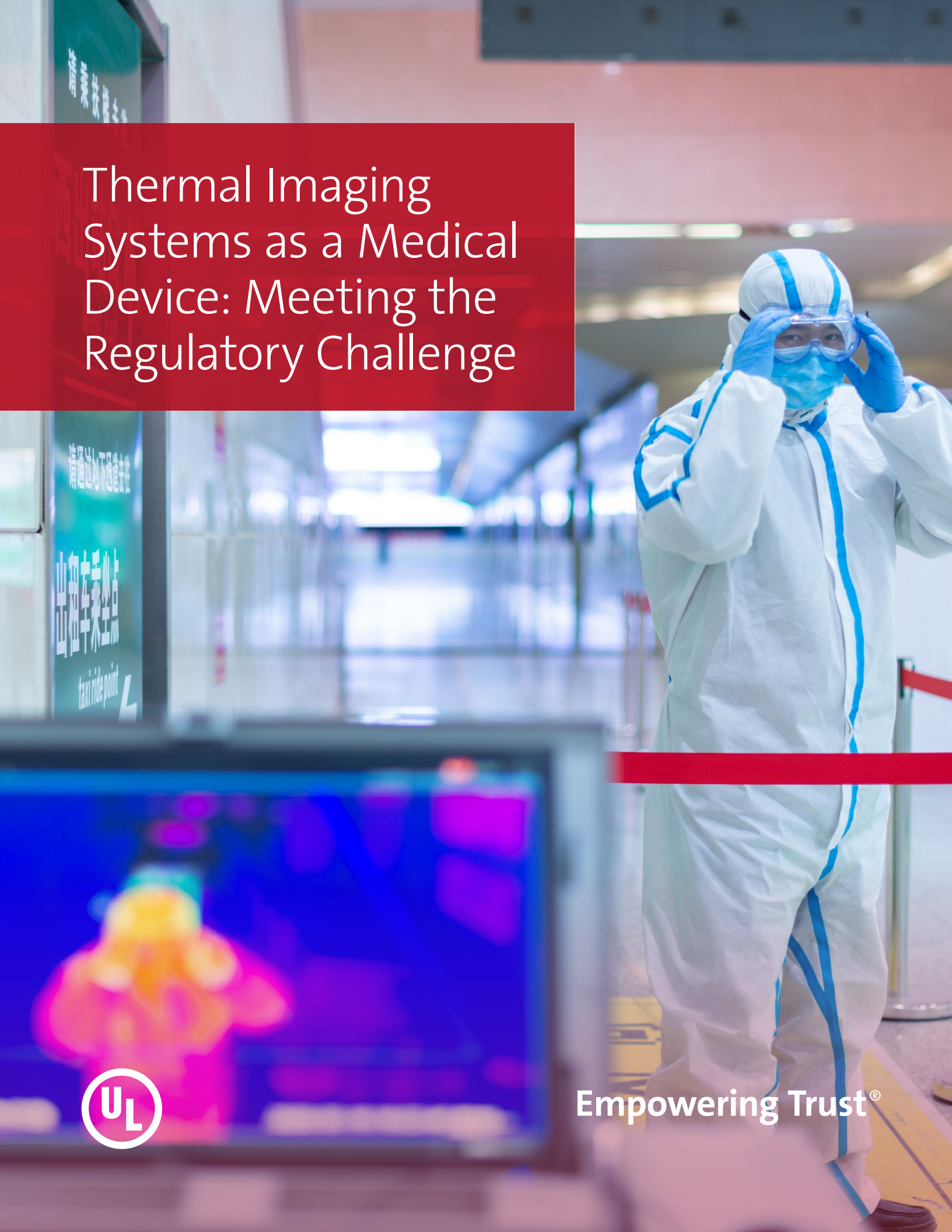
Thermal Imaging Systems as a Medical Device: Meeting the Regulatory Challenge



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Executive summary

Thermal imaging systems, cameras and other thermographic technologies have long been used in a variety of industrial and commercial applications. By measuring various levels of infrared radiation and then converting those measurements into temperature readings, thermal imaging systems and devices are being successfully deployed to monitor temperature and heat conditions in factories, to detect petroleum spills in rivers and seas, and to assess vehicular and pedestrian traffic patterns. Thermal imaging technologies are even being deployed in crucial military operations to safely identify risks and to help protect the lives of military personnel.

