Questions for Temperature Kiosks

Please clarify the bid due date?

Bibb Response: The bid is due on 7/20/20

Describe temperature accuracy range ≤ ± 1◦ F. The FDA has only approved accuracy ≤ ± 0.3◦ F. These devices also do not meet FDA requirements to differentiate the difference between Elevated Body Temperature and Elevated Skin Temperature. How are you going to ensure none of these devices are submitted? More important, from a liability and specification standpoint, are you willing to change the specifications to only accept devices approved by the FDA?

≤ ± 1◦ F does not allow for much variance between 98.6F and the 100.4F CDC Fever Threshold. Without a highly accurate precision camera in a temperature stabilized housing, you cannot attain accuracy recorded in test lab environments in the real-world. How do you plan to have a system perform with any level of accuracy when the ≤ ± 1◦ F is far out of range of even the poorest quality products on the market? Are you willing to make a change to tighten this specification to 0.3C in alignment with the April 2020 FDA COVID-19 system recommendations?

Bibb Response: Yes

We assume the purpose of this specification is to be able to establish a "Temperature Baseline" for people entering the building on a regular basis and be part of the Reporting requirements. Is this correct?

Bibb Response: Yes

Would Checkpoint Avoidance detection be an interest?

Bibb Response: No

Would Hand Sanitation verification be an interest?

Bibb Response: No

Would Spatial Reference (Social Distancing) verification be an interest?

Bibb Response: No

More than forty two (42) made in China devices have been banned for sale or use the U.S. by the US Government because they do not meet this NDAA (National Defense Authorization Act) criteria. https://ipvm.com/reports/aug-13-2019. Further, there is legislation being considered that will include federal charges for those who sell or procure these system knowingly or unknowingly. Are you going to consider restricting the solutions to US origin products only? Not unless they are banned at the time of this bid

On April 17, 2020 the FDA issued system recommendations for the use of thermal cameras for the detection of elevated body temperature in humans relative to COVID-19. https://www.fda.gov/media/137079/download

Enforcement Policy for Telethermographic Systems During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency Guidance for Industry and Food and Drug Administration Staff

Telethermographic systems are able to determine surface skin temperature, which is then used to estimate the temperature at a reference body site (e.g., oral, tympanic membrane).

www.fda.gov. Page 5 cites these points. These specifically address accuracy, and the related components. In the first section, they reference the global IEC 80601 standard which states that the only reliable method is the interior canthus or tear duct area for measurement, and cites all other methods are unreliable. Further, it requires the use of an accurate black body temperature calibration source, and that the stability and drift do not exceed 0.2C or .0.36F. Do you plan to write the specification to only allow systems that meet the latest FDA system recommendation and the two global standards (IEC and ISO) on thermal temperature screening?

Bibb Response: These are the specifications and they should meet all regulations and standards