



PRESS STATEMENT MINISTRY OF HEALTH

SAFETY ISSUES OF NON-CONTACT INFRARED THERMOMETERS

3rd August 2020

Ministry of Health (MOH) Malaysia is concerned about the safety issue of non-contact infrared thermometers which is viral in social media. They have been claimed to be associated with brain injury especially to pineal gland. The thermometers and thermal scanner cameras have been used widely as part of screening and preventive measures during the COVID-19 pandemic.(1)

Non-contact infrared thermometer is not a shooting device emitting radiation. It is designed to detect and absorb heat in the form of infrared rays emitted from human body and converts it into electricity. The electronic circuit within the thermometer processes the electrical signal to determine the temperature and display the reading on a screen. Since infrared thermometers do not emit harmful radiations, it is safe to be used (2,3,4). Some infrared thermometers used laser to aim the spot where the temperature is to be measured. The laser used is usually within the range of 630 – 670 nm that emits energy less than 1 mW cm² which is lower than infrared from sunlight.(5)

There are two common sites for infrared thermometers measurement, namely forehead or tympanic membrane in the ear. Even though, the accuracy of temperature measurement on tympanic membrane is better, forehead site is more easily access for population screening. There are studies that evaluated wrist as a site for temperature measurement. However, the available evidence unable to determine its accuracy.

A rapid review conducted by Health Technology Assessment Section (MaHTAS), MOH found no scientific evidence on the adverse events of infrared thermometers used on the forehead. (6)

LEGAL ASPECT

Thermometer, including non-contact infrared thermometer, that is intended to be used in measuring temperature of human body is a medical device and subject to registration requirement under Medical Device Act 2012 (Act 737). However, in emergency situation, such as during the COVID-19 pandemic, importation and supply of infrared thermometer may be allowed via special access route subject to certain conditions and for a limited timeframe.

For the thermometer to be registered and subsequently placed in Malaysian market, it must comply with various standards demonstrating its safety and performance. Amongst the standards applicable to infrared thermometers are as follows:

- *ISO 13485 Medical devices - Quality management systems - Requirements for regulatory purposes*
- *ISO 14971: Medical devices - Application of risk management to medical devices*
- *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*
- *ISO 14155: Clinical investigation of medical devices for human subjects - Good clinical practice*
- *IEC 62366-1: Medical devices - Part 1: Application of usability engineering to medical devices*
- *IEC 62304: Medical device software - Software life cycle processes*
- *EN 1041: Information supplied by the manufacturer of medical devices*
- *ISO 80601: Medical electrical equipment. Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement*

To-date, a total of 64 brands of infrared thermometer have been registered and permitted to be imported and supplied in Malaysia. Under special access route, another seven brands of the thermometer have been given permission to cater the needs during COVID-19 outbreak. MOH is aware of the availability of infrared thermometers

that are not registered or have no special access permission in the market. Through the Medical Devices Authority, the ministry is monitoring this situation and will take action against any breach of the law as provided under Act 737.

Thank you.

**DATUK DR. NOOR HISHAM ABDULLAH
KETUA PENGARAH KESIHATAN MALAYSIA**

3rd August 2020 @ 3.00 PM

References:

1. Tattersall GJ. Infrared thermography: A non-invasive window into thermal physiology. *Comp Biochem Physiol A Mol Integr Physiol.* 2016;202:78-98.
doi:10.1016/j.cbpa.2016.02.022
2. Luo Yaping, Design of data acquisition system based on LabVIEW for infrared thermometer, *Intelligence Detection.*5(2014)52-56.
3. Li Nana, Design of infrared temperature measurement system based on MLX90615 and MSP430, *Journal of Sensors and Systems.* 9(2011) 115-117.
4. Guangli Long, Design of A Non-Contact Infrared Thermometer, *International Journal on Smart Sensing And Intelligent Systems* Vol. 9, No. 2 June 2016
5. User's Guide OMEGASCOPE Handheld Infrared Thermometer with Laser Sighting. Available at https://stevenengineering.com/tech_support/PDFs/33HHOS530.pdf
6. Non-contact infrared thermometer. MaHTAS COVID-19 Rapid Evidence Update. Ministry of Health Malaysia, 2020.