Thales Thermography Triage (3T) – Pilot Project

Short Title: Developing a thermal camera that accurately records participants' temperature from images of their face

Investigators:

Chief Investigator:	Dr David Lowe, QEUH, NHSGGC
Co-investigators:	Dr Iain D. Carrie (Thales UK) Dr Barry Connor (Thales UK) William Alexander (Thales UK)
ClinicalTrials.gov ID	

Sponsor: **Thales UK**

Address: 350 Longwater Avenue, Green Park, Reading, Berks RG2 6GF

Protocol Reference:	
Version Number & Date:	Version 2, 9 September 2020
Effective Date:	TBD
Superseded Version Number & Date (If applicable)	-

IRAS Number: 287901

Sponsor Reference Number: INGC20AE396

Contents

Section:

1. Background:

In the fifty years since the emergence of thermal imaging technology, Thales has built up a world leading capability in the design, manufacture and supply of Thermal Imaging cameras. In addition to the cameras, Thales has a particular expertise in developing image processing algorithms (conventional and artificial intelligence based) to allow the cameras and systems to perform critical user tasks beyond mere imaging.

Thermal imaging cameras have been used to screen for fever as a potential indication of pathogenic infection in transportation hubs since the early 2000's, especially in countries that dealt with SARS. Fever is a key symptom of covid-19 (ref). One of the major limitations of existing systems is thermographic accuracy. Most current thermographic camera systems offer an accuracy of ± 0.5°C. This can be reduced to ±0.3°C with the inclusion of a "Black Body" calibration source, although this limits the portability of the system. Using their unique knowledge and expertise in high resolution and precision thermal imaging and thermal image processing, Thales aims to develop a fever screening system with an accuracy of ± 0.1°C to enable more effective identification and triage of people with fever.

In a pilot study conducted in the Emergency Department, Queen Elizabeth University Hospital (20/NS/0064), the Thales High Temperature Detection (HTD) system was found to be more accurate than a tympanic thermometer (Ref) which captures Infrared radiation emitted by the tympanic membrane in the ear. (Figure 1) or forehead thermometer. Tympanic temperature measurements are typically used in the hospital setting in Scotland whereas forehead IR measurement is common in transportation and workplace settings.