In the current global health crisis, thermal imaging systems are also serving as a front-line tool to assist in the screening and assessment of human body temperatures, and can help detect those who may have an underlying health condition. However, not all thermal imaging devices currently in use meet the regulatory criteria or specifications applicable to medical devices. As a result, the use of non medical thermal imaging systems as a health diagnostic tool increases the likelihood of an inaccurate diagnosis, thereby potentially putting additional people at risk.

In this UL white paper, we'll discuss the use of thermal imaging systems, and how thermal imaging technology can be used to assist in the diagnosis of underlying medical conditions. We'll also provide an overview of the regulations and standards applicable to thermal imaging systems used as medical devices. Finally, we'll discuss how UL is working with medical device developers and manufacturers to introduce new and advanced thermal imaging systems and devices to the market.

What are Thermal Imaging Systems and Devices?

Thermal imaging, or thermography, is a remote sensing technology that detects light in the infrared portion of the electromagnetic spectrum, with wavelengths between 780 nanometers (nm) and 1 millimeter (mm). Positioned just above the frequency range dedicated to microwave radiation, infrared light is generally not visible to the human eye. But thermographic technologies can detect infrared light emitted by objects that are not illuminated or that are otherwise obscured from view.

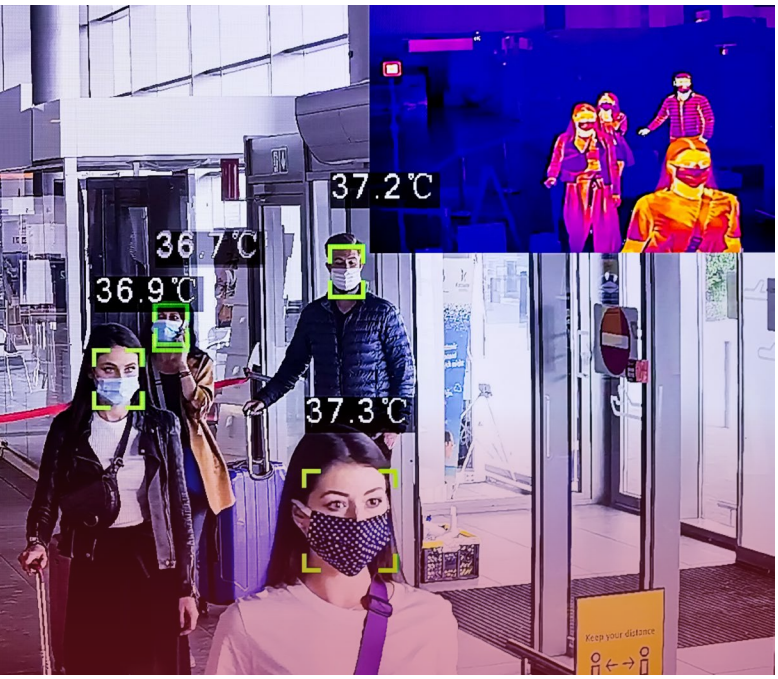
Thermographic imaging systems were reportedly first used in the early 20th century as part of Great Britain's nighttime anti-aircraft defense system following World War I.[1] Today, thermal imaging systems are widely deployed in sophisticated military applications, including target acquisition and surveillance activities. But thermal imaging technologies are also being used in a range of commercial and industrial applications, such as building and infrastructure inspection activities, for monitoring the status of mechanical installations and equipment, and in public and private security operations.

