

Non-Contact Temperature Measurement Devices: Considerations for Use in Port of Entry Screening Activities

Who this is for: This document is intended for public health officials and airport authorities for use in screening prior to boarding aircraft from countries with active outbreaks.

What this is for: *This document provides information and consideration of non-contact thermometers for use in port of entry screening. A non-contact thermometer is a way to take someone's temperature without touching them.*

How to use: Use this document to learn about different non-contact temperature measurement devices.

Key Points

- *A non-contact thermometer is a way to take someone's temperature without touching them.* Non-contact infrared thermometers (**NCIT**)¹ are as accurate as contact thermometers and are low cost. Training is easier and the thermometers are easier to use and do not need as much work to set them correctly.
- Thermal scanner cameras² can measure temperature from a greater distance although they have not been evaluated for use as a primary diagnostic tool or for screening multiple individuals in an uncontrolled environment, such as an airport. They are not as accurate as NCIT's and may be more difficult to use effectively.

Background:

This document provides information and consideration of non-contact thermometers for use in port of entry screening. A non-contact thermometer is a way to take someone's temperature without touching them.

Temperature measurement is just one tool used to find out if a traveler might have Ebola. Other tools, such as looking carefully at the traveler, health questionnaires, and interviews can give a fuller picture of the risk so that authorities can do more effective screening and take appropriate public health action.

Fever

- The average normal body temperature is 98.6°F (37°C).
- Fever is a measured body temperature above normal.
- Fever is often a sign that the body is fighting a disease that could be infectious.
- For different infectious diseases, fever is considered to be significant if the temperature is above a specific measurement.
 - For Ebola, a fever of 100.4°F (38.0°C) or higher is considered significant.
- Other causes of fever include other medical conditions, severe trauma or injury, and some medicines.
- Infected persons will likely not have a fever during the incubation period for Ebola (2 to 21 days).

¹ Non-contact infrared thermometers cleared by FDA under Product Code "FLL"

² System, Telethermographic (Adjunctive Use) cleared by FDA under Product Code "LHQ"

- An ill person's temperature could be normal after taking fever-reducing medicine.

Types of Temperature Measuring Devices

- Usually, temperature is measured using contact thermometers on many places on the body; commonly the mouth, ear, forehead, armpit, and rectum.
 - Some devices such as non-contact thermometers also measure temperature on the forehead.
- A rectal thermometer is the most accurate way to measure body temperature, especially in small children.

Non-contact infrared thermometers (NCITs)

- Depending on the manufacturer, NCITs are held between 1.2 and 6 inches (3-15 cm) from the body.
- Most NCITs measure temperature by placing a probe over the middle of an individual's forehead.
 - Temperature over other body surfaces may also be measured depending on the manufacturer's specifications, including the neck, navel, and armpit.
- Since NCITs do not touch any body surfaces, the risk of cross-infection is low and probe covers do not need to be disinfected or thrown away, unless they come in contact with the skin.
- Some NCITs are FDA-cleared or CE-Marked for use as thermometers and will not need to have temperature confirmed.
 - Another measurement can be taken if needed during secondary screening evaluation.
- Operational advantages: non-contact, accurate, lower cost, smaller size, easier training and use, and less need for re-setting to correct readings. Because some models are FDA-cleared or CE-Marked for use in medical facilities, they can be repurposed if no longer needed at airports.
- Operational disadvantages: slower for screening large numbers of people, meaning that more units and personnel are needed to operate them compared to mounted, camera-style scanners.
- Optimal conditions for use vary by manufacturer but include measuring:
 - Over dry body surfaces; over non-hairy body surfaces; in a draft-free room; at a constant temperature between 60.8°F (16°C) and 104°F (40°C); and at humidity below 85%.
- Ability of NCITs to detect fever
 - Product-to-product comparisons are difficult because: different targets are used, there are few direct studies which compare specific devices, and new devices are developed.
 - From a few review studies (2005 – 2011), overall performance characteristics reported were
 - Sensitivity: 80% - 99%
 - Specificity: 75% - 99%
 - Positive predictive value: 31% - 98%
 - The optimal cut-off point for predicting fever is different for each device and may be different from how fever is defined for a specific disease.
 - So for any device used for fever-screening, the choice of the cutoff value can result in false-positive and false-negative results.
 - Some reports suggest that taking the average of several readings improves accuracy.

