NON-CONTACT CORE BODY TEMPERATURE MEASUREMENTS: PROPOSED PERFORMANCE STANDARD AND TEST METHODS

OVERVIEW

SITUATION DESCRIPTION

Due to the SARS-Cov-2 pandemic, the market for non-contact body temperature measurement has greatly expanded. However, there are serious issues with current market offerings as well as the standards relied on for assessing these systems. Many marketed devices, including some with FDA 510(k) clearance, do not report an accurate number, but rather an inappropriately adjusted number that provides only the appearance of accuracy, while failing to report actual core body temperature.

The potential impact of this problem is hard to overstate. In the case of properly operated forehead IR scanning systems that have been marketed for several years, we have found systems that will report healthy temperatures for both extremely low and high core temperatures (e.g. a human suffering from severe hypothermia of 95F or a moderately severe fever of 103F may be reported as 97.4 and 99.2F, respectively). This means many existing products perform little or no better than chance and have the potential to cause harm by producing a false sense of safety.

OBSTACLES

The reason this has not been discovered is a lack of awareness that a clinical trial alone may not detect this problem. The algorithms that are masking these inaccuracies are simple, however they are difficult to detect, particularly when the only comparison is between the body temperature output and body temperatures of a pool of human subjects, because the range of normal healthy body temperatures does not vary widely. In short, a clinical trial may appear to validate such a system but fail to detect a system that reports normal temperatures for any human being measured.

ADDITIONAL OBSTACLE: EXISTING STANDARDS NOT FULLY DEFINED

The IEC 80601-2-59:2017 standard for a non-contact screening thermograph defines equipment requirements for core body temperature measurement, and the associated ISO/TR 13154 defines operational requirements, or protocols for core body temperature measurement. However, some of these requirements are incompletely or improperly defined such that a screening system can be devised that fully meets the standard's requirements yet fails to meet the scientific requirements for determining core body temperature measurement.

Examples of thermograph standards lacking specificity:

- Item 201.101.2.2 in the IEC equipment standard defines a requirement of ±0.5C accuracy over the range 34°C to 39°C, but does not state whether this refers to the *skin surface temperature obtained from the thermograph or the extrapolated human core body temperature.*

- Secondly, item 201.5.3 states the "The range of environmental conditions for NORMAL USE shall include: a temperature range of 18°C to 24°C". The ISO protocol further restricts this range to 20 to 24°C, however it does not specify or sufficiently describe *the role of the environmental temperature when using the inner canthus surface temperature to identify a potential febrile core body temperature.*

There exist such systems that fail to meet the scientific requirements yet meet and are being marketed as meeting the standard. In order to appear accurate despite lacking the ability to produce an accurate measurement, these systems may be using an inappropriate adjustment as described above. Whatever the case, a key scientific requirement for febrile temperature estimation is fidelity to a range of surface temperatures.

ACTIONS

We propose a pair of simple tests for determining if the system can meet the scientific requirements for febrile temperature estimation. These tests can be performed in under an hour in any nationally recognized test lab with access to an infrared (IR) calibrator (aka blackbody). The first test, described in detail in ***Appendix A: Surface Temperature Range Test Protocol***, examines the fidelity of a system to the full range of surface temperatures that are of interest in febrile temperature estimation. The second test, described in detail in ***Appendix B: Operating Temperature Test Protocol***, describes the ability of the system to react to changes in operating environmental temperature. A third test, described in less detail in Appendix C describes a subtlety of clinical trials that may fail to discern accuracy at feverish temperatures.

Rationale 1 - The Physiologic Correction

The use of appropriate thermographic equipment and procedure (see IEC and ISO standards and Reference 1) can obtain inner canthus or face maxima surface temperatures that can be used to identify whether individuals have febrile core body temperatures. However, the inner canthus or face maxima surface temperature is reduced from the core body temperature by the insulating effect of skin and film coefficient of still air surrounding the body. For a full treatment of bioheat transfer[2], including the effects of perfusion and different tissue layers, see Section 4 in Reference 1. In still air conditions typically encountered however, the effect reduces to that of static thermal equilibrium for the aforementioned thermal resistances of skin and air and thermal radiation between the skin and the environment. These effects are approximated well by a linear relationship, which has been documented in the literature over typical ambient air temperatures between 30F and 100F[3,4].