As thermographic technology advances, innovations are opening new areas for the deployment of thermographic imaging systems. Thermal imaging is increasingly being leveraged in fire safety operations, with devices that enable firefighters to more quickly locate and evacuate occupants of burning buildings.[2] Further, in some areas, thermal imaging is being used to support the safe deployment of self-driving cars and other autonomous vehicles. Thermal imaging camera systems that detect far infrared light are now being tested to determine if the technology can complement existing sensor technology in detecting human and animal activity on crowded roadways or at nighttime.[3]

Thermal Imaging Systems as Medical Devices

Since the amount of infrared radiation emitted by an object increases with temperature, thermal imaging technology is also ideal for use in a number of healthcare applications. Currently, thermography is most widely used as a diagnostic tool in oncology, neurology and rheumatology, and is seen by many as a preferred method for detecting breast pathologies, certain types of blood vessel issues, and arthritis, neuro-muscular conditions and other forms of nerve damage.

Thermography systems and devices used in medical applications offer some important advantages over traditional diagnostic tools. First, since the technology measures infrared radiation emanating from the body, thermal imaging is a non-invasive procedure that requires no surgical incisions and poses no potential safety risks to patients. Thermography devices can also collect the information required for an accurate diagnosis without the need for direct contact with a patient. This can be especially important in situations where a patient may have a highly contagious medical condition that has not yet been diagnosed, or for which a patient who has a contagious condition is seeking treatment.



At the same time, because of their high degree of sensitivity, thermography systems and devices used in diagnosing medical conditions are usually deployed in highly controlled environments in order to help ensure the validity of testing results and to reduce instances of false-positive or false-negative findings. Factors such as room temperature, humidity levels, drafts or other excessive air movements, and direct sunlight or strong lighting can each affect the accuracy of thermographic technology in diagnostic procedures.

Other factors that can affect the usefulness of thermography systems in medical diagnostic applications include the training that users receive on the correct application of the technology, as well as whether patients have been properly prepared for thermographic examination. In the latter case, for example, vigorous physical activity or exercise by a patient immediately before testing can elevate temperature readings, potentially rendering the test results invalid.

These considerations are especially relevant in the current COVID-19 global pandemic, in which thermal imaging systems and devices are being widely deployed to screen people for elevated body temperatures, one of several potential symptoms of the virus. Although thermographic technology can be an important tool in this effort, such as with the use of non-contact infrared thermometers to screen individuals, it is far less accurate when used as a screening thermography system for “mass fever screening,” that is measuring the temperature of multiple people at the same time.

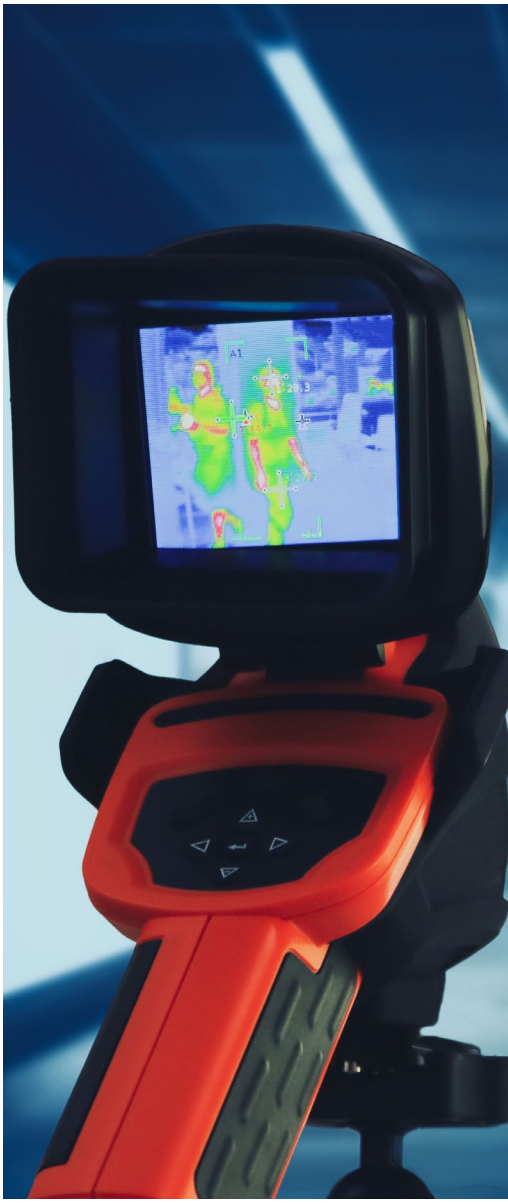
Further, not all thermal imaging systems currently being used to measure human temperature have been designed for compliance with the performance and safety requirements of a screening thermograph. General requirements regarding electrical and mechanical safety are more rigorous for medical devices than they are for comparable electrical and electronic systems and devices used in industrial, commercial or consumer applications. Regulatory approval of medical devices also typically requires adherence to risk management and usability standards as well as the adoption of good manufacturing practices (GMP). For thermographic technology used for human febrile screening, requirements addressing device calibration and accuracy are also critical in helping to ensure the accuracy and usefulness of temperature data collected by a device.