Thermal Scanner Camera Devices

- These devices are FDA cleared specifically for adjunctive use only – meaning they are only cleared to be used in addition to another clinical diagnostic procedure. These devices are not cleared as a sole primary screening/diagnostic tool. No thermal scanner cameras are cleared or approved specifically for mass screening of fever or specific diseases.³
- Temperature readings from thermal camera scanners should only be interpreted along with an FDA-cleared (or CE-Marked i.e. EU approved) thermometer.⁴
- Operational advantages: non-contact and relatively accurate.
 - Thermal scanner cameras can measure temperature from a greater distance than other non-contact temperature devices. However, Ebola is not spread through the air, so there is no real safety advantage from the greater separation distance.
 - Mounted camera models can screen large numbers of people, meaning that fewer devices and screening personnel are needed.
- Operational disadvantages: much higher cost, more difficult to use, more extensive training requirements, more frequent re-setting and calibration to correct readings for variations in ambient environmental conditions, less precise, maintenance needs, and a FDA-cleared temperature-measuring device must be used to confirm temperature.

Device Approval

- Different countries may have different medical device approval process and criteria.
- In the United States, medical devices are cleared or are exempted from review by the Food and Drug Administration (FDA).
 - FDA does not develop or test products. FDA experts review the results of laboratory, animal, and human clinical testing done by manufacturers.
 - If FDA grants a 510(k) clearance, for a thermometer, it means the agency has reviewed that the product is as safe and effective as other currently marketed thermometer products.
- In the European Union, the approval process is called CE Marking.
 - Valid CE Marking on a product indicates it complies with European product safety standards.
- FDA-cleared devices for measuring temperature are categorized into the following types:
 - Clinical color change thermometer (21 CFR 880.2900)
 - A disposable device used to measure a patient’s oral, rectal, or armpit body temperature using heat-sensitive chemicals sealed at the end of a plastic or metal strip. These chemicals change colors depending on the temperature.
 - Clinical electronic thermometer (such as non-contact infrared thermometer) (21 CFR 880.2910)
 - An electronic device used to measure body temperature that has a display unit.

³ For some FDA-cleared manufacturers’ devices, the 510(k) summaries indicate the devices can be used in both healthcare and public environments, such as airports; however, the performance of the device may vary depending on the ambient environmental, and any estimated temperature needs to be confirmed with an FDA-cleared thermometer.

⁴ At optimal cutoff values for detecting fever, temperature estimates by some thermal scanners have been found to be relatively accurate; however, they can yield false positive (i.e. incorrectly high temperature readings) and false-negative results (i.e. incorrectly low temperature readings) and are less precise than NCITs.

- Clinical mercury thermometer (21 CFR 880.2920)
 - A device that measures oral, rectal, or armpit body temperature using mercury, which expands and contracts depending on temperature.
- Liquid crystal forehead temperature strip (21 CFR 880.2200)
 - A device applied to the forehead that monitors body temperature by displaying the color changes of heat-sensitive liquid crystals that are sealed in plastic.
- Telethermographic system (“thermal scanners”) (21 CFR 884.2980)
 - A device intended for measuring changes in body temperature as an adjunctive tool to another diagnostic test. This electronic device does not require physical contact to measure infrared radiation that goes along with body temperature variations.
- A searchable FDA database for FDA-cleared products and firms is available at:
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm>
- FDA warns consumers about fraudulent Ebola treatment products:
<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm410086.htm>