepare for coronavirus disease 2019 (COVID-19)?</u> Ann Intern Med. 2020 Mar 11. Note: included for background only; does not address temperature screening. Requires free registration.
- Normille D. <u>Why airport screening won't stop the spread of coronavirus</u>. *Science*. 2020 Mar 6.
- IR Information. [cited 2020 Aug 25].
 - Chandler C. The use of thermography in elevated body temperature screening. [cited 2020 Aug 25].
 - Yaffe-Bellany D. <u>'Thermometer guns' on coronavirus front lines are 'notoriously not accurate'</u>. 2020 Feb 15. Note: reprinted from *The New York Times*.



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- McCartney M, Heneghan C. <u>More marketing than evidence: Infrared thermometers to screen for COVID-19</u>.
 2020 Aug 3.
- Medscape. [cited 2020 Aug 25].
 - Davis CP, Stoppler MC. Fever in adults. [reviewed 2020 Jun 4].
 - Gompft SG. Fever of unknown origin. 2018 Mar 1.
- StatPearls. Cascella M et al. <u>Features, evaluation and treatment coronavirus (COVID-19)</u>. [last updated 2020 Aug 10].

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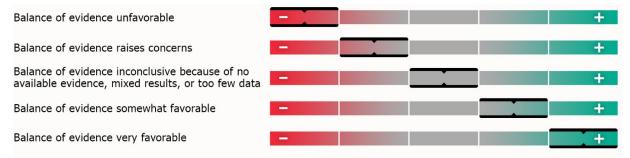
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The Evidence Bar[™]

ECRI developed The Evidence Bar[™] to provide a visualization of our judgment about the balance of benefits and harms of the technology after assessing the available published clinical evidence in light of key outcomes and comparisons of interest. The Evidence Bar[™] rubric shows five possible choices for our expert judgment. After review and analysis of evidence identified through literature searches conducted by master's level medical librarians, ECRI research analysts, extensively trained in methods of evidence assessment, weigh potential benefits and harms of a technology to arrive at their expert judgment.



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