This effect is correctable, if the ambient air temperature is known, and the physiologic calibration factor is known and applied correctly. This is dependent on the total effective resistance of the skin-to-core blood insulation, plus the skin-to-air combination of conductance, convection, and radiation to ambient air. (This skin-to-air resistance can also vary in ways that aren't monitored routinely today and is the subject of a planned follow-on technical research and development. For this report, skin-to-air resistance is assumed to be constant).

The reason for targeting the inner canthus is the relative thinness and consistency across people of this insulative skin above the vasculature fed by the angular artery (fed by the

facial artery, which in turn is fed by the external carotid). This region is considered the most reliable area of normally-exposed skin for non-contact core body temperature measurement. The forehead also has arteries near the surface, but they are more variable in location and the skin at the forehead is more variable in thickness from person to person. A recent clinical trial[5] involving regions of interest encompassing the forehead, inner canthi and whole face maxima revealed a large difference between forehead and inner canthi, with inner canthi significantly more reliable, and surprisingly, whole face maxima to be the most reliable for detection.

$$T_{surface} = T_{core} - 0.2 * (T_{core} - T_{ambient}) \qquad \text{Equation 1}$$

The physiologic calibration factor can be obtained using a suitable population of test subjects with core body temperature measurements and inner canthus surface temperature measurements in at least two stable ambient air temperatures after each subject being scanned has fully equilibrated to each ambient air temperature. Our physiologic calibration factor study was performed using a population of 32 individuals each scanned after equilibration in three different areas having ambient air temperatures of 45F, 70F and 85F and with oral thermometry performed once with a clinical heated probe oral thermometer (Welch Allyn SureTemp Plus 690) which had its accuracy tested in an immersion circulator water bath accurate to 0.1C traceable to NIST calibration standards (PolyScience SD7LR-20). For each scan, the ambient air temperature was recorded.

The physiologic calibration factor is obtained by fitting the surface temperature data to the oral temperature data, where the range in ambient temperatures must be sufficiently far apart to minimize the error of the resulting fit. We share our physiologic correction formula with a calibration factor that is sufficiently close for test and demonstration purposes to the proprietary factor we use in our products. Equation 2 is merely Equation 1 rearranged for ease of use because in most conditions, the user is trying to determine the core temperature from the surface and ambient air temperatures.

$$T_{core} = T_{surface} + 0.25 * (T_{surface} - T_{ambient}) \qquad \text{Equation 2}$$

These equations may be used for temperatures in any of Fahrenheit, Celsius or Kelvin. For example, in a room temperature of 68F, using the first formula, a core body temperature of 98.6F would correspond to 92.3F. Conversely, using the rearranged Equation 2, a surface temperature of 95F in room temperature of 68F would correspond to a core body temperature of 101.25F, which is above a mild fever threshold of 100.4F. If the room temperature were increased to 75F, a surface temperature of 95F would correspond to a core body temperature of 100F, and would be considered below (most) fever thresholds. In fact, if a correction was based on a single temperature anywhere in the ISO standard's 20-24C (68 - 75.2F) range, the *resulting core body temperatures would then be allowed to vary by as much as 1.8F* depending on the actual ambient air temperature at the time of scan.

LACK OF AMBIENT AIR (ROOM) TEMPERATURE MEASUREMENT

Given the other sources of variance inherent in measurement systems and the fact we desire to use a threshold that is only 1.8F greater than the assumed normal core body temperature, the need to monitor and react to ambient temperature more closely is a *critical deficiency in the standard*. One could either control ambient carefully or monitor ambient and use the resulting information to react to these changes in ambient.

One method for compensating for changes in ambient temperature is to use a moving average over the last N subjects scanned. However, the effectiveness of this method is limited by the variability of normal body temperatures, the presence of potential actual abnormal temperatures in the last N subjects, any effects of air and wind on these last N subjects, and time passed since the first and last of these N subjects. If the number of subjects is increased, the effect of variability is decreased, but then the time and potential for air temperature to affect the system will increase. Being on guard for these effects increase the burden on the operator and increase the likelihood of errors that would not be introduced when using a calibrated physiologic correction.

To-date we have not seen a system with a confirmed ambient temperature-based physiologic correction. There may be systems that do so. Regardless, the system's sensitivity to ambient temperature should be tested for both healthy and lowest desired fever threshold temperatures.

