Fever Screening Performance and Deployment Recommendations

(as required by FDA Guidance for Industry Dated April, 2020)

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Measurement Accuracy

Both the April 2020 FDA Enforcement Policy for Telethermographic Systems and the IEC 80601-2-59 standard for safety and performance of screening thermographs for human febrile temperature screening referenced in that document define the necessary accuracy for fever screening to be .5°C.

All Optris infrared cameras marketed for fever screening applications are specified for 2% (of target temperature) or 2°C (whichever is greater) which is not compliant with this requirement. Optris cameras equipped with the Optris BR 20AR blackbody reference source deliver .5°C accuracy for target temperatures between 86°F and 104°F which is compliant with both the IEC and FDA recommendation. Measurements from Optris Infrared cameras should be checked for accuracy every two years or earlier as dictated by the buyer's ISO policies for calibrated measurement instrumentation.

Fever Diagnosis and COVID-19 diagnosis

While Optris infrared cameras can be useful as a screening tool to identify subjects with elevated temperature, they should not be used to diagnose fever or to diagnose COVID-19 infection.

- If elevated temperatures are detected, these should be confirmed with secondary evaluation methods (e.g. an NCIT or clinical grade contact thermometer.)
- Public health officials, through their experience with the device in the particular environment of use, should determine the significance of any fever or elevated temperature based on the skin telethermographic temperature measurement.
- Measurements should be made on the tear duct area which has been found to yield the highest temperatures on the face that correlate more closely with core temperature measurements.
- "Crowd Screening" more than one subject at a time is not recommended. Each subject should position in front of the camera long enough to remove eyewear and orient the face in a perpendicular plane to the IR camera lens ensuring the tear ducts are both in the camera line of site. Markings should be clearly visible indicating the precise location where focus is optimal. When the BR-20 is used to improve measurement accuracy to .5°C, it should be positioned close to the subject head and roughly the same distance from the IR camera lens.
- Visible thermal patterns are only intended for locating the points from which to extract the thermal measurement. All Optris camera systems are shipped with PIX Connect software that automatically selects the pixels with the maximum temperature inside an area. Fever screening layouts with rectangular areas that facilitate maximum temperature measurements of subject tear ducts should be used to extract the maximum temperature for each subject.

Establishing alarm thresholds

- It is important to note that thermographic systems measure outside skin temperature which is typically lower than core temperatures as measured with an oral thermometer. For this reason, the medical definition of a fever (100.4°F) should not be used as an alarm threshold because subjects with this core temperature but with lower skin temperatures could register as a false negative.
- It is also important to understand the impact outside temperatures can have on subjects exposed to colder ambient temperatures. Three to four minutes of exposure to lower temperatures typical in northern climates is enough to influence temperature measurements made with a thermographic instrument.
- Refer to quick start guides with instructions for loading standard screening layouts.

Recommendations for Establishing Alarm Thresholds
Normal temperatures (as measured at the tear ducts) for subjects in room temperature conditions are typically between 95°F and 97°F. Infrared cameras have proven effective in screening subjects grouped in common ambient conditions such as those in an airport customs cue. In a scenario where all subjects to be screened are in a room temperature environment, average temperature measurements should be made of several subjects (5 – 8) to establish a normal baseline temperature. Alarm thresholds should be set at 2°F above this baseline temperature. Again, subjects with elevated temperatures should be confirmed with a clinical grade contact thermometer.

The COVID-19 pandemic has expanded the use of thermographic cameras beyond airports and ports of entry to factories, distribution centers, schools, hospitals and office buildings. Each of these presents a unique ambient temperature exposure scenario for subjects to be screened with a thermographic camera. The method used to establish a normal "baseline temperature" for any group of subjects seeking access to a building should be informed by the ambient temperature conditions subjects are exposed to before they are screened with a thermographic camera.

For example, if the average walk time from a parking lot to the entrance of a manufacturing facility is 4 minutes, the baseline temperature should be established based on measurements made on several subjects who walk 4 minutes outside before they are measured. The baseline measurement should be made closely approximating the time subjects will spend inside the building before they are scanned. Also, outside ambient temperatures typically increase throughout the day so a baseline temperature for a morning shift beginning at 7 a.m. will be different than the baseline temperature for employees working the 3 p.m. shift.

All PIX Connect Layouts used for fever screening will include an alarm threshold setting that should be modified to 2°F over the baseline temperature established using the above procedure.

Factors that can Influence Skin Temperature Measurements
Most of the science on the use of thermographic instruments has been based on the room ambient temperature screening scenario such as an airport. More studies are necessary to identify all the factors that can influence skin temperature measurements, but some variables are emerging from early placements that have resulted in false negative or false positive screening results.

- Screening of subjects in vehicles positioned the correct distance from a camera with the correct lensing has been implemented in some locations. (Please note this method of screening cannot be used in conjunction with the blackbody reference source necessary to meet the .5°C accuracy guideline). Some drivers heat up the vehicles to temperatures that increase cabin temperatures resulting in a false positive.
- Subjects wearing hardhats for more than 15 minutes have been found to be warmer than subjects without headgear particularly if the hardhat remains on for several minutes after entering a heated environment.
- Subjects exposed to outdoor temperatures of 40°F for one hour have been measured with readings 4°F lower than subjects exposed to room temperatures. Subjects exposed to temperatures at 40°F for 3 minutes have been measured with readings 2°F lower than subjects exposed to room temperatures.
- Subjects in warmer environments may perspire after climbing stairs or walking a long distance through a parking lot. This moisture evaporatively cools skin surfaces resulting in lower temperature readings even though the subject's core temperature has increased. Excess perspiration should be wiped from the tear duct area before scanning.

Camera Positioning
Infrared cameras are most accurate when allowed to operate in a stable temperature environment. Position cameras in a location away from doors that frequently open and impact the ambient temperature at the location where the camera is positioned.

Additional instructions for IR camera use
Your camera will be delivered with a quick start guide with more details on how to set up your camera and install the PIX Connect software layouts to be used for fever screening. Please refer to these before you use the camera for fever screening purposes. Camera, PIX Connect software and Blackbody Reference Source manuals also include important information you should review before you use the camera for fever screening.