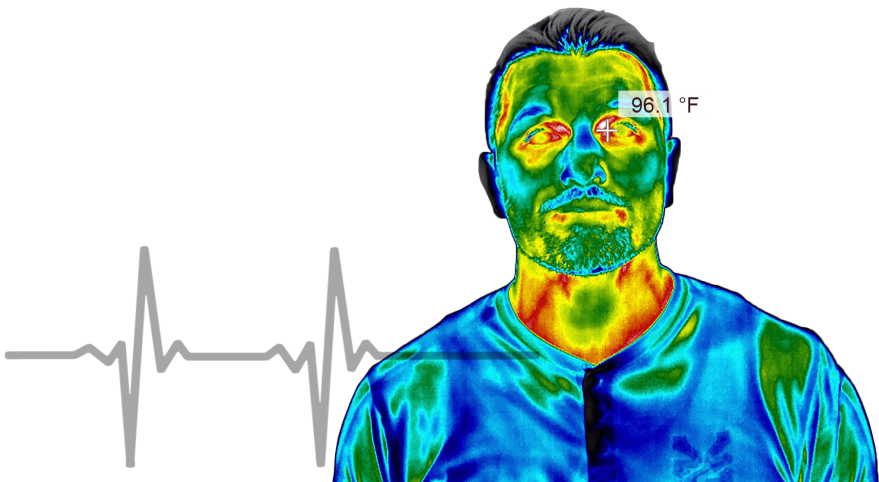




SCREENING THERMOGRAPHY SUPPLEMENTAL USER LABELING COVID-19 PUBLIC HEALTH EMERGENCY MANUAL



PLEASE READ THIS MANUAL BEFORE INSTALLING THE UNIT(S).
IMPORTANT GUIDELINES AND INFORMATION INSIDE.

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1. General Information

The COVID-19 pandemic has dictated the need for measures to be taken to provide a means to conveniently screen persons for elevated skin temperatures which may be predictor of fever. ICI Thermal Imaging Camera Systems are one of the solutions capable of this mission.

The US Food and Drug Administration (FDA) issued an Enforcement Policy for Telethermographic Systems During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency in April of 2020. You can find this policy on the FDA's website at:

<https://www.fda.gov/media/137079/download>

The FDA guidance states that FDA does not intend to object to the distribution and use of telethermographic systems intended for initial body temperature assessment for triage during the public health emergency where such devices do not create undue risk to the public. To support this position the FDA stipulated specific device performance criteria and labeling be provided to the users of the telethermographic systems addressing the proper use and limitations of thermographic screening devices. This supplement is intended to be used in addition to the user manual that accompanied the system.

THE TEMPERATURE MEASUREMENTS OBTAINED UTILIZING THE THERMOGRAPHIC SCREENING DEVICE SHOULD NOT BE SOLELY OR PRIMARILY RELIED UPON TO DIAGNOSE OR EXCLUDE A DIAGNOSIS OF COVID-19, OR ANY OTHER DISEASE.

The thermographic screening system is considered an adjunct device intended for the initial screening of a subject and the results of the screening must take into consideration the following:

- Any elevated body temperatures measured by the system should be confirmed with a clinical grade contact thermometer. It is important to understand that skin temperature does not solely depend on body-core temperature and can be affected by other physiological and environmental factors (example – sunburn);
- Users of the device, with input from Public Health Officials, should determine the significance of any fever or elevated temperature based on the skin telethermographic temperature measurement based on their experience with the device as installed in the particular environment;
- Visible thermal patterns are intended for locating the points from which to extract the thermal measurement.

THE THERMOGRAPHIC SCREENING SYSTEM SHOULD ONLY BE USED TO MEASURE ONE SUBJECT AT A TIME.

2. Device Performance Specifications

Find documentation online:

<https://infraredcameras.com/product-resources/>

3. How to accurately make a temperature measurement with an ICI Thermographic Screening System and factors to consider in the design of the facility protocol:

ICI recommends that the thermographic screening system be set up in accordance with the guidelines outlined in **ISO/TR 13154:2017 Medical electrical equipment - Deployment, implementation and operational guidelines for identifying febrile humans using a screening thermograph**.

When installing an ICI thermographic screening system, you should consider the location, viewing angles, blackbody location, flow of subjects through the area, etc.

