



FDA Non-Medical Telethermographic System Guidance Detail

- 1) Temperature measurements should not be solely or primarily relied upon to diagnose or exclude a diagnosis of COVID-19, or any other disease.
- 2) Elevated temperatures measurements should be confirmed with secondary evaluation methods (e.g., an NCIT or clinical grade contact thermometer).
- 3) Temperature measurements are dependent on the measurement being taken from the forehead, fist, or wrist and temperatures taken from any other location on body may cause inaccurate readings.
- 4) Infrared sensor in use reads at an overall repeatability of 0.5 degrees Celsius.
- **5) All temperature sensors are calibrated prior to deployment by Team Ray Technologies by measuring the temperature of a person with a trusted secondary device and adding the applicable offset to system settings. Field calibration may be needed when there are changes to the ambient temperature or environment. Field calibrations can be performed by taking the temperature of a person with a trusted secondary temperature measuring device and determining the offset between temperature sensor for the same person and adjusting offset accordingly in system settings. Field calibration changes are password protected and documented. Calibration offset values will vary depending on if temperatures are taken from forehead, fist, or wrist.
- 6) Known factors to influence temperature measurements
 - a. Ambient Temperature – May lower or elevate temperatures respectively
 - b. Person Acclimated to a Low/High Temperature – May lower or elevate respectively
 - c. Perspiration or Moisture – May lower temperature readings
 - d. Skin Irritation – May elevate temperature readings
 - e. Hair – May lower temperature readings
 - f. Electrical Ground Issue – May cause sporadic temperature readings
- 7) Imaging Distance is controlled by a distance sensor programmed initially by Team Ray Technologies to provide consistent distance from forehead, fist, or wrist during temperature checks.

**Units were originally equipped with a blackbody temperature reference source for field calibrations, but it was found after additional testing that a secondary adjustment was also needed to compensate for skin temperature versus body temperature, so it was discontinued to minimize field calibration complexity. A blackbody temperature reference is used for factory calibration above 100.4° F and is used to ensure that elevated temperatures are reading accurately and consistently providing a two-point check.