COVER PAGE

Document name:

Continuous Temperature Measurement by Thermal Imaging Camera. Participant Information Sheet

Title of the study:

Continuous Temperature Measurement by Thermal Imaging Camera: Concordance, Patterns, and Intelligent Prediction of Events in Critical Patients

NCT number:

Not yet available

Date:

December 15, 2023

Participant Information Sheet

STUDY TITLE	Continuous Temperature Measurement by Thermal Imaging Camera: Concordance, Patterns, and Intelligent Prediction of Events in Critical Patients
STUDY CODE	*TERMOCAMUCI1- V2 (15-12-2023)*
SPONSOR	*Samuel Gonzalez López*
PRINCIPAL INVESTIGATOR	*Samuel González López*
CENTER	*Hospital HLA Moncloa*

Introduction

We reach out to inform you about a research study in which you are invited to participate. The study is titled 'Continuous Temperature Measurement by Thermographic Camera in Critical Patients: Concordance, Validity, Thermal Alterations, and Pattern Description' and has been approved by the Drug Research Ethics Committee of the University Hospital of Getafe, in accordance with current legislation, Organic Law 3/2018, of December 5, on the Protection of Personal Data and guarantee of digital rights, and European Regulation 536/2014 of April 16.

Our intention is for you to receive accurate and sufficient information so that you can decide whether or not to participate in this study. To do this, please read this information sheet carefully, and we will clarify any questions that may arise. If you have any doubts, you can contact Dr. Samuel González López or any physician from the Intensive Care Unit (ICU) at Hospital HLA Moncloa (Av. de Valladolid, 83, Moncloa - Aravaca, 28008 Madrid, phone 917 58 11 96). Additionally, you can consult with anyone you deem appropriate

Voluntary Participation

If you are reading this information sheet, it is because you or a family member you represent is admitted to the Intensive Care Unit (ICU) of Hospital HLA Moncloa in a room equipped with continuous thermal monitoring through a thermographic camera.

The thermographic camera is an infrared light measurement device capable of determining body temperature from a distance. This camera is permanently installed in the room, approximately 3 meters away from you, so it will not interfere in any way with your care, and you will not feel or be affected by it.

You should be aware that your participation in this study is voluntary, and you can decide NOT to participate. If you choose to participate, you can change your decision and

withdraw consent at any time without altering your relationship with your doctor or experiencing any harm to your healthcare.

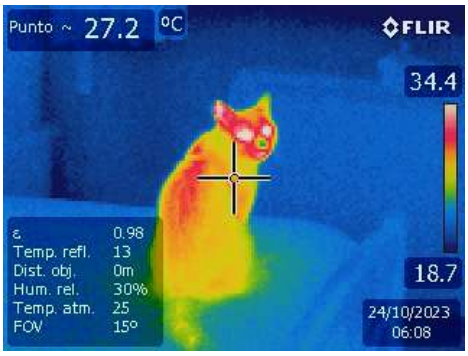
We only ask for permission to review and collect the necessary information to fulfill the study objectives. The information will be collected from the data recorded in your medical history in a process known as pseudonymization (we will explain this process later).

Study Objective

Thermographic cameras help us obtain continuous temperature values, every second, without the need to 'touch' the patient and without causing any side effects to you. However, it is necessary to ensure the agreement of this method with respect to conventional methods (axillary temperature measurement) before being able to generalize its use. Our main objective in this study is to demonstrate that temperature measurement by thermographic cameras is consistent with axillary temperature in patients admitted to the ICU.

Study Activities

The study will extend over 11 months between the years 2023 and 2024, but specifically, the study activities that will be carried out on you will only last for the duration of your stay in the ICU. These activities involve temperature recordings by the thermographic camera (without your perception) and axillary temperature measurements (according to the usual practice). No other complementary exploration or extra activity will be required from the patient. In some patients, the axillary temperature measurement may need to be repeated three or more times if these measurements are significantly different.



Example of thermographic image

Simultaneously with the temperature collection, the camera will capture and record thermographic images, which will also be used in the study to provide additional information about thermal distribution according to different body zones. Thermographic images represent the distribution of temperature in an object or scene by capturing and visualizing emitted infrared radiation.