The users should be aware the following aspects impact the accuracy of the measurements made with the system:

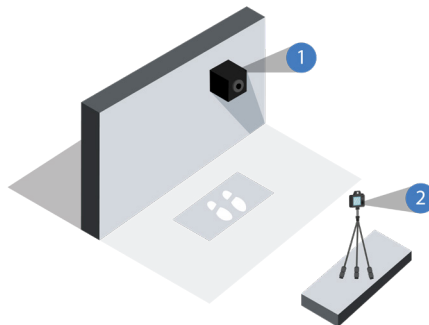
- Make sure you have all system equipment and component items (refer to the Package Includes section of relevant documentation).
- Devices are meant to be used indoors only.
- Ensure setup area has a stable ambient temperature between 20 °C and 24 °C.
- Setup in a humidity-controlled environment.
- Select an appropriate area free of immediate airflow from doorways, as well as air conditioning/ventilation systems. Airflow can influence temperature readings.
- Select an appropriate area free of intense ambient heat or cooling from doorways/windows. Temperature fluctuations can influence temperature readings.
- Target area must have a non-reflective background.
- The viewing angle of the camera to the target zone should be 90°.
- Ensure the thermal device is the appropriate distance from the blackbody (refer to the relevant manual)
- Make sure the temperature reference is positioned off center to keep the person being imaged as centered as possible.

- When fully assembled, make sure the system does not block the direct path of person(s) to be imaged. This ensures it will not be moved or knocked down. Using a dividing barrier will help keep tripods separate from the path.
- The temperature reference source (used for thermal drift compensation) is important in obtaining an accurate temperature assessment. Allow at least 45 minutes for the temperature reference to warm up. This will provide the most accurate skin temperature measurements.
- Measure only one subject's temperature at a time.
- Elevated body temperature should be confirmed with secondary evaluation methods (e.g., an NCIT or clinical grade contact thermometer).
- Measurements should not be solely, or primarily, relied upon to diagnose or exclude a diagnosis of any disease.
- Calibrate systems annually to maintain accurate device specifications.
- Read the current government regulations regarding skin temperature measurements.

4. Why is a blackbody reference source included with the ICI Thermographic Screening System?

A blackbody (also known as an external reference temperature source) is a calibrated temperature source used in the background of the temperature screening area. The blackbody is included with the thermographic screening system for thermal drift compensation. Having a known temperature reference in the frame with the subject being screened allows the device to self-correct for drift in temperature measurements in between calibration intervals.

- 1 Temperature reference source (blackbody)
- 2 Thermal device

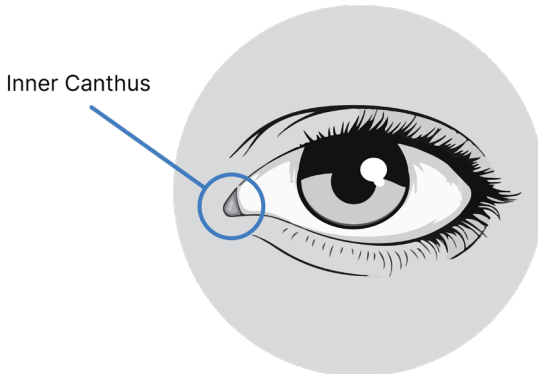


THE ICI SUPPLIED BLACKBODY TEMPERATURE REFERENCE MUST BE USED FOR ACCURATE TEMPERATURE ASSESSMENTS.

5. Where and how does the ICI Thermographic Screening Systems measure temperature of the subject?

Infrared cameras and thermal imaging systems don't actually measure temperature — they measure the radiated energy from the first 1/1000 of an inch of a surface, in this case the subject's skin. The radiant energy is then converted into an electronic signal that produces a thermal image with temperature calculations.