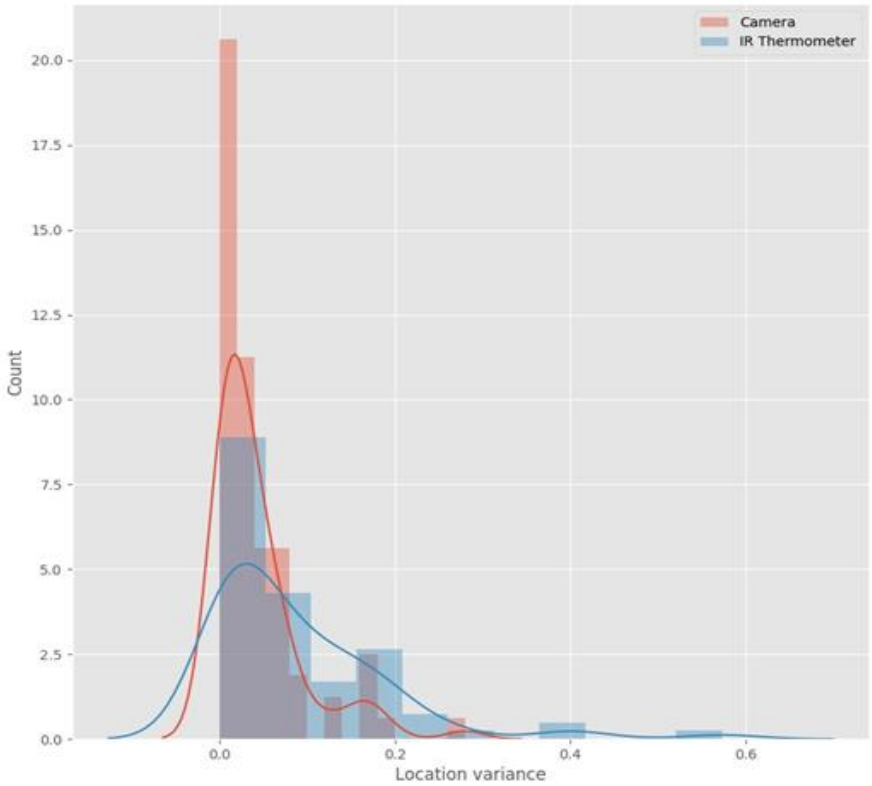

Figure 1: Distribution of variance between measurements for each subject for tympanic thermometer and HTD (n = 80)

The HTD has been redesigned in response to three key findings from the pilot study:

- The relative temperature of some facial features correlated more strongly with tympanic temperature than others.
- Having an external Black Body (BB) calibration source in the scene at all times was impractical in a clinical environment
- Camera systems require to be compact and portable to be useful to clinical staff.

As a result, the HTD is now significantly reduced in size, including peripheral devices. A novel calibration solution has been designed (and patented) that not only removes the need for the black body source but allows for a more accurate temperature evaluation. In addition, facial feature detection has been integrated into the software to allow it to automatically locate the patient's head and in the near future, automatically determine the temperatures of individual facial features. This development will capture facial feature detection – not facial recognition.

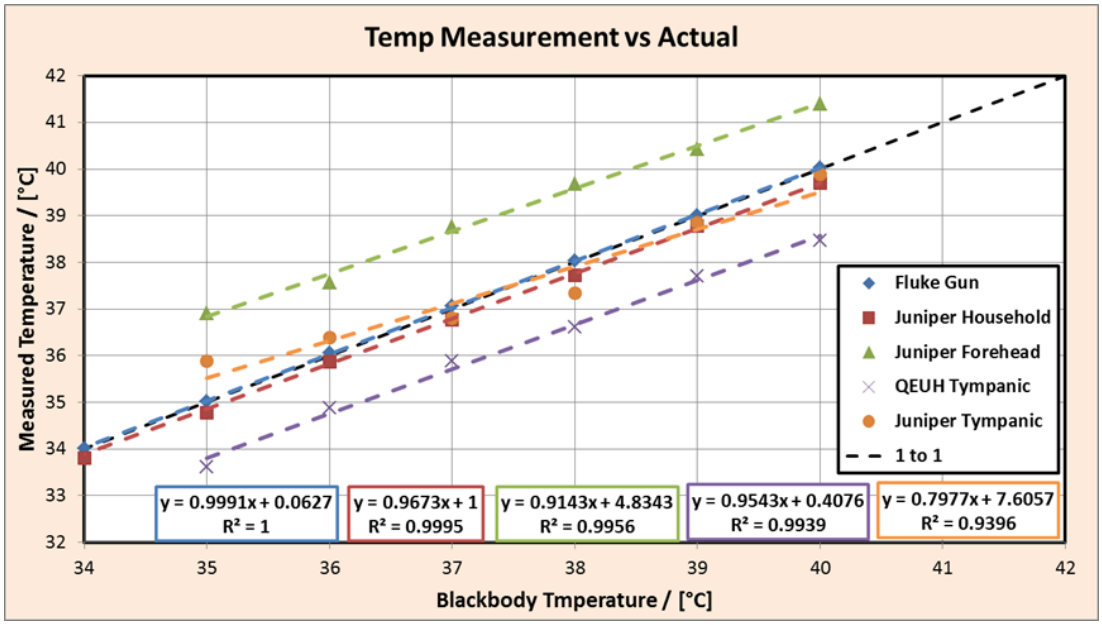

Figure 2: Temperature Measurement vs Actual

Figure 2 shows that the thermometer (juniper) in forehead mode appeared to return measured temperature + an offset to estimate core. The HTD can be calibrated in the same way i.e. to use the actual forehead temperature returned from the HTD plus the same offset. For tympanic comparison, the maximum temperature returned by the HTD (probably the canthus) correlates best – but it is still likely that some post processing will be required to ensure that a direct comparison can be made.