TESTING BASED ON AMBIENT AIR TEMPERATURE

The test requires an infrared (IR) calibrator set to surface temperatures corresponding to core body temperatures of 98.6F and 100.4F, and the system output be recorded while operating in two room conditions: ambient temperatures of 68F and 75F. Alternatively, if the manufacturer specifies a wider operating temperature range, the endpoints of this range should be used for the ambient air temperatures. The system's core body output at both temperatures should not deviate by more than the quoted (or desired) accuracy of the system over this ambient temperature range.

Rationale 2 - Existence of Pseudo Methods

There are now numerous non-contact fever detection systems that have been examined and found to be reporting core body temperatures that do not correspond to the surface temperatures and a realistic physiologic correction. Most concerningly, these systems report numbers closer to an expected normal core body temperature despite being tested with IR calibrators set to surface temperatures corresponding to healthy and febrile core body temperatures.

FEVER DETECTION DEVICES MANIPULATING EQUATIONS AND DATA

The most prevalent method appears to be a nonlinear curve that "pushes" numbers closer to 37C (98.6F), regardless of how inappropriate this is. This has the side effect of making a system appear accurate when tested against oral or core body temperatures when only people with non-febrile oral or core body temperatures are examined, making this technique nearly impossible to detect with the resources typically available to customers. A polite term for this type of technique is "pseudo-method".

We define pseudo-method as a method devised to accept a variety of inaccurate thermal sensor data and output temperature results that appear consistent with expectation when tested in the general population. One example pseudo-method could be to output a constant average human body temperature plus or minus some small random number matching the variability of the human population. Many other pseudo methods are possible, including ones which would linearly correlate with oral temperatures in large populations yet fail to detect actual fevers. Because there is little variation in oral temperature measurements in the vast majority of the population, a system devised with a pseudo-method is undetectable from a system devised for accuracy unless the testing population includes wider variation in core body temperature due to fever, and the accuracy test is weighted to include equal contributions from core body temperatures further from the average. Without weighting the test to balance non-normal temperatures with normal temperatures, a large enough normal population will overwhelm any test statistic produced, with the result a pseudo-method would appear accurate by the test metric.

However it is possible to detect pseudo-methods in laboratory settings by testing whether the system is a) responsive to changes in ambient temperature and b) has an appropriate transfer function relating surface temperature to core body temperature estimate. These can be determined most effectively with an IR calibration source set to a range of temperatures encompassing the range of surface temperatures expected in the population of healthy and feverish individuals, as described in this document.

TESTING BASED ON SIMULATED CORE BODY TEMPERATURES

The test requires an infrared (IR) calibrator set to surface temperatures corresponding to core body temperatures ranging from 95F to 104F based on the ambient air temperature during the test. These surface temperatures are obtained by applying Equation 1 to the desired body temperatures and the air temperature. For heating-only IR calibrators, it is generally more efficient to begin at the lowest temperature and proceed in a stepwise fashion through the range of temperatures towards the highest temperature. At each setpoint, the IR calibrator must be allowed sufficient time to fully stabilize, and this time can be obtained from the manufacturer of the IR calibrator or measured by the test laboratory. The system's output estimated body temperature is recorded for each setpoint, and at the conclusion of the acquisition, the system's outputs are plotted against the simulated core body temperature setpoints.

If the deviation is more than 1.8F in either direction anywhere in its range, this implies the presence of a pseudo method. If the deviation is present for elevated temperatures, the system will have reduced sensitivity to fevers. Furthermore, if the deviation is present for below-normal temperatures, then the system is likely to hide improper operation causing these abnormally low temperatures, such as testing individuals in a windy environment, and this would also translate to reduced sensitivity because the system would not discourage this usage, in contravention of ISO/IEC 60601-1-6 medical usability standards.

EXAMPLE TEST OF SURFACE TEMPERATURE FIDELITY

We here provide an example. The system under study was a forehead IR temperature measurement system (Model QY-EWQ-01, system manufacture date 2020/04/19), specifying a

measurement range of 2cm to 3cm. A jig was constructed from foam-core poster board to restrict the measurement distance to within 1mm of 2.5cm when placed to press flat against the front cover of the blackbody during each measurement.

