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TractManager

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Thermal Imaging Screening for COVID-19

Executive Summary

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Situation

Social distancing is key in diminishing the spread of Covid-19. The incubation period for COVID-19 can be up to 14 days. However, a person exposed to the virus typically will show signs within 4 to 5 days (CDC, 2020). Due to the wide span of days an individual can be pre-symptomatic to symptomatic, the United States faces difficulty identifying those who are contagious. This also proposes challenges in high flow point of entries such as hospitals, mass transit and office buildings. Strategies are being developed for rapid screening of individuals that are symptomatic in order to isolate them from the public (Morgan, 2020).

The CDC recommends a triage process for rapid screening of patients with symptoms of COVID-19. Currently this is a manual process, which includes checking their temperature before entering the facility and asking if they have a fever or symptoms of COVID-19. Symptoms include cough or shortness of breath, sore throat, myalgia or chills. Screening for symptoms and appropriate triage, evaluation, and isolation of individuals who report symptoms should be performed (CDC, 2020). Tele-thermographic systems are recognized as an effective technology for measuring surface skin temperature with high accuracy rates (FDA, 2020).

Problem Statement:
Is Thermal Imaging Screening an effective tool for screening symptomatic COVID-19 individuals?

Technology Under Evaluation:

- Tele-thermographic Systems

Background

There are multiple symptoms associated with COVID-19. Two of the most common symptoms are fever (83–99%) and cough (59–82%) (CDC, 2020). Taking a patient's temperature with a thermometer is the best method to capture a patient's true body temperature. This can be performed by either contact or non-contact thermometer.

A contact thermometer is used for each patient and must be singled out in order to have their temperature taken. This can be very labor intensive in high flow traffic areas and point of entries, and careful attention to infection prevention measures must take place. A non-contact thermometer allows temperature to be taken with little to no contact with individuals. This is also a reliable and accurate form of temperature measurement and is acceptable during the COVID-19 pandemic as it requires no contact. Thermal imaging systems, also known as tele-thermographic systems, are non-contact methods for evaluating body temperature.

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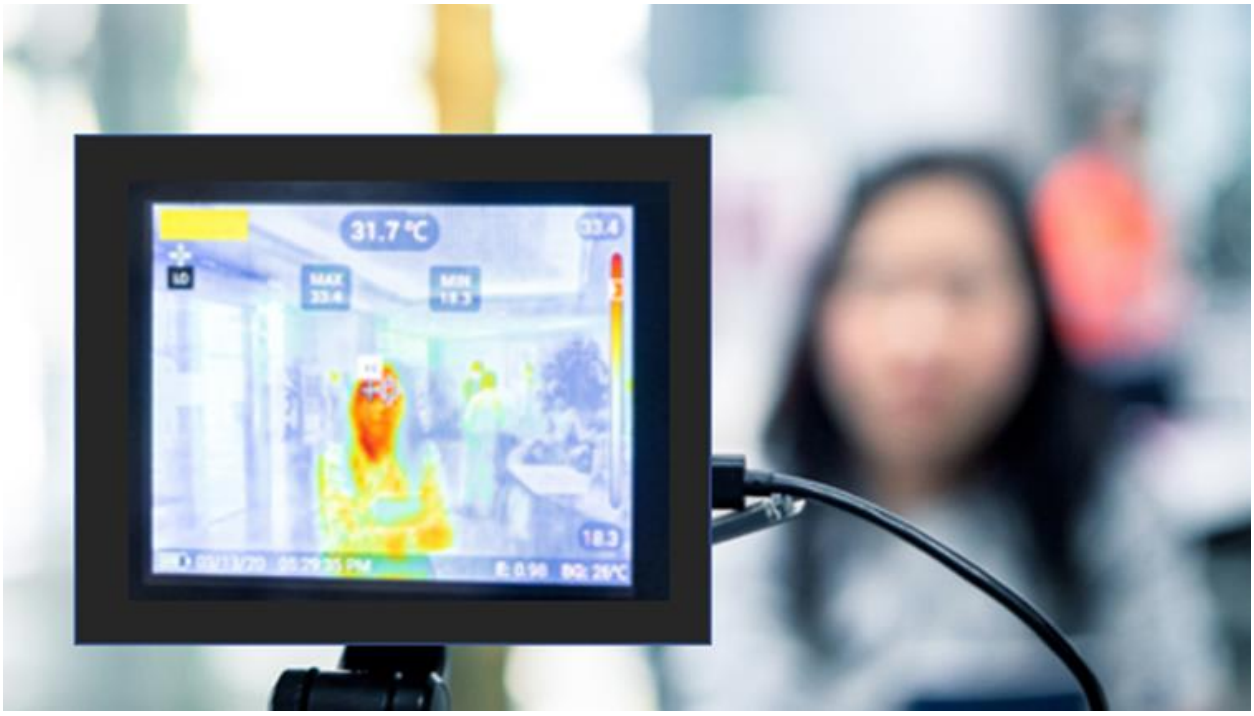
Technology Description:
Tele-thermographic technology is designed to use infrared radiation, and convert it into a temperature measurement. There are two types of thermal imaging, active and passive. **Active thermography** is based on applying energy to a surface and recording the surface temperature. It is typically used for material testing. **Passive thermography** measures the natural thermal energy of an item of interest. ***Passive thermography can be used for surveillance of people and medical diagnosis***(FDA, 2020).