ICI Thermographic Screening Systems measure the temperature of the inner canthus of the eye as shown below:

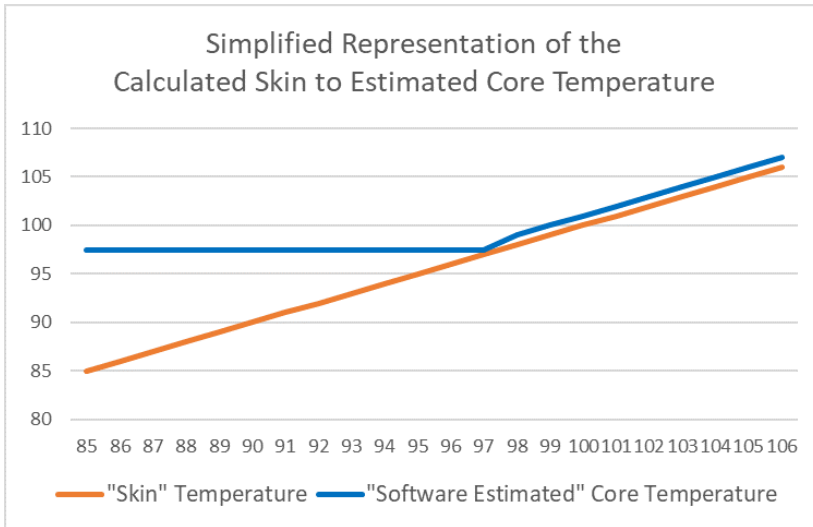


The temperatures obtained from the inner canthus of the eye are translated to an estimated body temperature via the device software and an indication of the subject's body temperature is displayed to the user.

The principle upon which the temperature correction is based, is the human thermoregulatory system. In a non-febrile person, the thermoregulatory system operates in a vasoconstrictive mode where the capillaries in the upper epidermis restrict blood flow to retain body heat. In a febrile person the capillaries open increasing blood flow and in turn increasing the energy radiated from the skin which is imaged with the system.

The software algorithm is based on non-febrile persons having an average body temperature of 97.5°F (range 96 to 99°F) which will be the close to the estimated core temperature shown on the device display. For febrile persons, the algorithm correction for the displayed estimated core temperature includes the approximate one degree difference (see next page).

THE DEVICE(S) SHOULD BE INSTALLED BY A QUALIFIED SERVICE PROFESSIONAL OR SYSTEM INSTALLATION PERSONNEL. IF YOU DO NOT EMPLOY SERVICE PROFESSIONALS PLEASE CONTACT ICI FOR INSTALLATION ASSISTANCE.



- Devices are shipped calibrated.
- Annual re-calibration is recommended for all thermal and temperature reference devices.

6. Environmental Factors and System Set-Up can affect the accuracy of the measurement

At ICI, we follow and urge our customers to follow the ISO/TR 13154 standard when it comes to using Thermographic Systems. This document covers the deployment, implementation, and operational guidelines for identifying febrile humans using a screening thermograph. According to this technical reference, users should ensure that the environment of use comply with the following:

- Be indoors in a temperature and humidity controlled environment
- Located away from A/C ducts that might blow on the person being screened, the camera, or blackbody temperature reference.
- Be free of reflective backgrounds like glass panels.
- Be free of sunlight or strong lighting.

7. Installation and qualification procedures

You should follow the ICI installation and qualification procedures during the initial installation of the thermographic screening system and after any relocation of system equipment. The installation and qualification procedures are provided separately with the device.

Find documentation online:

<https://infraredcameras.com/product-resources/>

PLEASE CONTACT ICI SHOULD YOU NEED ASSISTANCE IN QUALIFICATION TESTING OR IF YOU CAN'T LOCATE THE DOCUMENTATION.

8. What is the correct distance between the camera and subject being screened?

Each ICI thermographic camera and lens combination has an optimal measurement distance which is based on the spatial resolution of the image sensor in the camera.

- 8640/FMX 640/IR Pad 640
 - 12.5 mm @ 2'
 - 25 mm @ 4'
- 8320/FMX 320/IR Pad 320
 - 8 mm @ 15"
 - 12.5 mm @ 23.75"
- Centurion 384/ FM 384
 - 10 mm @ 1.5'
- FM 400/ FMX 400
 - 7.8 mm @ 1'
- FM 320/FM320+
 - 18 mm @ 2.5'
- FM 640/FM 640+
 - 18 mm @ 2.5'
- T-Cam 160 XT
 - 9 mm @ 1.6'

9. FDA Regulation of Telethermographic Systems Intended for Adjunctive Diagnostic Screening

9-1 Indications of Use

The FDA currently regulates Telethermographic Systems Intended for Adjunctive Diagnostic Screening under 21 CFR 884.2980, product code LHQ. The ICI P and S series infrared cameras and IR Flash Software version 1.0 have the following indications for use:

The ICI Series P and S IR Cameras, which provides capture of skin surface temperature of any part of the body, and the IR Flash Software version 1.0, which provides visualization and reporting functionalities, are intended for use as an adjunct to other clinical diagnostic procedures in the diagnosis, quantifying, and screening of relative skin surface temperature.

