

Email Questions:

What is Meridian's position that the kiosk is not a medical device?

This product has been reviewed and meets the minimum performance requirements outlined in the enforcement policy allowing for Meridian's device to be exempt for the duration of the public health emergency declared by the Secretary of HHS as outlined in the attached letter from Meridian's attorney. Meridian is also currently pursuing 510(k) certification.

What evidence or US law does it base its position on?

See above

What is Meridian's position about the country of origin of this device?

Meridian does not represent that our product, as a whole, is "made in the USA". Our product contains components sourced from the US, China and Germany, as made clear in our documentation. The head unit, made in China, and the Thermopile Sensor, made in Germany, are components of the full kiosk which is manufactured and assembled in the US.

Article Questions/Comments:

Device Set up:

Was the device set up correctly based on manual, and was everything under the Caution section considered?

Manufacturer:

Meridian has a proprietary source for our components. None of our components are sourced through BEMS or other resellers, thus we are not a relabel of the BEMS unit. We can provide further evidence to this fact if needed.

Missed Elevated Skin Temperatures:

Please provide how you tested this in your article. Based on your previous article we have attached a photo. Is this how it was tested? <https://kioskindustry.org/temperature-kiosk-tablet-tested-and-scored/>

How bad are some temperature tablets? An excerpt from our newest test
<https://lnkd.in/djHBGWy>



Auto Calibration:

In our manual, we specify how to set up the device correctly. Please see our attached Manual under the Instructions for Use.

Hats and Glasses:

In our manual, we state that hats and glasses can affect the temperature of the reading. We have seen instances where the subject was wearing hats and/or glasses and the device was unable to read the temperature. Examples were a baseball cap and motorcycle helmet.

Strong Accuracy Deviations When Outside Recommended Distance:

We advise that users measure their temperature at the recommended distance. This is up to the customer to regulate. The 20" - 36" distance is all within the device's tolerance readings that we specify in our manual. The device displays a silhouette to guide users to properly center their face in the frame.

Measurements Reduced When Subject Moving:

In the manual, we recommend that users approach the front of the kiosk until their face fits within the designated area on the screen. Also, the results that you reported on subject movement are all within the advertised overall +/- .9 degrees Fahrenheit tolerance of the device's temperature readings.

Mask Detection Easy to Spoof:

This would be a violation of acceptable use or business codes of conduct for most businesses. It is up to each business to evaluate those policies and ensure they are being followed.

Software:

Meridian Kiosk – Software Version 2.0.0.21 – This is proprietary software on the side of Meridian that is why it is at a different software version.