2. Aims

The Thales HTD (High Temperature Detection) System is a thermal camera based, human temperature measurement system.

This study will compare the HTD system with the two routinely used temperature measurement systems (tympanic and forehead) to understand the level of agreement that can be achieved and so its potential utility in triage and in a transportation and workplace setting. A secondary objective of this study are to assess if skin tone adds any additional differences

between a thermal camera based system temperature assessment and the routinely used tympanic and forehead based methods.

If results are encouraging the aim would then be to undertake a clinical investigation in order to get CE marking for use in a clinical setting.

100 staff and 100 patients will be consented with thermal images of their face taken as well as having their temperatures taken. The following measurements and information will be recorded:

- Forehead temperature from the HTD System
- Head temperature from the HTD System
- Tympanic temperature from a tympanic IR thermometer
- Forehead temperature from a forehead IR thermometer
- Age
- Ethnicity

A sample of size 100 will give 95% confidence intervals for the limits of agreement of +/- 0.34 standard deviations (**https://www-users.york.ac.uk/~mb55/meas/sizemeth.**). These limits of agreement will then allow determination of how close the temperature readings are between 1. Tympanic vs. HTD and 2. Forehead vs HTD and whether or not these are within +/- 0.2 degrees. It will demonstrate if there is a trend over the temperature range to understand consistency. The bias will be quantified using the mean difference (significance determined using a t-test).

The larger sample size (200) is proposed to gather a wider range of skin tone measures. Staff members will be recruited in addition to patients as this is likely to increase the diversity of the sample.

Although a BB source is not required for the new HTD system, a BB will be housed in the room where staff measurements are taken. Its inclusion gives another source of ground truth and will allow the calibration of all systems to be checked at regular intervals throughout the study.

3. Research Questions

Primary

- To determine the diagnostic accuracy of HTD for the measurement of fever, using an equivalence comparison with the maximum temperature recorded with two routinely used temperature measurements (tympanic and forehead), margin ±0.2°C.

Secondary

- To determine if skin tone is an independent confounding factor in the measurement of fever using HTD
- To establish performance of internal calibration of Thales device
- To power for a definitive Clinical Investigation to determine clinical efficacy and safety cut off with HTD

4. Study Design

Patient Identification

Two groups will be identified

1. Patients who present to the Emergency Department (ED) in QEUH will be approached either by ED nurses or clinical fellows they can approach reception staff/nurse directly for information after reading posters on the ED wall.

2. QEUH ED staff will be approached either by ED nurses or clinical fellow.

Inclusion criteria

- *Patients ≥ 16 years old with no upper age limit*
- *Patients able to read and understand English*
- *Patients able to give informed consent*
- *Patients being triaged through ED for any complaint (not necessarily COVID-19)*
- *QEUH ED staff*

Exclusion criteria

- *Patients not meeting the inclusion criteria*
- *Patients who do not have capacity to consent*
- *Patients attending ED who are fast-tracked without triage*

Consent

Participants will be given a participant information sheet (PIS v2) to read while they are in waiting to be triaged (patients) or working in the ED (staff). There will be posters displayed publicising the study, and if people are interested they can ask reception staff or a nurse for more information. The nurse or fellow will go through the PIS and provide opportunity to ask questions. Due to the circumstances there is no opportunity for patients to take the PIS away and discuss it with friends/family which would be preferred. If the patient/staff member wishes to participate, a consent form will be provided which has some statements to agree to and sign. The participant can keep a copy of the signed consent form as well as the PIS. Failure to consent will not change clinical care for patients.

The PIS will make it clear that Thales will hold a copy of the identifiable images for a maximum of 1 year. Thales will securely store and analyse visible and thermal data required for future algorithm upgrades. It is anticipated that Thales will require to hold onto both visible and thermal data long enough to be required for regulatory purposes. For example, it is anticipated that the thermal data, and associated metadata, will be required for a maximum of ten years and the visible data for a maximum of one year, after which time the data will be securely destroyed.

