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EVALUATING ELEVATED SKIN TEMPERATURE (EST) SYSTEMS

Top five questions to ask when evaluating Elevated Skin Temperature (EST) systems

In light of recent events, discussions surrounding the implementation of Elevated Skin Temperature (EST) systems for use in commercial facilities are on the rise as organizations consider all measures possible in response to the COVID-19 global health crisis. Following are just a few of the most fundamental questions to ask when evaluating these solutions as part of your overall security program.

Is the system FDA-cleared?

As FDA-regulated medical devices, telethermographic and EST technologies used to provide an initial screening of human body temperature are subject to various FDA pre-market clearance, registration, labeling, complaint handling, and quality regulations, among others.[1]

While the FDA has temporarily relaxed certain pre-market clearance and registration guidelines and has stated that it is "committed to maximum regulatory flexibility" amid the COVID-19 global health crisis, it's important to keep in mind that the more stringent regulatory requirements are expected to be reinstated post-pandemic.[2] In evaluating different vendors and solutions, ensure the manufacturer's device is FDA-cleared for use as a telethermographic system intended for adjunctive diagnostic screening under 21 C.F.R. 884.2980(a).[3] In the event that the device is not FDA-cleared for this purpose, ensure the manufacturer otherwise: (1) meets the requirements set forth in the FDA's April 2020 Enforcement Policy for Telethermographic Systems[4]; (2) meets the necessary requirements to achieve FDA clearance; and (3) has plans to immediately seek FDA clearance when the period of regulatory flexibility expires.

Does the system meet FDA accuracy requirements?

In order to take advantage of the FDA's temporary flexibility, the FDA recommends, among other things, that the temperature accuracy of an EST screening system be less than or equal to ±0.5°C (±0.9°F) over the temperature range of at least 34-39°C, or 93.2-102.2°F.[5] Ensure the device being evaluated delivers accurate, repeatable results.

What kind of warranty programs, training and technical support are offered by the manufacturer?

Protect your investment by confirming your solution is paired with a comprehensive warranty program and quality technical support by a strong manufacturer.

Does the application present any employee or consumer privacy issues?

Especially given the widespread application uses being considered for EST systems amid the COVID-19 pandemic, employee and consumer privacy issues must always be a top consideration. It's imperative that businesses seek legal guidance to develop protocols following the confirmation of an individual with an elevated temperature and ensure their collection of skin temperature and fever data complies with all applicable laws concerning privacy and confidential health information.

Is a secondary screening process required?

In many cases, manufacturers have obtained an FDA 510(k) pre-market clearance for the product.[6] To be eligible for such clearance, the FDA requires that an EST device be used alongside a primary means of confirming a fever, such as a medical thermometer, and should not be used for sole screening or diagnosis for any disease or condition. It's important to note that elevated skin surface temperature on its own is not indicative of illness, and that COVID-19 positive individuals may be asymptomatic and still be contagious; any claims by manufacturers that a device can detect individuals who are COVID-19 positive are baseless and misrepresentations of these solutions' capabilities.

[1]See Section 201(h) of the FD&C Act (21 U.S.C. 321(h)).
[2]For further FDA guidance, please visit: https://www.fda.gov/media/137079/download
[3]For those products that have FDA clearance, it is useful to determine whether the FDA clearance covers over-the-counter use of the device or whether the device's clearance is limited to prescription use only. If for prescription use only, it may be necessary to rely on FDA's Temporary Enforcement Policy guidance and/or seek a new clearance if the product will be marketed and used by a non-healthcare professional.
[4]See FDA Enforcement Policy for Telethermographic Systems During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency at https://www.fda.gov/media/137079/download.
[5]For further FDA guidance, please visit: https://www.fda.gov/media/137079/download
[6]For further guidance on FDA 510(k), please visit: https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k#se

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