Thermal imaging can be used to detect elevated body temperature (EBT), especially in high-traffic areas for rapid individual screening. This technology can detect elevated body temperature in certain areas of the screen to warrant necessary additional screening for infection (Appendix A).

Sample Visual of Thermal Imaging Technology (FDA, 2020):



Thermal imaging systems can either be handheld or fixed. Fixed or “standoff” systems screen the subject at a distance, making it safer for the operator. Fixed systems consist of an imaging camera, a processor, and software. The software can be used to increase the accuracy of the scan by comparing the temperature to a known database of normal temperatures for the area.

Depending on the placement and the type of the camera, thermal systems can either image the whole body or just sections. In most instances, the face is one area that is exposed. One of the most accurate areas to measure is the area over the tear duct. This area correlates to the inner body core temperature and has been found to the most reliable location on the face (Adams, et al., 2020).

One primary factor that determines the accuracy of a system is the number of pixels, or spatial resolution. The more pixels present in a thermal scan, has the more accurately it can measure the skin surface temperature. With the limited amount of pixel resolution available, this poses a challenge when imaging a subject, even at a modest distance. Basic cameras used to measure body temperature screening have a resolution around 320 x 240 pixels to 640 x 512 pixels. High end camera systems marked for triaging potentially infected patients have pixel ranges up to 1920 x 1080 (Servers Check, 2020).

Assessment

Guidelines and Recommendations:
Tele-thermographic systems for medical use are regulated by the FDA. The April 2020, the FDA issued an Enforcement Policy for extending the use of tele-thermographic systems to triage patients by measuring body temperature (CDC, 2020). *The guidance sets forth an enforcement policy that is intended to apply to all thermal imaging systems that are intended for medical purposes for the duration of the public health emergency related to COVID-19 and provides recommendations regarding performance and labeling of such systems (FDA, 2020).*

Per the FDA in regard to thermal imaging and COVID-19:

- When used correctly, thermal imaging systems generally have been shown to accurately measure 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 contact to measure temperature (for example, non-contact infrared thermometers or oral thermometers).
- ***Fever may or may not be present in COVID-19 positive patients. Temperature-based 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.***
- Thermal imaging systems have not been shown to be accurate when used to take the temperature of multiple people at the same time. The accuracy of these systems depends on careful set-up and operation, as well as proper preparation of the person being evaluated.
- Thermal imaging systems have been used by several countries during epidemics, although information about their effectiveness as part of efforts to reduce the spread of disease has been mixed (FDA, 2020).

Clinical Evidence

Only one abstract was located specific to screening for COVID-19 with fever detection. Quilty and colleagues (2020) evaluated thermal screening at airport exit and entry points and concurred with the FDA that COVID-19 infected travelers would ***not*** be identified, estimating ~56 % may go undetected.

Similarly, in past disease outbreaks, that include Dengue Fever, Ebola and influenza, relying on fever detection alone for disease detection was as low as 37 % - 68% (Nishiura & Kamiya, 2011; Kuan et al., 2010; Sun et al., 2017). One airport screening study done during a seasonal flu epidemic (Priest, 2012), did agree that thermal imaging fever detection was sensitive to 86% sensitive by comparing with tympanic temperatures. They tested 1,275 travelers who also agreed to a nasal Swab for Influenza A or B. However, none of the 30 travelers that were positive for the flu had tympanic temperatures > 37.8 ˚ C and the authors again agreeing fever screening alone would be ineffective for virus detection.

