

MPBE COVID-19 Rapid Technology Assessment Bulletin

Kangyoumei T-01 Infrared Non-Contact Forehead Thermometer

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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 technologies 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 devices 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 technologies and innovations being considered for use in the hospital. Summaries of the evaluations are provided in short Bulletins 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. These reviews are not presented as exhaustive assessments.

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: Kangyoumei Infrared Non-Contact Thermometer

The device assessed is a **Kangyoumei Infrared Non-Contact Forehead Thermometer** manufactured by *Zhangye nuo’an medical equipment co. Ltd* (Ganzhou, Zhangye, Gansu, China) - **Model:** *Kangyoumei T-01*.

2. Classification

While the device has a CE label (and is considered a Class 2a medical device), there are no details regarding the notified body number, or if it complies with the EU 93/42/EC medical device directive. A number of markings on the device indicate that it has temporary emergency licenses for production and product registration. The manual indicates that it is electrical safety Class II Type B.

This product is subject to the following standards and guidelines: *ISO 80601-2-56:2017(E)*; *ASTM E1965-98(2016)*. Additionally the FDA has published useful advice with respect to use of non-contact infrared thermometers during the COVID-19 emergency <https://www.fda.gov/media/136698/download>.

3. General Performance & Key Findings

MPBE reviewed a sample of 3 out of 20 infrared thermometers. Key findings were:

- **High sensitivity to distance from patient:** the device values were sensitive to changes in perpendicular distance from patient forehead, i.e. a change of +/-1 °C for a 1cm change from the blackbody source (moving from 4-5cm). Note the measurement was aimed at the same target point on the calibrated black body.
- **Device Accuracy:** it was not possible to test the device absolute temperature accuracy as there were no reference data available with the device describing the relationship between values reported in body temperature mode and a black body source, nor was there a suitable testing protocol available through the manufacturer.

On this basis we did not advise the clinical use of these devices at St. James's Hospital since we anticipated that they would produce highly variable measurements which are very dependent on device distance from the patient's forehead.

4. Other Technical & User Considerations

- The device was **easy to use**.
- Mechanical **construction appears prone to damage** and of lower durability.
- Standards recommend a short term reliability of $\pm 0.2^{\circ}\text{C}$. Test-to-test **repeatability on same day was $\pm 0.1^{\circ}\text{C}$** while the device was in a fixed rig (rather than in a moving hand which we found increased this error).
- **Literature:** Recent meta-analysis and international literature indicates that the accuracy of peripheral thermometers is not within acceptable clinical limits of agreement (LOA) when compared to gold standard core temperature measurements [8][9].
- **Infection risk**
 - The close distance required (3-5cm) to properly take a person's temperature represents a risk of spreading disease between the person using the device and the person being evaluated [1].
 - The device can be cleaned with alcohol to avoid cross contamination between patients as per manufacturers guidelines.
- **Changing settings** – the **measurement mode appears prone to accidental change** (single button push), i.e. from body to surface measurement mode. This could result in inappropriate clinical use since the temperatures reported in these modes can have large differences (a few degrees).
- **Measurement Affects:** How and where the device is used can affect the measurement (for example, people wearing head covers, environment, positioning on forehead). **Measurement protocols should closely control** the following:
 - **Patient condition:** In preparation for taking a temperature measurement with a non-contact infrared thermometer (NCIT), the person using the NCIT should typically ensure that the test area of the forehead is clean, dry and not blocked (e.g. by hair) during measurement. Ensure that the person's body temperature or temperature at the forehead test area has not been recently increased or decreased by wearing excessive clothing or head covers (for example headbands, bandanas), or by using facial cleansing products (for example cosmetic wipes).
 - **Environment:** NCITs should be used in a draft-free space and out of direct sunlight or near radiant heat sources. Determine if conditions are optimal for use. Typically, the environmental temperature should be stable between 60.8-104 °F (16-40 °C) and relative humidity below 85%. Place the NCIT in the testing environment or room for 10-30 minutes prior to use to allow the NCIT to adjust to the environment. Keep away from extreme heat sources.
- The user **instruction manual was not easy to understand** and was not always coherent.

5. References

- [1] <https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/non-contact-infrared-thermometers>.
- [2] <https://www.fda.gov/media/136698/download>.
- [3] Enforcement Policy for Clinical Electronic Thermometers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency.
- [4] Guidance on the Content of Premarket Notification [510(K)] Submissions for Clinical Electronic Thermometers.
- [5] U.S. National Library of Medicine: MedlinePlus. (2019 February). Body Temperature Norms. <https://medlineplus.gov/ency/article/001982.htm>.
- [6] ASTM E1965-98(2016), Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature, ASTM International, West Conshohocken, PA, 2016, www.astm.org DOI: 10.1520/E1965-98R16.
- [7] ISO 80601-2-56:2017(E) Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement. 2017, International Organization for Standardization.
- [8] Niven, D.J., Laupland, K.B. and Stelfox, H.T., 2016. Accuracy of peripheral thermometers for estimating temperature. *Annals of internal medicine*, 165(1), pp.73-74.
- [9] Fletcher, T., Whittam, A., Simpson, R. and Machin, G., 2018. Comparison of non-contact infrared skin thermometers. *Journal of medical engineering & technology*, 42(2), pp.65-71.

APPENDIX 1:

Document Log			
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