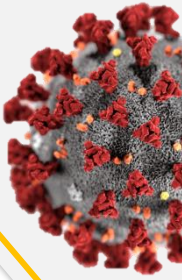




NON-CONTACT INFRARED THERMOMETERS

Based on available evidence up to 4 August 2020



INTRODUCTION

Thermometers with infrared technology are widely used nowadays for fever screening. The basic principle behind their operation lies in the design of the detector that have the ability to receive infrared radiation (heat energy) emitted from human body. These thermometers convert radiation energy to measurable units of temperature [Celcius ($^{\circ}\text{C}$), Fahrenheit ($^{\circ}\text{F}$)].¹ Non-contact infrared thermometers (NCITs) allow temperature to be taken with minimal or no contact with the subject, avoidance of any discomfort and require minimal or no disinfecting process.² The temperature is taken typically on the forehead or temple with the thermometer is held three to 15 cm away from the subject. A temperature reading can be obtained within 0.5 to 3 seconds (varies between models).²⁻⁴ Some of the models are equipped with laser sighting (target indicator) for pinpointing target area.⁵⁻⁸ The laser wavelength is between 630-670nm with maximum output optical power of <math><1\text{mW}</math>. The radiation energy emitted is considered very much lower than what we have been exposed to from the sunlight infrared radiation.⁹ The laser sighting is considered Class II laser product which carry harmful risk of optical radiation.^{8, 10}

EVIDENCE ON EFFECTIVENESS AND SAFETY

Based on searching conducted through available scientific databases (Ovid MEDLINE, Cochrane Database, PubMed) and Google search engine, one systematic review, two diagnostic accuracy studies and one experimental study were identified that evaluate the effectiveness of NCITs for detecting febrile individuals.

Effectiveness

A systematic review conducted by Canadian Agency for Drugs and Technologies in Health (CADTH) (2014) reported an equivocal finding of evidence on the accuracy of NCITs for fever screening.² The review included seven studies comprising of one systematic review and six non-randomised studies. The ability of NCIT targeting the forehead area to detect elevated

temperature varied enormously across studies. The sensitivity varied from 4.0% to 97%, the specificity from 75.4% to 99.6%, the positive predictive value (PPV) from 0.9% to 99.3% and the negative predictive value (NPV) from 86.1% to 99.7%. The reported Area Under Receiver Operating Characteristic Curve (AUROC) from two included studies were 0.852 and 0.853 when compared with pulmonary artery catheter temperature and axillary temperature respectively. The review reported variation across the included studies in term of devices used to measure skin temperature, the mode of the device, the number of measurements, studied population and comparator used.²

An experimental study by Chen HY et al. (2020) assessed the performance of NCIT and the threshold temperature for screening for fever by comparing tympanic temperature in both ears (reference) and the temperature at the forehead.¹¹ The results showed that NCITs provide good precision. The coefficient of variance (CV) value was less than 1.0% for tympanic temperature and for forehead was 1.129%. A fixed offset between tympanic and forehead temperature were found. The findings showed the tympanic and forehead temperatures measured by BRAUN IRT were $36.9\text{ }^{\circ}\text{C} \pm 0.286^{\circ}\text{C}$ and $34.714^{\circ}\text{C} \pm 0.392^{\circ}\text{C}$, respectively. The mean forehead temperature was 2.017°C lower than the mean tympanic temperature. Considering the measurement uncertainty of infrared thermometers and the requirement of practical operation (ease of use, speed and convenience), the authors proposed a standard operating procedure (SOP) to screen for fever by measuring forehead temperature using an infrared thermometer. The suggested threshold for the forehead temperature is 36°C for screening of fever when the threshold for fever level for tympanic temperature is 38°C . Forehead infrared thermometers are suited for rapid screening but cannot be used to represent the actual body temperature as tympanic temperature measurement.¹¹

Apa H et al. (2013) reported that infrared forehead non-contact thermometers had high sensitivity (94.3%), high specificity (90.5%), and a high AUC [0.96, 95% Confidence Interval (CI) 0.95,0.97; $p < 0.00$], but also a high value of bias [mean difference between the mean of both axillary and forehead temperatures was -0.38 with an SD of 0.55°C (95% CI -1.47°C , 0.70°C) in paediatric population.¹² Axillary temperature was used as criterion method with 38°C as axillary temperature cut off value. The authors concluded that infrared forehead non-contact thermometer is very useful for the screening of fever in the paediatric population and may be the preferable method for health care providers due to its easy application. However, the authors recommended that the thermometer must be used with caution due to its high value of bias. The large agreement limits should also be considered.¹²