Risks and Discomforts of Participation

Your participation in this study involves no additional risk or inconvenience for you, as the thermographic camera automatically gathers information without any contact. The cameras do not emit any form of radiation or other energy; they solely receive the thermal radiation emitted by the patient.

Potential Benefits

If you decide to participate, you will be contributing to advancing scientific knowledge regarding temperature monitoring in critically ill patients, which may, in the future, contribute to improving the treatment of patients at risk of temperature abnormalities.

Pregnancy Warning

There are no contraindications.

Protection of Personal Data:

In the Intensive Care Medicine Service at Hospital HLA Moncloa in Madrid, we are committed to protecting your personal information. Both healthcare personnel and all researchers with access to patient data pledge to maintain the strictest confidentiality in accessing, collecting, and processing the data collected in the databases, while also committing to strict compliance with current legislation: Law 41/2002, of November 14, the basic regulation of patient autonomy and rights and obligations regarding clinical information and documentation; Organic Law 3/2018 on the protection of personal data and guarantee of digital rights; and Regulation (EU) 2016/679 of the European Parliament and of the Council of April 27, 2016, on the protection of individuals concerning the processing of personal data and the free movement of such data, repealing Directive 95/46/EC (General Data Protection Regulation).

In any case, to prevent all data from being observed or used by third parties, it will be collected in a pseudonymized form, including thermographic images. For this purpose, two databases will be created, one including your personal data (medical record number, name, and surname) associated with a code. This database will be safeguarded by the principal investigator and the collaborating medical team, and only they will have access to it. The other database will not contain any personal data and will be constructed with association codes and clinical data. Other collaborators will be able to access this database for data analysis.

Under no circumstances will we sell the information to third parties for our commercial benefit.

Financing

This study has been funded by the Asisa Foundation through the Asisa-UEM Chair. This funding has been used for the acquisition of the necessary materials for the study and for publication expenses of articles. Neither the researchers nor the participants will receive any remuneration

Contact for Questions

If you have any doubts or need more information during your participation, please contact Samuel González López, the principal investigator of the study and associate doctor of the Intensive Care Medicine Service at HLA Moncloa Hospital. You can request his contact information at the Intensive Care Unit of HLA Moncloa Hospital (Av. Valladolid 83, 28008 Madrid).

Participant Consent Form/INFORMED CONSENT

STUDY TITLE	Continuous Temperature Measurement by Thermal Imaging Camera: Concordance, Patterns, and Intelligent Prediction of Events in Critical Patients
STUDY CODE	*TERMOCAMUCI1- V2 (15-12-2023)*

I, _____:

☐ Have read the information sheet provided to me about the study.

☐ Have had the opportunity to ask questions about the study.

☐ Have received sufficient information about the study.

☐ Have spoken with <<investigator's name>>.

☐ Understand that my participation is voluntary.

☐ Understand that I can withdraw from the study:

At any time.

Without having to provide explanations.

Without affecting my medical care.

I will receive a signed and dated copy of this informed consent document.

I freely give my consent to participate in the study.

Participant's Signature

Date: / /____

Investigator's Signature

Date: / /____

When obtaining IC from individuals with modified capacity to give their IC:

Legal representative, family member, or de facto related person's signature

Date: / /____

Investigator's Signature

Date: / /____

(Name, signature, and date in the participant's own handwriting)

Participant Consent Form with Witnesses/INFORMED CONSENT

STUDY TITLE	Continuous Temperature Measurement by Thermal Imaging Camera: Concordance, Patterns, and Intelligent Prediction of Events in Critical Patients
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I, _____, as a witness, affirm that in my presence, D/Dª _____ has been informed and has read the information sheet provided about the study. Thus:

☐ Has had the opportunity to ask questions about the study.

☐ Has received sufficient information about the study.

☐ Has spoken with <<investigator's name>>.

☐ Understands that their participation is voluntary.

☐ Understands that they can withdraw from the study:

- At any time.
- Without having to provide explanations.
- Without affecting their medical care. I will receive a signed and dated copy of this informed consent document.

Witness's Signature

Date: **/** /____

Investigator's Signature

Date: **/** /____