IEC 80601-2-59 and Thermal Imaging Systems Used for Human Temperature Screening

IEC 80601-2-59, Medical electrical equipment – Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening, is the internationally accepted standard that details safety and performance requirements specifically applicable to thermal imaging systems used as a medical device for human screening.

Last updated in 2017, IEC 80601-2-59 is a particular standard in the IEC 60601 standard series for medical electrical equipment. As such, IEC 80601-2-59 specifies requirements unique to screening thermographs that are not expressly addressed in the general standard, IEC 60601-1, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

Perhaps the best way to illustrate the detailed level of technical requirements uniquely applicable to thermography devices used for human febrile screening is to provide a summary of the requirements detailed in IEC 80601-2-59. Here is a list of some of the key terms and concepts detailed in this standard:



- Target area — The standard defines the required target measurement site of a thermal imaging device as the median area between the inner corner (canthus) of each eye;
- Temperature imaging range — The device must be capable of creating a thermograph of the face over at least the range of 30-40 degrees Celsius;
- Temperature accuracy — The laboratory accuracy of temperatures measured by the device must be less than 0.5 C minus the calculated uncertainty of the system over the range 34-39 C.
- Threshold temperature — The device's alarm threshold temperature must be adjustable in increments of not greater than 0.1 C over at least the range of 34-39 C;
- External temperature reference source — The standard details both size and performance requirements for the mandatory external temperature reference source used by the device; The reference source is typically a blackbody radiator in the camera's field of view at a setpoint for useful comparisons to human body temperature.
- Drift and stability measurement — Both the drift and stability of the device shall be not greater than 0.1 C over an interval of 14 days or the calibration interval specified for the device, whichever is longer;
- Minimum resolvable temperature difference — The minimum resolvable temperature difference (MRTD) for the device must be not greater than 0.1o C. The standard references the test methodology in ASTM E1213-14 to verify compliance with this requirement;
- Uniformity of workable target plane — The permissible temperature difference measured at various locations across the target area must not be greater than 0.2o C. The standard details the test methodology to be used to assess compliance with this requirement;
- Face position — The workable target area of the device must be able to screen a face positioned between 0.75 and 2.2 meters above the floor. The plane of the scanning device must be parallel to and in line with the face.
- Spatial resolution — The horizontal and vertical spatial resolution of an image pixel generated by the device must be less than or equal to 1 mm at the workable target plane. The resolution across the typical human face is specified as 240 x 180 mm, imaged by at a minimum of 240 x 180 image pixels.