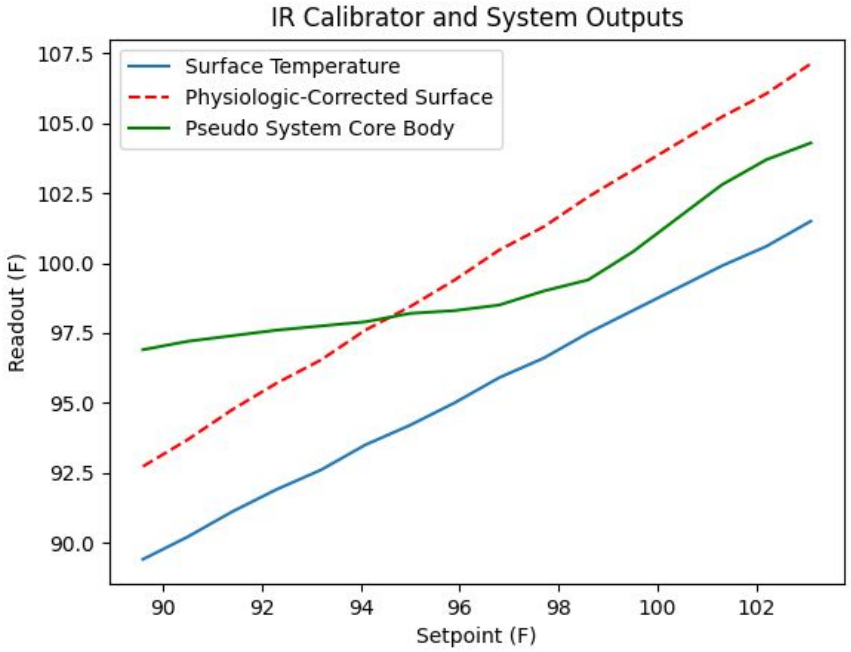
The following testing was performed in a 72F room. An IR calibrator (Fluke 4181 Precision IR Calibrator) was set to 0.5C increments between 32 and 39.5C (0.9F increments between 89.6 and 103.1F), corresponding to core body temperatures ranging from 92.5F to 108F. This range is larger than might be needed except the system being investigated does not contain an ambient air temperature sensor and it is possible (albeit unlikely) the system assumes a lower ambient temperature. More likely, and additional testing supports this hypothesis, the system's pseudo method merely translates surface temperatures to core body temperatures regardless of the ambient temperature, a serious deficiency that was the subject of Rationale 1 above.

When heating in small increments, this IR calibrator has a time constant of approximately 30 seconds (time for the calibrator to reach 1-1/e of the setpoint on first powering the unit). The IR calibrator was set to each setpoint in turn, with a stabilization time of 3 minutes (6.5 time constants) between each measurement. The system was set to body mode on initial operation, placed in front of the calibrator in its jig and operated, removed when complete (the device outputs a short audible beep when complete) and the measurement recorded before the system was put into surface temperature mode and the measurement repeated. In practice, we repeated each surface and body measurement 3 times, and all repeats were within 0.1C of each other. This was repeated for each setpoint.