Environment of use: hospitals, sub-acute healthcare settings, public areas, i.e., airports.

9-2 Device Changes

As compared to the original FDA cleared version of the device, ICI has made the following changes to the device(s):

- Updated device software to track the human face.
- Updated the device software to track and measure the hottest pixel on the human face (generally, the inner canthus of the eye) and report an approximate core temperature based on surface temperature readings.
- Added a calibrated external temperature reference device (blackbody) to promote accuracy.
- Testing to IEC 80601-2-59 Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening
- Recommended use according to ISO/TR 13154:2017 Medical electrical equipment - Deployment, implementation and operational guidelines for identifying febrile humans using a screening thermograph.

IT IS RECOMMENDED USERS READ THE CURRENT GOVERNMENT GUIDANCE REGARDING THE USE OF TELETHERMOGRAPHIC SYSTEMS FOR SKIN TEMPERATURE MEASUREMENTS. ADDITIONAL INFORMATION CAN BE FOUND BY READING ISO/TR 13154:2017 MEDICAL ELECTRICAL EQUIPMENT - DEPLOYMENT, IMPLEMENTATION AND OPERATIONAL GUIDELINES FOR IDENTIFYING FEBRILE HUMANS USING A SCREENING THERMOGRAPH.

10. Cleaning and Maintenance

10-1 Cleaning the Germanium Lens

It is not recommended to use corrosive chemicals on the germanium glass surface which has an anti-reflection coating. Dust, grease, and fingerprints will produce harmful substances and lead to a decline in performance, or cause scratches. If dirt is found, the following methods should be used:

1. Use a blown up balloon or a soft brush to clean the lens surface to avoid dust particles scratching the anti-reflection film on lens surface during the wiping process.
2. Use a soft cotton cloth or lens wiping paper and dip in alcohol or lens wiping liquid. Gently wipe the lens surface from the middle to the edge, paying attention to not crack the lens, or use too much wiping liquid. If the lens is still not clean, replace the cloth and repeat operation.

10-2 Device Calibration

Annual re-calibration is recommended for all thermal and temperature reference devices. Contact customer service to schedule maintenance (see About ICI).

10-3 Cautions

- This product is a precise electronic device that must be handled with care during use, storage, and transportation so as to prevent damage by external forces. During transportation and storage, the original packaging or hard cases should be used.
- Under no circumstances (powered on or off) should the imager(s) be pointed directly at a strong radiation source (such as the sun, direct or reflected laser beams, etc.), otherwise permanent damage may be caused to the device(s).
- Do not expose the device(s) to electric shocks.
- Do not submerge the device(s) in water or other liquids.
- Do not drop or throw the device(s).
- Do not put the device(s) into a fire.
- If the device operates abnormally, contact ICI customer support and do not attempt to dismantle or fix the device on your own (see About ICI).

11. About ICI

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You may reach a representative by phone or email Monday – Friday 8:00AM - 5:00PM CST.

ICI manufactures complete systems and software. We can provide complete engineering, software, and OEM solutions. Our Fortune 500 clients rely on us for infrared equipment and thermography training (which we offer through the Infrared Training Institute).

In addition to providing custom germanium, silica, and sapphire optics, we also build windows for enclosures, as well as custom pan and tilt units. We can even provide customizable explosion explosion-proof systems.

Our knowledge and experience stems from years of using infrared imaging and temperature measurement instruments to provide solutions to: managers, engineers, scientists, inspectors and operators in space, power companies, medical, pulp and paper, food industry, research and development, and various process industries. You can see our products and services used in industrial, commercial, and government applications worldwide.

Originally named Texas Infrared (still DBA), Infrared Cameras Inc. has been in business since March, 1995.

Thank you for your dedicated and continued support.