MPBE COVID-19 Rapid Technology Assessment Bulletin

Hikvision Thermal Camera

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About MPBE COVID-19 Rapid Technology Assessment Bulletins

As the COVID-19 emergency evolves, an increasingly wide range of technology is being offered for supply to hospitals and other healthcare providers. This technology extends beyond the standard and familiar medical equipment deployed in clinical settings. These 'new' technologies may be completely new innovations targeted at COVID-19, devices previously regarded as niche that are finding a role in COVID-19 applications, medical equipment or models that have not been routinely used in Ireland, or consumer devices that have been adopted for COVID-19 applications. It is important that healthcare providers can quickly assess the suitability of these technologies for application in their environment.

The Dept. of Medical Physics and Bioengineering at St James's Hospital, Dublin Ireland, has been providing a rapid COVID-19 technology assessment service to the hospital in order to quickly evaluate specific equipment being considered for use in the hospital. These reviews are not presented as exhaustive assessments. Summaries of the evaluations are provided in short *Bulletin*s highlighting the main findings. The *Bulletins* are intended to assist clinical and other staff assess suitability of the technology, and to highlight any important operational or other issues.

Disclaimer: Bulletins are provided outside St James's Hospital to assist the wider health service and do not in any way amount to a recommendation of any specific provider, technology, machinery, software or otherwise. Furthermore, the Bulletins are providing a *review* of usage and are not suggestive as to suitability, transferability or advice. Assessments are considered with regard to the specific physical and clinical environment in St James's

Hospital and not all findings may be transferable. Assessments in these Bulletins focus on technical aspects; clinical efficacy, cost, legal and infection control issues are generally not in the scope of the technical reviews. As such, St James's Hospital accepts no liability whatsoever in relation to the issue and/or usage of any of the product(s) being reviewed in any particular Bulletin.

1. Device: *Hikvision Thermal Camera*

The device assessed is a **Hikvision Thermal Camera** supplied by *ForwardVision Security* (Ballymount, Dublin 12) - **Model:** *Hikvision Thermal Bi-spectrum Network Dome Camera - Model: DS2TD1217B-3/PA [1]*.

2. Classification

The device is not CE marked as a medical device. It should not be considered as a substitute for a clinical grade thermometer. MHRA guidance advises against the use of non-medical grade thermal imaging cameras for screening for COVID-19 symptoms [2].

3. General Performance

Accuracy: We were not able to determine the accuracy of this specific model of thermal camera, as a calibrated and traceably certified temperature reference device (i.e. a blackbody test device required for checking accuracy) was not available from the supplier company to determine this information.

This category of device is considered not accurate for clinical-grade measurement of temperature and is not recommended for mass temperature/fever screening purposes for COVID-19, as per recent MHRA advice [2].

4. Other Challenges and Comments

- **Setup & Positioning:** The device needs **careful arrangement** and setup for use – such as a **long "warm up" time** and controlled, **stable ambient conditions (light and convection air currents; away from heat/cold sources).** The measurement should be made within a specific distance from the camera (e.g. 1.0m-1.6m which is adjustable in the settings).

- **Avoid Simultaneous Measurement of Multiple Individuals:** While the device appears to measure multiple individuals simultaneously, it should not be used on more than one person at a time, as per FDA recommendations [4, 5].

- **Temperature Reference Devices (Blackbody):** From ISO [6] and FDA policy documents for non-medical grade devices, a calibrated and certified temperature **reference (blackbody) should** be used with every thermal camera. This would be placed in each camera's field of view (at a fixed position relative to the camera) during normal screening, to maintain accuracy during fluctuating ambient conditions. These would need to be recalibrated at regular intervals (as per International standards). Such temperature reference devices must be accompanied by a recent traceable calibration certificate provided by an accredited national measurement lab. Traceable calibration certification was not available for the blackbody provided during this review.

- The **device "settings" can greatly affect the measurement accuracy** and need to be set correctly for each device, if being deployed or relocated. The important settings include 'body compensation', 'blackbody compensation' and set working distances for both the blackbody and person being screened.

- **Data Protection**: The device has the **ability to store facial images with the person's temperature** annotated on the captured image. The associated data protection/security risks (e.g. password protecting system) should be considered accordingly and reviewed by relevant hospital groups, i.e. IT departments/DPO. In addition, it should be considered whether the audible notification of an elevated temperature poses a privacy/dignity risk for individuals being screened and if it should be turned off.

- **Non-Diagnostic:** The thermal camera device must not be used to determine that an individual has a fever. A clinical grade thermometer should be used for such purposes – as per ISO guidelines [6, 7].

- **Threshold Selection:** Local clinical input is required to determine/specify a suitable **threshold temperature alarm** setting when screening for febrile individuals, i.e. the temperature at which an individual is highlighted as having an elevated temperature and is followed up with a clinical grade thermometer.

- **Patient Condition: Measurement accuracy can be affected by** sweating, make-up, eating, post-exercise, being in cold weather, wearing a hat, wearing glasses etc. Removal of glasses, hats is advised. The FDA also recommend each person wait at least 15 minutes in a 'measurement room' before having a measurement taken (or 30 minutes after exercise) [4]. This may prove difficult and even hazardous (in terms of social distancing) in certain areas where space is very limited.

- **From an electrical safety perspective, the camera mounted on a trolley with associated devices (as was the case during review) is not suitable for use in a clinical environment**, with a number of electrical safety adjustments required (e.g. earth bonding).
- A short but **detailed guide for deploying medical grade screening thermographs** is given in PD ISO/TR 13154:2009 and should be consulted for further information [3].

5. References

[1] Thermal Camera Specifications: Internet: https://www.hikvision.com/en/products/Thermal-Products/Thermography-thermal-cameras/temperature-screening-series/ds-2td1217b-3-pa/.

[2] MHRA Guidance on Temperature Screening Products for Detection of COVID19 (03-07-2020). Internet: https://www.gov.uk/government/news/dont-rely-on-temperature-screening-products-for-detection-of-coronavirus-covid-19-says-mhra

[3] PD ISO/TR 13154:2009 (Medical electrical equipment —Deployment, implementation and operational guidelines for identifying febrile humans using a screening thermograph).

[4] FDA guidance on Thermal Imaging Systems (12-01-2021). Internet: https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/thermal-imaging-systems-infrared-thermographic-systems-thermal-imaging-cameras

[5] Enforcement Policy for Telethermographic Systems During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency, FDA (April 2020). Internet: https://www.fda.gov/media/137079/download.

[6] BS EN IEC 80601-2-59:2019 (Medical Electrical Equipment Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening (IEC 80601-2-59:2017)).

[7] BS EN IEC 80601-2-56 (Medical electrical equipment —Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement (ISO 80601-2- 56:2017)).

APPENDIX 1:

Document Log			
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