Other important requirements detailed in IEC 80601-2-59 for thermography systems used for human temperature screening include:

- Screening thermography alarm conditions (Clause 201.102)—The thermal scanning device must include a physiological alarm mechanism to indicate when the temperature recorded within a target area exceeds the prescribed threshold temperature. The device must also include a separate alarm mechanism to prevent a newly activated device from being used before it has completed the device start-up process;
- Accuracy of controls and instruments and protection against hazardous outputs (Clause 201.12)—In addition to meeting the relevant requirements in Clause 12 of IEC 60601-1, the thermal scanning device must meet new requirements in IEC 80601-2-59 regarding the device display. Specific aspects covered in the standard include the display size, color scale, temperature resolution, and response time and throughput;
- Equipment identification, marking and documents (Clause 201.7)—The standard references the identification, marking and documentation requirements in Clause 7 of IEC 60601-1, but also requires additional operating instructions to ensure that the face being scanned is unobstructed by hair, eyeglasses or other objects. IEC 80601-2-59 also recommends that the operator perform a secondary screening with a clinical thermometer when the thermal scanning device detects a temperature reading within the target area that exceeds the prescribed threshold temperature.

Annex C of the standard offers more detailed guidance on marketing and labeling requirements for thermal imaging systems and equipment.

As a particular standard, IEC 80601-2-59 also expressly references the relevant clauses of IEC 60601-1, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (the general standard) for additional safety and performance requirements in the following areas:

- Electrical hazards (Clause 201.08)
- Mechanical hazards (Clause 201.09)
- Unwanted/excessive radiation hazards (Clause 201.10)
- Unwanted/excessive temperatures and other hazards (Clause 201.11)
- Hazardous situations and fault conditions (Clause 201.13)
- Equipment construction (Clause 201.15)
- Electromagnetic compatibility (Clause 201.17)

Finally, IEC 80601-2-59 includes a number of informative annexes that provide further guidance on the application of the standard's requirements. In addition to Annex C previously mentioned, Annex AA offers guidance and rational for the unique requirements in the standard.

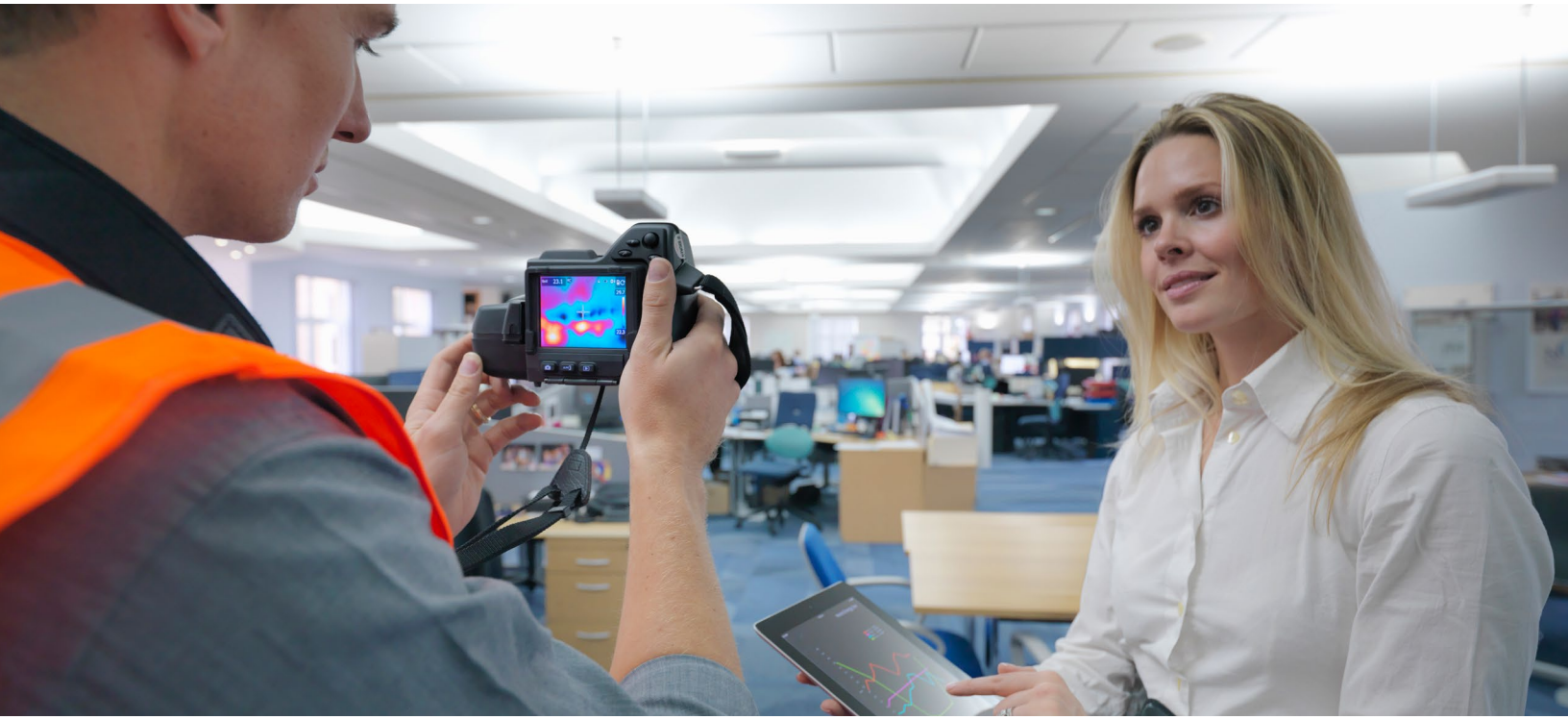
U.S. FDA's Requirements for Thermal Imaging Systems for Human Temperature Screening

