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Certificate Number 10088
ISO 9001

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ALERT

Fevir Scan 2 Telethermography Device

Customers and users of the FevIR Scan 2 telethermography product are advised that Thermoteknix are producing an updated user manual that will be issued to all customers and include additional and more prominent regulatory warnings. On receipt customers are requested to destroy printed copies and delete any digital copies of the user manual originally supplied with the system. A Field Change Notice is being mailed and emailed to all customers that contains these details. The updated manual delivery will be completed by May 21, 2021.

If you have not received your updated manual by May 21, 2021, or if you have questions or concerns in respect of this update please email fevirscanupdate@thermoteknix.com

Please review this important regulatory information which will be included in the new manual:

1. FevIR Scan 2 skin temperature measurement system is not FDA-cleared or approved and its usage should be wholly in accordance with the enforcement policy for telethermographic systems.
2. Skin temperature measurement from the FevIR Scan 2 skin temperature measurement system should not be solely or primarily relied upon to diagnose or exclude a diagnosis of COVID-19, or any other disease.
3. Elevated body temperature in the context of use should be confirmed with secondary evaluation methods (e.g., a non contact infrared thermometer (NCIT)or clinical grade contact thermometer).
4. 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.
5. The technology should only be used to view and measure the temperature of one person at a time directly facing the camera.
6. Visible thermal patterns are only intended for locating the points from which to extract the thermal measurement.
7. For use instructions, device performance specifications and the methodology, and frequency of any calibration needed to maintain the labelled specifications please refer to the documentation and labelling supplied with the system.

8. The equipment should be used with the Blackbody reference source supplied with the system. This is used to compensate for thermal drift and is vital to obtain an accurate temperature measurement.
9. Automatic face detection software will identify the region of interest for temperature measurement (typically the inner canthus (inner angle of the eye socket)). Software compensation is available to correlate with oral temperature.
10. The system should be set up in accordance with the directions provided in the system User Guide with particular regard to environmental factors such as screening background, ambient temperature and humidity, and airflow and camera and temperature reference location within the field of view.
11. It is important that subjects are provided with sufficient time to equilibrate to the environment where scanning is performed, particularly following entry from external extremes of environmental temperature.
12. FevIR Scan 2 skin temperature measurement system must be operated in accordance with ISO/TR 13154: 2017: *Medical electrical equipment — Deployment, implementation and operational guidelines for identifying febrile humans using a screening thermograph*.
13. The full FDA Guidance for Industry and Food and Drug Administration Staff: Enforcement Policy for Telethermographic Systems During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency can be viewed on the FDA website here: https://www.fda.gov/media/137079/download