Some improvement in infection detection was noted when heart rate and respiratory rate were measured via various means (Negishi et al.2018). Others noted that optimization of test methods for image uniformity and other metrics improved accuracy (Ghassemi et al., 2018).

Financial Considerations

Handheld systems are less costs but only have a limited accuracy of approximately 2C plus or minus. These systems range from $3,000 to $13,000. Fixed systems have an accuracy rate better than 1C and offer a higher resolution. These systems can have multiple cameras and start at $20,000.

Fixed systems start at $20,000, but as with most capital outlays there are other costs associated with thermal imaging systems. These include labor, service, software and installation costs. Service for this technology is approximately 18-22% of the systems original costs for basic or standard software maintenance, and 12-15% for basic or standard hardware maintenance (TractManager database). Software for fixed systems is dependent on features and applications and start at $500 and may require a licensing agreement. Some vendors offer “turnkey” solutions and training modules. These costs vary depending on the complexity of the system.

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Table 1. Tele-thermographic Specifications:
TractManager Capital Database, March, 2020

Vendor	Website	Model	Accuracy	Pixels	Remote Monitoring
Ametek-Land	www.ametek-land.com	vIRalert 2	.5C	80 x 64	Yes
Linespex	linespex.com	Smart Fever Detection Camera		1920 x 1080	Yes
Invidtech	Invidtech.com	SEC-BODYTEMPCAM1	.3C	400x300	Yes
CreativeStar Solutions	www.cssinco.com	TI-CS-T11	.3C	1920 x 1080	Yes
FLR	www.flir.com	FLIR A400/A700	2C	1280 x 1024	Yes
Athena	athena-security.com	Elevated Body Temperature Detection System	.3C	1920 x 1080	Yes
OptoTherm	www.optotherm.com	Thermoscreen	.3C	640 x 480	Yes
Thermoteknix	www.thermoteknix.com	FevIR Scan			

Vendor	Website	Model	Parameters	Scan rate	Price
Sotor Technologies (Multiparameter Vital Signs Screening)	www.symptomsense.com	SymptomSense	blood oxygen levels, temperature (0.2C degrees of accuracy), heart rate, respiration rate, shortness of breath, lung congestion, height and weight.	1,500 per hour	$35,000

Operational Considerations

It is important to develop internal processes and protocols for the use, operation, staffing, and education of thermal imaging systems. The following are FDA tips and proper usage protocols:

- The person who handles the thermal imaging system is not required to be physically close to the person being evaluated. In fact, the person who handles the thermal imaging system could be in a different area or room.
- The person who handles the system (including calibration and setup) should follow all manufacturer instructions to make sure the system is set up properly and located where it can measure surface skin temperature accurately.
- The person who handles the system should be trained to properly prepare both the location where the system will be used, and the person being evaluated, to increase accuracy.
    - Most systems require at least 20 to 30 minutes to stabilize and warm up in addition to calibration by means of a blackbody or simulator. The distance of the from the device to the subject will also greatly affect the accuracy. This puts the subject within the 6-foot parameter recommended for social distancing making it a safety concern for the operator.
- Environmental conditions such as humidity and temperature affect the accuracy of the system.
- Reference the FDA's Thermal Imaging Systems page for further details regarding Preparing the Area Where You Will Use a Thermal Imaging System, Preparing the Thermal Imaging System, Preparing the Person Being Evaluated, and Using the Thermal Imaging System:
    - https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/thermal-imaging-systems-infrared-thermographic-systems-thermal-imaging-cameras
- ***Mass Triage Screening is not recommended for thermal imaging systems.***
    - Infection Prevention measures are more effective in nursing homes.
    - Use thermal imaging as an *initial* assessment of temperature measurement and risk management is preferred over screening large groups of people.
    - Thermal imaging may assist triaging patients in an emergency room.

Recommendation

Mass temperature screening at the point of entry is a relatively new concept for the healthcare industry. The FDA has eased the restriction on thermal imaging systems and as a result multiple vendors have entered the market. Accuracy, throughput, and operator safety are key factors in making an informed decision. Because of the narrow margins between a healthy and febrile patient, accuracy is critical with this technology. False negatives could lead to putting others at risk, while false positives will lead to added costs and loss of time. Optimization of test methods improves accuracy; however, evidence has shown that infection detection is optimal by assessing additional vital signs as fever screening alone is ineffective for virus detection.

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