The U.S. Food and Drug Administration (FDA) is federal authority responsible for the regulation of medical devices produced or distributed within the U.S. The most common route for obtaining the FDA's authorization to place a medical device on the market is the agency's 510(k) program, in which manufacturers and importers submit a premarket notification to the agency and then obtain FDA clearance for their system or device.

Obtaining 510(k) clearance from the FDA typically requires the submission of extensive documentation regarding the safety of a given device. The extent of documentation required to support a 510(k) premarket notification varies considerably depending on the degree of risk presented by the device. For that reason, providing evidence that a device has been tested and found in compliance with the requirements of a voluntary standard recognized by the FDA is essential to avoid lengthy delays in the device clearance process.

Screening thermographs and thermal imaging systems intended for use as febrile screening devices, fall under the scope of the FDA's 510(k) program. Existing product registrations for this product category in the FDA database fall under LHQ, a Class 1, non-exempt category, meaning that a 510(k) and FDA review is required prior to marketing the medical device. At the same time, IEC 80601-2-59 is an FDA-recognized standard. Therefore, certification in accordance with the requirements of the standard can help facilitate the FDA's review and approval process.

Even under optimal conditions, the FDA's review and eventual clearance of medical devices through the 510(k) process can take months. However, during the current pandemic, the FDA is facing unprecedented demand to quickly review and approve potentially lifesaving technologies. At the same time, the demand for human temperature screening devices and other essential medical devices is outstripping demand. As a result, thermal screening systems and devices that have not been evaluated as medical devices are being placed on the market to help fill the gap.



The FDA's Guidance on Telethermographic Systems Enforcement During the COVID-19 Pandemic

Recognizing the importance of telethermographic technology in controlling the spread of COVID-19, the FDA has issued a guidance that effectively allows the temporary distribution and use of certain telethermographic systems that have not received 510(k) clearance from the agency. The guidance, "Enforcement Policy for Telethermographic Systems During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency," applies to thermal screening systems that are intended for "adjunctive diagnostic screening," and includes systems and devices that "normally are not considered devices under the FD&C [Federal Food, Drug and Cosmetic Act], but that may be used for medical purpose during the COVID-19 pandemic to address availability concerns of such products."