Study procedures

After the participant has consented to take part, the research will take a front view with the thermal imaging camera. The following data is routinely collected at triage and a copy of the data will also be entered into the Thales electronic Case Report Form (eCRF). No patient name or personal details will be held by Thales.

- Temperature
    - Oral
    - IR Forehead
    - Ear
- History of Fever Y/N
- Age
- Ethnicity
- If they are wearing contact lenses

While desirable to have uncovered face thermal images, it is accepted that some patients may choose to wear facemasks. Patients will be asked to remove spectacles.

It is expected that the thermal imaging system will sit on a table or worktop and image patients approximately 1.5m to 2.0m away. The system will require access to a mains wall socket. The kit will remain set up in a locked room when not being used.

The system will comprise of:

- Surface Pro Tablet PC;
- Thales camera mounted on a portable tripod;
- Thermal calibration Black Body source (for calibration validation purposes only).
- MiFi internet connection
- Forehead thermometer
- Tympanic thermometer

The tablet will auto-run easy to use software allowing hospital staff to record:

- Thermal and TV image of the patient front on;
- Non-personal patient metadata:
- Patient temperature measured by existing clinical methods

The system will be simple to use and aims to minimise the disruption of the QEUH staff. Thales will have provided training of QEUH staff on how to operate the equipment and support of the equipment during the data collection activity. Training will take the form of a pdf, training video and if required a video conference call.

Follow Up

There is no follow up required – patients are only required to commit to one hospital visit when they initially present at ED and have their picture taken with the thermal imaging camera. Staff will require only to have their picture taken.

5. Withdrawal

If participants wish to withdraw their consent after the intervention (after the image has been taken) they can do so and it will not affect their clinical treatment. They may withdraw from the study at their own request and are not required to give a reason for this. They will be made aware that this will not affect their future care. Participants will be made aware that should they withdraw the data collected to date will be retained and used in the final analysis.

6. Data handling, analysis and archival

Data Handing

All the information obtained about participants in the course of the study is confidential and will be held in accordance with the General Data Protection Regulation (GDPR 2018). Data will be entered into a custom graphical user interface (GUI). Once the images and metadata have been recorded they will be regularly and periodically encrypted and then the unencrypted images deleted from the device automatically. Encrypted data will by synced with an encrypted dropbox and then transferred to Thales secure servers. Data will be unencrypted when it reaches the secure Thales servers.

Data are stored on dedicated storage area implementing Mandatory Access Control for an explicit list of authorised users. The management of those IT resources are performed by Thales UK ltd. Thales UK ltd is certified against the Cyber Essential Plus scheme.

Data Analysis

Personal data will be collected and processed only for the purpose of answering the research questions. The thermal images are Personally Identifiable Information (PII) and will be retained by the company for as short a time as possible before being permanently deleted. The other data items are not PII and are low risk in terms of identifying the patient from anonymised data. Personal information will not be shared with anybody outside the study.

The feasibility study data will primarily be analysed using statistical methods looking for relationships between facial feature temperatures and patient metadata. Artificial Intelligence (AI) /Convolutional Neural Network (CNN) based feature detection algorithms *may* be used to find the coordinates of the key points on the face in the visible image. The corresponding coordinates can be found with fine camera alignment and calibration. The thermal features may then be extracted for analysis along with the patient metadata. A manual feature extraction method may be used instead of the AI/CCN method if deemed more efficient for the smaller, initial dataset of 200 patients. Manual inspection of thermal images will be used to look for patterns and anomalies.

Three readings will be done per participant and comparisons done between:-

1. Tympanic vs. Thermal
2. IR vs. Thermal

A sample of size 100 will give 95% CIs for the limits of agreement of +/- 0.34 standard deviations (i.e. about a third of the standard deviation)

A sample of size 200 will give 95% CIs for the limits of agreement of +/- 0.24 standard deviations (i.e. about a quarter of the standard deviation)

Accuracy for other pre-defined sample sizes can be computed as +/- 1.96 sqrt(3/n) as the multiplier of the standard deviation.