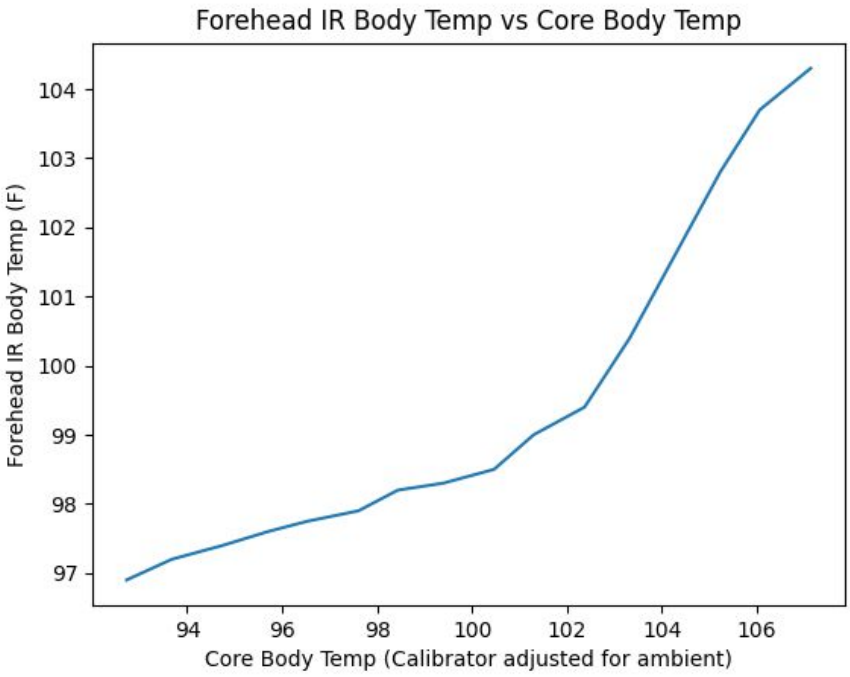
We plot the resulting data below, with the x-axis corresponding to the IR calibrator setpoint and the y-axis to the system's two outputs. The system's surface temperature output is plotted in blue and the physiologic correction equation we provided above, applied to this same surface temperature, is plotted in dotted red. This dotted red shows what a human core body temperature (oral thermometry) would theoretically read for a human with inner canthus temperatures. The system tested here is intended for the forehead, which is likely to require a larger physiologic correction coefficient (which we have not measured) and have greater subject-to-subject variability. The forehead physiologic correction would likely push the red line higher and increase its slope slightly, although we have not measured this. If we were to

measure the physiologic correction for the forehead and apply it here, it is likely to only make the system under test appear even worse than it does, so to be conservative, we use the canthus correction.

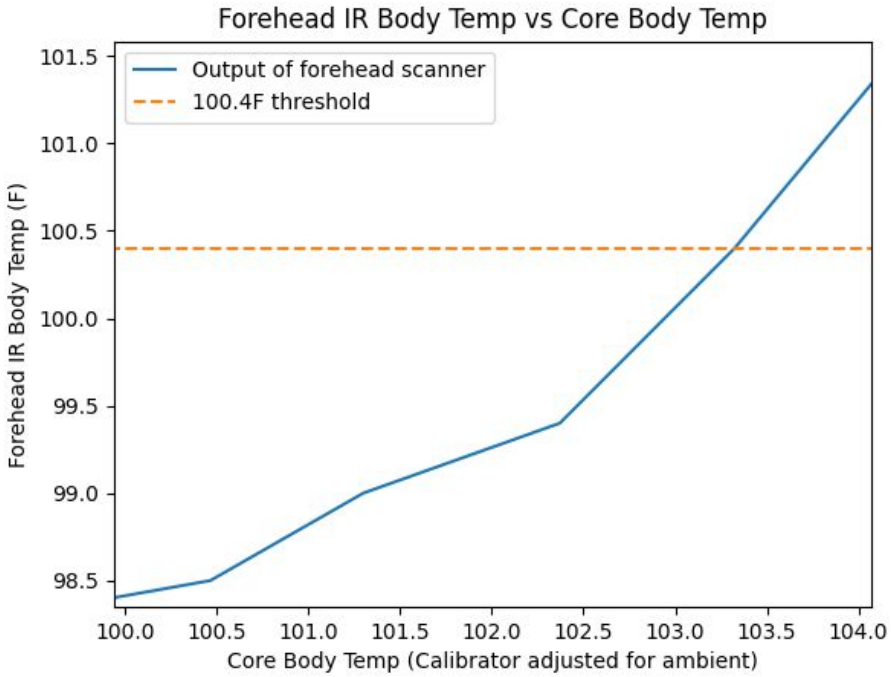
This red dotted line is what an appropriate physiologic correction should produce when given a non-contact system's surface temperatures. *We are not aware of any justification why any system should substantially deviate from a nearly linear physiologic correction.* Finally, the example system's core body temperature output is plotted in green, which reveals a form disconcertingly different from the red dotted line. This s-shaped form in green will have the side effect of making the system produce readings between 97.5 and 99F despite the actual core body temperature varying from 92.5F (severe hypothermia or death) to 102.5F. Note, this plot shows the IR calibrator setpoint on the x-axis, not the core body temperature - a setpoint around 98F corresponds to a core body temperature of 102.5F.



We can inspect the transfer function the system uses to convert what it reads as surface temperature into its output core body temperature by plotting the system's core body output vs the system's physiologic-corrected surface output, or the green line versus the red dotted line (see next Figure).