For telethermographic systems and devices not currently cleared through the FDA's 510(k) process, the guidance states:

"To help ensure the availability of products that might offers benefit to health care providers and the general public during the public health emergency, FDA does not intend to object to the distribution and use of telethermographic systems intended for initial body temperature assessment for triage use ... without compliance with the following regulatory requirements where such devices do not create an undue risk in light of the public health emergency."

However, although the guidance permits manufacturers and distributors to temporarily distribute thermographic screening systems and devices that have not received 510(k) clearance for use in human temperature screening, it nonetheless conditions its enforcement waiver on their ability to demonstrate that their products "do not create an undue risk." As evidence of meeting that threshold, the guidance recommends that such devices be tested and labeled consistent with the requirements of IEC 80601-2-59 or, at a minimum, an alternative performance specification that provides results similar to those achieved through compliance with the standard.

The FDA's enforcement policy regarding thermography systems used for human temperature screening will remain in effect only for the duration of the current public health emergency declared by the U.S. Department of Health and Human Services (HHS). Also note that guidance documents issued by the FDA and other federal agencies are intended only to provide insight into how the agency currently views a particular issue, and do not have the force of law.

Nonetheless, the terms of the FDA Guidance provide an opportunity for manufacturers and importers of thermal imaging systems and devices to make their products available for remote human temperature testing in triage screening activities in crowded environments, such as airports and large event venues.

How UL Can Help Thermographic Device Developers Navigate Medical Device Approvals

As previously discussed, thermographic technologies and thermal imaging systems used as febrile screening devices must typically obtain formal clearance under the FDA's 510(k) program before being used in diagnosing a potential medical condition. As a leader in the testing and evaluation of medical devices, UL is well-positioned to assist manufacturers and importers in evaluating their products for compliance with the requirements of IEC 80601-2-59.

Whether the objective is to obtain 510(k) clearance from the FDA or simply to achieve compliance with the essential requirements of the standard to demonstrate conformity with the FDA's Guidance recommendations, UL's team of medical device experts can facilitate your company's efforts to introduce advanced thermographic technologies to the market, both in the U.S. and in other major medical device markets around the world.

Summary and conclusion

As previous pandemics have all too clearly shown, the COVID-19 outbreak has placed severe strains on the healthcare systems and healthcare providers everywhere. Although an elevated body temperature is only one possible symptom of viral infection, the ability to conduct human temperature screening quickly and efficiently is essential to providing critical data on human health and safety, thereby helping to reduce the spread of the virus.

Advanced thermal imaging systems and devices have become an important diagnostic tool in healthcare services. Even more essential in the current environment, thermographic screening systems can provide healthcare providers and screeners with the tools they need to help contain the effects of COVID-19. The requirements detailed in IEC 80601-2-59 provide a thorough and objective benchmark for assessing the safety and performance of these products.

For more information on IEC 80601-2-59 and how UL can support your company's efforts to develop safe and effective thermal screening systems and devices, go to ul.com/healthcar. Or contact us at medical.inquiry@ul.com.

Endnotes

1. "The History of Thermal Imaging Cameras," blog posting on the website of EcamSecure, no date. Web. 22 June 2020. https://www.ecamsecure.com/blog/thermal-cameras/history-thermal-imaging-cameras/.

2. "Thermal cameras give Glendale firefighters X-ray-like vision," story published on the website of the Glendale (CA) News-Press, January 30, 2020. Web. 22 June 2020. https://www.latimes.com/socal/glendale-news-press/news/story/2020-01-30/thermal-imaging-cameras-allow-glendale-firefighters-to-see-through-smoke.

3. "Sensing an Autonomous Vehicle Future," posting on the website of the International Society for Optics and Photonics (SPIE), 1 March 2020. Web. 22 June 2020. https://spie.org/news/photonics-focus/marapr-2020/sensing-an-autonomous-vehicle-future?SSO=1.

4. "Enforcement Policy for Telethermographic Systems During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency: Guidance for Industry and Food and Drug Administration Staff," issued by the U.S. FDA, April 2020. Web. 22 June 2020. https://www.fda.gov/media/137079/download.

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