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HEALTH

Industry Calls for More Oversight of Covid-19 Temperature Scanners



By Robbie Whelan

Security camera manufacturers are asking government regulators for tighter oversight of temperature-detecting cameras, saying that a flood of new products prompted by the Covid-19 pandemic endangers public safety by providing inaccurate fever screenings.

Since last spring, hundreds of merchants have begun selling telethermographic systems—a category that includes dozens of devices such as cameras and kiosks that use infrared scanning and thermal imaging to detect body heat from a distance.

School administrators, managers of government office buildings and corporations have been purchasing the technology and installing it at the entrances of schools, hospitals and other buildings in the hope that it will mitigate the spread of Covid-19 by screening out people with fevers, a key symptom of the virus.

But many of these devices aren't capable of providing accurate body temperature readings that would indicate fever, manufacturers and experts in infrared technology say. Instead, many of them are used to accurately detect security risks such as unauthorized people entering a building, or even the presence of a concealed weapon. Others are used to take the temperature of industrial machines. But few are accurate enough to detect fevers in humans.

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Fearing shortages of temperature-screening equipment, the U.S. Food and Drug Administration opened the floodgates in April, issuing new guidance that loosened the rules governing the telethermographic devices.

The agency, which regulates medical devices, said it wouldn't object to the distribution of thermal cameras and other temperature-taking devices that hadn't received agency approval, as long as the devices were properly labeled and used to test for fevers.

The move prompted many new sellers, including many with little or no experience with medical devices. Many of these sellers rely on inexpensive imports from China that they rebrand, sometimes using misleading marketing materials to target school districts, airports, hospitals and businesses at a steep markup, longtime vendors and scientists say. "The public just doesn't know how to evaluate these products and they're being bamboozled into buying this garbage," said Dan Dietrich, president of Jogan Thermal Checkpoint, a manufacturer and vendor of temperature-measuring equipment in Denver. "School districts are notorious for getting flooded in their bid responses with these garbage thermal scanner kiosks, and they just don't know the difference."

In late October, the Security Industry Association, a trade group that represents hundreds of companies that manufacture technology for private security providers, sent a letter to U.S. Food and Drug Administration Commissioner Stephen Hahn, pleading with the agency to step up enforcement of devices that don't comply with agency guidance.

Among other complaints, the letter said that many new products used to detect fevers violate FDA recommendations by trying to scan more than one person at a time, scan subjects while outdoors, scan subjects wearing hats or face masks, or scan subjects in

front of windows, all of which reduce accuracy.

“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,” read the letter, which was signed by Don Erickson, the association’s chief executive. “The result has been confusion in the market which can lead to a false sense of public safety.”

The FDA has acknowledged receiving the trade group’s letter.

An agency spokeswoman declined to comment on the letter but said the public health emergency caused by the coronavirus made it necessary to relax enforcement of regulations to ensure an adequate supply of temperature-taking devices.

“The accuracy of these systems depends on careful set-up and operation, as well as proper preparation of the person being evaluated,” wrote Abigail Capobianco, the spokeswoman, in a prepared statement.

The FDA and the National Institutes of Health have said that fever alone isn’t an adequate indication of whether a person has Covid-19, the disease caused by the coronavirus, but the FDA says thermal imaging devices have been used to positive effect in previous epidemics.

New entrants into the market say they are simply trying to fulfill an important public health need and help customers provide a sense of safety to their clientele so that they can reopen their businesses.

Henry Valentino, a Las Vegas entrepreneur who spent the last decade selling point-of-sale security software to casinos, jumped into thermal imaging cameras in May, soon after the FDA relaxed its guidance on the devices.

His company, eConnect Inc., buys cameras made in China by Shenzhen Eledy Technology Co. Similar cameras retail on the e-commerce site Alibaba for about \$500.

Mr. Valentino says he installs his proprietary software on the cameras. He has sold more than 500 of these systems at a cost of \$3,600 each, including warranty, to casinos and resorts, as well as a hospital system in Los Angeles and several school districts in Oklahoma.

On eConnect’s website, the thermal camera system is described as “FDA Cleared,” but no device sold by Mr. Valentino’s company appears in the FDA’s public database for approved devices. Mr. Valentino explained that the language on the website refers to his

company's close adherence to the April FDA guidelines.

He says that the cameras were tested for accuracy by a physician at a Las Vegas hospital who is also a customer of eConnect.

However, eConnect doesn't follow other FDA recommendations, including that all thermal cameras use a "blackbody device"—a heat-producing element that comes standard with most high-end thermal cameras and that provides a reference temperature for the cameras to measure against—and that the cameras be calibrated frequently to ensure accuracy.

"Our system, you don't need to calibrate it," Mr. Valentino said. "Right out of the box, it's super accurate."

Experts in infrared imaging say it is impossible for low-end thermal cameras to produce consistent, accurate readings without a blackbody device, and few devices with that technology can be purchased for less than \$5,000 to \$6,000. "The greatest danger is getting false negative readings from devices that understate body temperature, so that infected people could slip through," said Jim Seffrin, director of the Infrasppection Institute in Burlington, N.J., which studies the thermal camera market. "I've seen a number of devices being used that don't meet the standard requirements. It really opens a Pandora's box."

The problem, Mr. Seffrin said, is that the FDA's April guidance was a recommendation, not a requirement, and gave a signal to camera merchants that no enforcement was forthcoming for selling devices that don't work properly.

"With the guidance as written, they've left the ethics up to the manufacturers, and relied on them to do the right thing, but when there's money involved, that doesn't always happen," Mr. Seffrin said.

Established thermal camera makers say that the relaxed rules have allowed hundreds of companies to undercut them and steal away customers who don't know the difference between accurate thermal cameras and cheap knockoffs.

"What's happened is that essentially the snake-oil salesmen have jumped back into the business," said Gary Strahan, chief executive of ICI Thermal Cameras, a manufacturer in Beaumont, Texas.

ICI's camera systems, which can cost up to \$20,000, have had FDA clearance since 2008, and were used to help detect febrile patients during the Ebola and the H1N1 epidemics.

“The market is flooded with competition that knows nothing about the standards. Anyone can sell anything and everything, and it absolutely is being abused by hundreds of companies,” Mr. Strahan said. “Guys who were selling printers and copiers switched to this.”

In June, the school district in Alabama’s Baldwin County spent just over \$1 million to purchase three cameras manufactured by the Chinese company Hangzhou Hikvision Digital Technology Co. for each of its 48 schools. At a school board meeting before the purchase, district officials said they were swayed by what they called an amazing display of the Hikvision cameras that showed that they could take temperature readings from 30 students at a time.

Hikvision was one of several brands banned last year for use by federal agencies over security concerns. The Baldwin systems don’t use blackbody devices. Hikvision didn’t immediately respond to requests for comment. The FDA guidelines recommend testing only one subject at a time and using blackbody devices to increase accuracy. District officials said at an August press conference about the cameras that it didn’t intend to follow FDA guidelines and that the cameras were meant as a first line of defense.

“The second line of defense is to get that child to the nurse to get a true reading,” said Carol Broughton, principal of Fairhope East Elementary in Fairhope, Ala. For most of September, several dozen students and employees remained out of school “for a countless number of reasons related to COVID-19,” according to the district’s daily “Covid Transparency” reports.

District officials didn’t respond to requests for comment on the cameras.

“I’m not an infrared expert, don’t claim to be,” said Baldwin schools superintendent Eddie Tyler at the August press conference. “We purchase these to protect our students and employees, and that’s what it’s doing.”

Write to Robbie Whelan at robbie.whelan@wsj.com