



October 20, 2020

The Honorable Stephen Hahn  
Food and Drug Administration  
10903 New Hampshire Ave  
Silver Spring, MD 20993-0002  
Cc: Division of Industry and Consumer Education (DICE)

Dear Commissioner Hahn,

On behalf of the Security Industry Association (SIA), I am writing to bring attention to the issue of some companies and solutions that are not following FDA guidelines and the standards within while claiming to detect elevated human temperatures for the purpose of mitigating the spread of disease. These non-compliant systems have the potential to endanger public safety.

SIA is a nonprofit trade association representing businesses providing a broad range of security and public safety products and services globally. In response to the COVID-19 global pandemic, the security industry has sought to provide customers with solutions to assist with responsible recovery and reopening.

The guidance released by the FDA – *Enforcement Policy for Telethermographic Systems During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency* – dictates clear guidance for devices and systems that are used to detect elevated human body temperatures amid the global pandemic.

Many of our member companies are taking measures to ensure these guidelines are followed, but it has become increasingly clear that there have been some products introduced during this time that are missing the mark when it comes to enhancing public safety. These failures come as a result of not following the guidance, specifically when it comes to being labeled consistent with *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 an alternate standard. Some products are deviating from this standard by being marketed as

- able to scan multiple subjects at a time
- able to scan subjects with an obscured procerus region (hats and glasses)
- able to scan subjects outdoors
- able to scan subjects with windows in the background

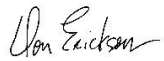
These claims are not supported by the guidelines or standards, and without enforcement of the FDA guidelines, the result has been confusion in the market which can lead to a false sense of public safety.

The proliferation of solutions that cannot function as marketed also negatively affects makers, resellers and users of solutions that do follow the guidelines.

SIA believes there is an opportunity for the FDA to support the agency's mission of protecting public health and safety by enforcing the guidelines that were released in April 2020. SIA plans to educate end-customers of these systems by highlighting these guidelines as a whole and particulars within the standards that they reference.

Please let us know if we can provide further information or assistance as you consider these important issues.

Sincerely,

A handwritten signature in black ink that reads "Don Erickson". The signature is written in a cursive style with a prominent initial "D".

Don Erickson  
CEO  
Security Industry Association