Finally, we can zoom in on a range of interest and place a 100.4F threshold on this plot. This reveals this *forehead IR system is likely to report all core body temperatures between 93F and 103.3F as below the 100.4F threshold* (see next Figure). This effect will depend on ambient air temperature, since a reduction in ambient air temperature of 5F will result in a reduction in the skin surface temperature of 1F.



THE STATE OF THE NON-CONTACT TEMPERATURE MEASUREMENT MARKET

It is possible that the predicate device for this class originally relied on such a pseudo method, which was then tested for clinical accuracy with a pool of normal body temperatures, which as seen above, will not reveal such insensitivity. If this were the case, then subsequent manufacturers would merely be following the same approved methods as the predicate device. Given multiple publications raising doubts as to the accuracy of these systems, manufacturers have an obligation to investigate these issues and report any deficiencies to the FDA.

POTENTIAL MANUFACTURER AND SELLER LIABILITY

If a manufacturer or seller is marketing a product approved by the FDA yet contains a pseudo method, they are unlikely to be found liable, given the regulatory decision on their product. However, many products are being sold without FDA approval for the intended use of fever screening but are marketed with language claiming their device is not a medical device. The FDA has reiterated that devices marketed or sold knowingly for the intended use of core body temperature measurement or screening are indeed medical devices. If a manufacturer or seller is claiming their non-approved device being marketed for body temperature measurement is not a medical device ***and*** their device uses a pseudo method, the manufacturer or seller may be liable for penalties from the FDA, the Consumer Product Safety Commission and the Federal Trade Commission, among other regulatory agencies, as well as potential criminal charges.

We propose that any non-contact core body temperature measurement system's body temperature output be tested with a simple process that can be performed in any independent test lab with modest room temperature control and access to an IR calibration target large enough to be resolved by the system and accurate to ±0.5C (0.9F) or better over the entire 32-37C range (90-99F). Changes in the body temperature output should correspond to changes in the IR calibration source according to the physiologic correction or another appropriate transfer function validated for body temperatures.

Appendix A: Surface Temperature Range Test Protocol

Materials Required:

- IR calibration target meeting the IEC equipment requirements for 80601-2-59:2017, in particular the compliance methods of sections *201.101.2.2* and *201.101.4*.
    - Here we specify one additional requirement:
        - Linearity with at most ±0.1C deviation from linear over the 32 to 40C (89.6 to 104F) range, taking into account the accuracy specification of ±0.5C.
    - Here we modify one requirement:
        - Emissivity of at least 0.98. This differs from that required by the standard, which requires 0.998. An emissivity of 0.998 is rarely, if ever, used in practice and is not required for this test. The difference between a 0.998 and 0.98 emissivity calibration target changes by about 18mK per degree C in ambient temperature change (or 0.01F per 1F change). To reduce

the impact of air temperature changes below 0.1F, the room temperature must be monitored and peak-to-peak differences throughout the test above 10F be used to either correct the target temperature or to invalidate the test. Alternatively, a lower emissivity may be used, but the effect of emissivity should be greater and as such, a lower air temperature would be necessary. In practice, room air temperature should not vary by more than 2F during the test procedure.

- Fixture or experimental setup to ensure consistent distance to target
- Device under Test, or the febrile scanning system under consideration, configured to output either the surface temperature or estimated body temperature.
    - It must be noted in the test report whether the device has been configured to output surface temperatures or body temperatures.
- A controlled air temperature environment having a room air temperature within the range of 68F to 75F
- Room air temperature measurement

Test is as follows:

a) Set up continuous monitoring of room air temperature, with the maximum and minimum temperatures thus far observed during the test being saved and the maximum peak-to-peak air temperature delta calculated, with a threshold on this delta of 6F being an alarm condition notifying the test operator of potential environmental effect on the results.
b) Set up the calibration target according to the calibration target manufacturer's operating manual and enter a setpoint of 32C (89.6F).
c) Wait until the stabilization period has passed or the calibration target indicates it has stabilized if it has such a function.
d) Set up the device under test at the specified distance from and oriented towards the calibration target according to the device manufacturer's operating manual.
    i) This step may be performed in parallel with step a).
e) Wait until the stabilization period has passed or the device under test indicates it has stabilized if it has such a function.
f) Operate the device to acquire three output measurements of the calibration target, recording the average of the three measurements.
g) Increment the setpoint temperature of the calibration target by 1F and wait until the stabilization period has passed or the calibration target indicates it has stabilized if it has such a function.
h) Repeat steps e) and f) until the measurement of a 99F calibration target is complete, comprising 9 steps.