Wrist As Measurement Site For Non-Contact Infrared Thermometer

There were two studies assessing the reliability of temperature measurement at the wrist using NCITs. One study was conducted in Taiwan¹¹ and another study was conducted in China¹³ (preprint version and has not been peer-reviewed). Chen HY et al. reported significant offsets of the measurement values for wrist temperature with the tympanic temperature.¹¹ The mean wrist temperature was 3.3°C lower than the mean tympanic temperature. The authors recommended that the wrist cannot be used as measurement site to screen fevers since the measurement for wrist temperature do not represent the actual body temperature.¹¹ However, findings of a study by Chen G et al. were in favour with the use of wrist as a site for body temperature measurement.¹³ Wrist measurement was found to be comparable to forehead measurement in fever screening among indoor subjects [wrist: AUC 0.790 (95% CI 0.725, 0.854; $p < 0.001$), forehead: AUC 0.816 (95% CI 0.757, 0.876; $p < 0.001$)]. The cut-off value of wrist measurement for detecting tympanic temperature $\geq 37.3^\circ\text{C}$ was 36.2°C with 86.4% sensitivity and 67.0% specificity, and the best threshold of forehead measurement was also 36.2°C with 93.2% sensitivity and 60.0% specificity. Wrist measurement was more stable than forehead measurement among outdoor subjects in different environment. The mean difference ranged from -0.96 to -0.61°C for the wrist measurements in different groups, and -1.72 to -0.56°C for the forehead measurements. Nevertheless, the results should be treated with cautious as the publication of this study has not yet been peer-reviewed.¹³

Safety

There was no adverse outcome reported with the usage of NCITs from the retrievable evidence.

Non-contact infrared thermometer does not require irradiation, hence presents no hazard to biological tissues.¹⁴

For the usage NCITs with laser sighting (Class II laser product), caution should be taken not to point the beam to the eyes or look directly at the beam because intense prolonged exposure may cause eye injuries^{8, 10} (retinal burns and cataractogenesis)^{15, 16}.

Legal Aspect

Thermometers, including NCITs, with the intention to be used in measuring temperature of human body, are medical devices and subject to registration requirement under Medical Device Act 2012 (Act 737). In crisis situation, such as the ongoing COVID-19 pandemic, importation and supply of infrared thermometers may be allowed via special access route, which are subjected to certain conditions and for a limited timeframe.^{17, 18}

For the thermometer to be registered and subsequently placed in Malaysian market, it must comply with specific standards demonstrating its safety and performance.¹⁸

Amongst the applicable standards for infrared thermometers are as follows:

1. ISO 13485 Medical devices - Quality management systems - Requirements for regulatory purposes
2. ISO 14971: Medical devices - Application of risk management to medical devices
3. IEC 60601-1-11: Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
4. ISO 14155: Clinical investigation of medical devices for human subjects - Good clinical practice
5. IEC 62366-1: Medical devices - Part 1: Application of usability engineering to medical devices
6. IEC 62304: Medical device software - Software life cycle processes
7. EN 1041: Information supplied by the manufacturer of medical devices
8. ISO 80601: Medical electrical equipment. Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement

CONCLUSION

The existing evidence on the accuracy of NCITs is inconclusive. The available evidence had shown that the ability of NCITs to detect fever is highly influenced by the environment where measurements take place, physical activity, adherence to measurement procedures and the different brand/model as well quality of the device used. The use of NCITs are considered safe as the method used is non-invasive, contactless and non-radiant. Based on limited available evidence, the accuracy of temperature measurement at wrist using NCITs is indeterminate. The use of NCITs may be preferable over more accurate and/or more invasive thermometers depending on the context of utilisation, the volume of measurements to be done and the age of the person to be measured. It is crucially important that NCITs are registered under Medical Device

Authority to ensure quality device for our local use. Strict adherence to standard operating procedure including proper device calibration will help in improving the accuracy of measurement.

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Disclaimer: This rapid assessment was prepared to provide urgent evidence-based input during COVID-19 pandemic. The report is prepared based on information available at the time of research and a limited literature. It is not a definitive statement on the safety, effectiveness or cost effectiveness of the health technology covered. Additionally, other relevant scientific findings may have been reported since completion of this report.

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