Data Archival

The participants will be allocated a unique ID number. Hardcopies of patient consent data and the patient identity/ study identifier key will be held in the ED site file and archived locally when the study is finished.

Only authorised research personnel will have access to the data collected in this study. They may also be looked at by representatives of regulatory authorities and by authorised people from NHS Greater Glasgow & Clyde and if an audit is required for quality assurance purposes. All will have a duty of confidentiality to research participants.

7. Regulatory & Ethics Committee Approval

The study shall not commence until the study protocol, information sheet and consent form have been reviewed and approved from a Research Ethics Committee and relevant NHS permission is obtained.

The sponsor will be responsible for deciding whether any protocol amendments are substantial and non-substantial in collaboration with the Chief Investigator. Where an amendment is required to study documentation that requires REC approval, changes will not be implemented until REC approval is received and local permission confirmed. Should an amendment be required to eliminate an apparent immediate hazard to participants this may be implemented immediately and the REC and R&D notified as soon as is possible. Minor amendments for logistical or administrative purposes may be implemented immediately. Amendments will be logged on the Sponsor's Study Amendment Log and stored in the Trial Master/Site File(s).

Annual Progress Reports shall be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given – until the end of the study. A final report shall (where possible) be submitted to the REC within one year after the end of the study. If the study is terminated prematurely the CI will notify the REC, including the reasons for premature termination.

8. Data protection and patient confidentiality

All study staff and investigators will comply with the principles of the Data Protection Act 2018 in protecting the rights of study participants with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's/Regulations core principles.

Each participant will be assigned a study identity number, for use on all trial documents and the electronic database. Other than the identifiable images, no personally identifiable Information will be stored. The identifiable images will be deleted as soon as possible – but certainly within 1 year. However, for the avoidance of doubt, all other unidentifiable images will be stored for up to 10 years. Very limited research data is required and this will be stored using the study identity number. Thales will not hold a key. The site will hold the key within the local site file until to link the images and the data, and this will be archived locally.

All data will be automatically encrypted shortly after acquisition. Original, unencrypted images will be securely deleted. All encrypted data will be held on the password protected tablet PC during the trial for backup purposes. All encrypted data will be synced with an encrypted

dropbox. The encrypted data will be placed on secure Thales servers and stored within password protected folders. Data will then be unencrypted for analysis.

Personal data will be stored for 10 years following the end of the study, so that the Chief Investigator may provide participants with a summary of the research (should they wish to receive a copy). Data generated as a result of this study will be available for inspection on request by NHS Greater Glasgow & Clyde, the REC, local R&D Departments and the regulatory authorities.

9. Indemnity

Insurance and indemnity for trial participants and trial staff is covered within the NHS Indemnity Arrangements for clinical negligence claims in the NHS. There are no special compensation arrangements, but trial participants may have recourse through the NHS complaints procedures.

10. Dissemination of results and publication

If results are encouraging the aim would then be to undertake a clinical investigation in order to get CE marking for use in a clinical setting - with a fever "yes/no" result. Nonetheless preliminary results may be publishable in a peer reviewed journal.

11. References

Allam Z, Jones DS. On the coronavirus (COVID-19) outbreak and the smart city network: universal data sharing standards coupled with artificial intelligence (AI) to benefit urban health monitoring and management. InHealthcare 2020 Mar (Vol. 8, No. 1, p. 46). Multidisciplinary Digital Publishing Institute.

Lee IK, Wang CC, Lin MC, Kung CT, Lan KC, Lee CT. Effective strategies to prevent coronavirus disease-2019 (COVID-19) outbreak in hospital. Journal of Hospital Infection. 2020 Mar 3.

Royal College of Physicians. National Early Warning Score (NEWS) 2 standardising the assessment of acute-illness severity in the NHS (2017). Available at: <https://www.rcplondon.ac.uk/projects/outputs/national-early-warning-score-news-2> (accessed 5 May 2020).