The recorded data output should be compared with the calibration target setpoints and a least-squares linear fit performed between the setpoints and the output data. The average standard deviation from this fit and the maximum deviation from this fit must be below 0.9F (0.5C). The test report should include the *plot of the output data and setpoints, the linear fit, a*

goodness-of-fit metric such as R2, and the average standard and maximum deviation from the fit. The device is in compliance if the maximum deviation from the fit is less than 0.9F.

Appendix B: Operating Temperature Test Protocol

Materials Required:

- All materials required for Appendix A: Surface Temperature Range Test Protocol with one modification:
    - The device under test must be configured to output body temperature estimation and must not be configured to output surface temperature.
- A controlled air temperature environment having one setpoint of between 68 to 70F and a second setpoint of between 73 to 75F. The initial temperature can be either setpoint.
    - Alternatively, a smaller temperature controlled chamber may be used, of sufficient size as to contain both the device under test and the calibration target
    - Alternatively, the calibrator may be located outside this temperature controlled chamber in a room having less variation in air temperature than the controlled chamber.
        - This variation must be noted as “Calibration target outside controlled chamber”.
- In the resulting test report, it must be noted whether any internal emissivity compensation for background is used by the calibration target.
- In the resulting test report, the actual emissivity of the calibration target must be noted.

Test is as follows:

i) Set up the calibration target according to the calibration target manufacturer’s operating manual and enter a setpoint of 34.5C (94.1F).
j) Wait until the stabilization period has passed or the calibration target indicates it has stabilized if it has such a function.
k) Set up the device under test at the specified distance from and oriented towards the calibration target according to the device manufacturer’s operating manual.
    i) This step may be performed in parallel with step a).
l) Wait until the stabilization period has passed or the device under test indicates it has stabilized if it has such a function.
m) Operate the device to acquire three output measurements of the calibration target, recording the average of the three measurements.
n) Adjust the room temperature to the second setpoint and wait until the room air temperature has stabilized.
    i) Stabilization can be estimated using time constant measurement and waiting at least 3.3 times this time constant for sufficient stabilization of below 0.1C.
o) Operate the device to acquire three output measurements of the calibration target, recording the average of the three measurements.

The effect of emissivity and background temperature on the results can be expected to introduce a difference of as much as 0.09C (0.05F) with the two setpoints used, depending on actual blackbody emissivity. For the purpose of this test, we are ignoring the effects of emissivity

because the effect of air temperature changing by 5F is expected to produce a change in body temperature estimation of 0.95 to 1.05F. To ensure this is the case, it should be required to note the calibration target's emissivity in the test report.

The difference of the output data at the two setpoint air temperatures is recorded as the *body temperature change* and the difference in the two setpoint air temperatures is recorded as the *air temperature change*. The body temperature change should be scaled by the proportion of air temperature change to 1F (e.g. if the setpoints were 4.8F apart, the body temperature should be multiplied by 1/4.8), and taken as the system reactivity to air temperature. Prior work has established that the physiologic correction is within 10% of 0.2 however this factor is still the subject of research. For the purposes of this test, we require only that the system reactivity to air temperature be within 0.1 and 0.3.

Appendix C: Clinical Validation

The final validation for devices seeking 510(k) or de novo status for non-contact core body measurement is a clinical trial enrolling individuals from the general population or a hospital population. This clinical trial should be designed to attempt to include a sufficient number of subjects having a range of core body temperatures extending to at least moderate fevers of 102F or above. The actual number of febrile subjects included will not be known initially but can be estimated in some cases, in particular a clinical internal medicine facility is likely to have an estimate of the percent of patients having febrile temperatures, and this estimate be used to inform the study recruitment size. Most importantly, any clinical trial result should perform separate accuracy analyses for groups of healthy, mild fever, moderate fever and severe fever if possible, or at minimum healthy and feverish groups, in order to avoid swamping the accuracy analysis with a large number of healthy results. In fact, a random number generator limited to within 1F of 98.6 would appear sufficiently accurate over groups of healthy subjects or larger groups with more than 90% healthy subjects. Alternatively, the data can be reweighted in the analyses such that the errors from febrile subjects are equally weighted with errors from healthy subjects.

