Finding Fevers: FDA Relaxes Rules On Temperature-Detecting Cameras

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As business people, airport management, and event hosts everywhere try to figure out how they can return to business as usual, many are considering telethermographic device systems. These are cameras that can detect human temperature in comparison to their surroundings to help identify fevers. Reuters reported last week that Amazon implemented thermal cameras at its warehouses to scan for feverish employees. This has prompted many to wonder how telethermographic devices are regulated.

FDA helped answer this question last Friday. In its "Enforcement Policy For Telethermographic Systems During the COVID-19 Public Health Emergency," FDA explains that use of such cameras to detect human temperature – even when used outside of a medical facility such as in an airport – may render the systems medical devices typically subject to pre-market clearance, registration, listing, and quality regulations. However, during the current pandemic, FDA is relaxing those regulations provided that the systems meet performance and labeling criteria.

The systems must be tested and labeled consistent with the following:

1) IEC 80601-2-59:2017: Medical electrical equipment – Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening; OR

2) Alternative performance specifications that provide similar results to IEC 80601-2-59:2017. The guidance lists several alternative standards.

FDA recommends labeling that includes the following:

1) A prominent notice that the measurement should not be solely or primarily relied upon to diagnose or exclude a diagnosis of COVID-19, or any other disease;

2) A clear statement that:

1. a) Elevated body temperature in the context of use should be confirmed with secondary

evaluation methods (e.g., an NCIT or clinical grade contact thermometer);

2. b) 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;
3. c) The technology should be used to measure only one subject’s temperature at a time; and
4. d) Visible thermal patterns are only intended for locating the points from which to extract the thermal measurement.

FDA also recommends labeling that explains the performance specifications, proper use, installation, and related technical considerations listed in the guidance.

Companies considering using these devices will want to keep in mind that FDA is likely to reinstate the regulatory requirements post-pandemic. When screening vendors, companies should consider whether the vendor will be able and willing to comply with the medical device standards once the economy has re-opened to a significant degree.

In addition, this technology raises employee and consumer privacy issues. Prior to using it, companies should consider applicable laws and policies around notice to the public or employees, capturing such data, potentially storing or sharing it.