Appendix D: Portion of Fevers Detected

For practical implementation, two values are usually of most interest: what portion of fevers will be identified as fever (portion of fevers that are true positives) and what portion of healthy will be identified as fever (portion of healthy that are false positives). The first translates into exposure probability reduction (and hence risk reduction) and the second translates into likelihood of implementation failure. From the transfer curve measured above (the plot of output core body temperatures versus the simulated human body temperatures created by the IR calibrator), we can estimate these values.

Human core body temperatures measured with clinical oral thermometry have an approximately normal distribution centered on 37C (98.6F) with a width of 1F (0.5C). The false positive rate for oral thermometry can be estimated by summing the area under a normal distribution above 100.4F (or other selected threshold). For standard clinical oral thermometry, the false positive rate for 100.4F is estimated as 3.6% (to see other thresholds, an online false

positive calculator can be used, entering a mean of 98.6, sigma of 1 and input a greater-than threshold). Non-contact methods can only perform as well as this and likely would perform a little worse. A simple estimate that should get us within 10% is vector-summing the estimated system surface temperature accuracy of 0.9F (0.5C) with the population mean of 0.9F (0.5C) to raise the standard deviation to 1.3F (0.7C), giving us a false positive rate of nearly 10%. Repeating the test will eliminate most of these false positives but carry the risk of a subsequent false negative, especially for actual core body temperatures that are near the threshold. However, with the transfer function seen above (the green line), the false positive rate will be zero because the pseudo method will simply eliminate them, along with most actual fevers.

The true positive rate can be estimated by assuming that 1) fevers have a uniform distribution between 100.4 and 104F, and 2) the measurement accuracy of 1.4F is a normal distribution convolved with the uniform, resulting in a blurred uniform distribution. Then, taking the area under the threshold over the total area gives us an estimate of detection sensitivity, or what portion of fevers the system could detect. This is an estimate with several assumptions but it provides a realistic way to compare systems. In most cases, it is not even necessary to consider the blurred edges of the distribution because the system's accuracy is so poor. For example, the last figure in the system examined above shows the 100.4F threshold is not crossed until a core body temperature of 103.6F. The relative area above the threshold is only 16.7%, meaning this forehead IR scanner is likely to catch only 16.7% of fevers. To have a true positive rate greater than 50%, the system must produce output core body temperature no greater than halfway between the 100.4 to 104F range, or 102.2F, meaning the system must have an actual (e.g. not just for 98.6 but over the full range) accuracy of no worse than 1.5F. We are unaware of any system not using a blackbody that can even approach this accuracy. With proper design, it is possible to achieve 0.9F total system accuracy and thereby catch the majority of fevers.

References

1. Izhar, LI and Petrou, M, "Chapter 2: Thermal Imaging in Medicine", Advances in Imaging and Electron Physics, Volume 171, ISSN 1076-5670, DOI:10.1016/B978-0-12-394297-5.00002-7.
2. Wissler EH, "Pennes' 1948 paper revisited", J Applied Physiology, 81:1, 35-41, 1998, https://doi.org/10.1152/jappl.1998.85.1.35
3. Tan, JH et al, "Infrared thermography on ocular surface temperature: A review". Infrared Physics & Technology 52(4):97-108. DOI: 10.1016/j.infrared.2009.05.002
4. Slettedal, J and Ringvold, A, "Correlation between corneal and ambient temperature with particular focus on polar conditions", Acta Opthalmologica, 93:5, 2015, 422-426, https://doi.org/10.1111/aos.12657
5. Zhou, Y et al, "Clinical evaluation of fever-screening thermography: impact of consensus guidelines and facial measurement location", J. of Biomedical Optics, 25(9), 097002 (2020). https://doi.org/10.1117/1.JBO.25.9.097002
6. IEC 80601-2-59:2008, Medical electrical equipment – Part 2-59: Particular requirements for basic safety and essential performance of screening thermographs for human febrile temperature screening

7. ISO/TR 13154:2009, Medical electrical equipment – Deployment, implementation and operational guidelines for identifying febrile humans using a screening thermograph.