

Participant Information Sheet

Study Title: Non-invasive textile sensor for skin hydration monitoring

Researcher: Alexandar Todorov
ERGO number: 70980

You are being invited to take part in the above research study. To help you decide whether you would like to take part or not, it is important that you understand why the research is being done and what it will involve. Please read the information below carefully and ask questions if anything is not clear or you would like more information before you decide to take part in this research. You may like to discuss it with others but it is up to you to decide whether or not to take part. If you are happy to participate you will be asked to sign a consent form.

What is the research about?

This study aims to develop a wearable, e-textile device that can be used for monitoring of skin hydration. This device would allow skin hydration to be measured quantitatively and will be housed in a compact and non-invasive body that can be used for continuous measurements.

Why have I been asked to participate?

Participants that are able bodied and have no known knowledge of disabilities and are over the age of 18 are welcome to take part in this study. Participants should have no known skin disorders, history of skin irritation or sensitivity; they should have no cuts, blemishes or bruising on the skin area under test.

What will happen to me if I take part?

The study will be conducted in a single visit to a laboratory in Building 59. Participants will be asked to relax for 20-30 minutes before undertaking the study, to avoid sweat being present during the measurements. Once the study starts, an electrode patch will be adhered to the volar arm or the outside of the palm using conventional bandages. The patch will be connected to an LCR meter, which will measure the capacitance and impedance across the electrodes. The participant should not be able to feel any sensation due to the small voltage applied and the high frequency of the AC signal. Discrete measurements will be collected across a time span of 20 minutes at equal time intervals. After the first measurement procedure, the experimental conditions will be changed and moisturising cream will be introduced onto the measured area, and the test will be repeated. The entire study will last between 1-2 hours for each participant.

Are there any benefits in my taking part?

There is no direct benefit to the participant in taking part of the study. The study would yield useful results for the development of a new type of e-health devices that allow for non-invasive continuous measurements.

Are there any risks involved?

There is a very slight risk of an electric shock from the electrodes. The LCR meter (Wayne Kerr 4300) is PAT tested as of 11/2019, but its output voltage is limited to 2V (harmless). Since this is a capacitor layout, no live current will be running through the body. The frequency of operation of the machine will be in orders above 100kHz, further reducing the possibility of any sensible current to be detected.

What data will be collected?

The data collected will consist of the data readings of the LCR meter (Wayne Kerr 4300) – capacitance value and frequency range, and the age and sex of the participants. The age and sex are considered to more effectively compare the findings to other studies in the literature. Personal data will be anonymised, this study is only for testing a prototype and not for clinical trial.

Will my participation be confidential?

Your participation and the information we collect about you during the course of the research will be kept strictly confidential.

Only members of the research team and responsible members of the University of Southampton may be given access to data about you for monitoring purposes and/or to carry out an audit of the study to ensure that the research is complying with applicable regulations. Individuals from regulatory authorities (people who check that we are carrying out the study correctly) may require access to your data. All of these people have a duty to keep your information, as a research participant, strictly confidential.

Do I have to take part?

No, it is entirely up to you to decide whether or not to take part. If you decide you want to take part, you will need to sign a consent form to show you have agreed to take part. Please contact the researcher by email (at1u18@soton.ac.uk) for more information.

What happens if I change my mind?

You have the right to change your mind and withdraw at any time without giving a reason and without your participant rights being affected.

If you wish to withdraw from the study, contact the researcher by email (at1u18@soton.ac.uk) to end your participation. Please note that once the data has been submitted for a peer-reviewed journal, it won't be possible to remove it, but this will not contain any personal information.

What will happen to the results of the research?

Your personal details will remain strictly confidential. Research findings made available in any reports or publications will not include information that can directly identify you without your specific consent.

The data obtained during this study will be used to prepare a progress report for the investigator's 9-month progression review. It would serve as evidence of the novelty of the approach taken in the context of e-textiles within e-health solutions.

The data will be stored within a repository (PURE), as per the University's policy, for 10 years. It will be actively used during the duration of the investigator's degree, because it may serve as valuable information to be published in a peer-reviewed journal.

The personal details of all participants will be kept confidential, following the University's policy.

For further questions about the results of the research contact the researcher: Alexandar Todorov (at1u18@soton.ac.uk)

Where can I get more information?

For more information contact Alexandar Todorov (at1u18@soton.ac.uk)

What happens if there is a problem?

If you have a concern about any aspect of this study, you should speak to the researchers who will do their best to answer your questions.

Investigator: Alexandar Todorov (at1u18@soton.ac.uk)

Supervisor: Russel Torah (rnt@ecs.soton.ac.uk)

If you remain unhappy or have a complaint about any aspect of this study, please contact the University of Southampton Research Integrity and Governance Manager (023 8059 5058, rgoinfo@soton.ac.uk).

Data Protection Privacy Notice

The University of Southampton conducts research to the highest standards of research integrity. As a publicly-funded organisation, the University has to ensure that it is in the public interest when we use personally-identifiable information about people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use information about you in the ways needed, and for the purposes specified, to conduct and complete the research project. Under data protection law, 'Personal data' means any information that relates to and is capable of identifying a living individual. The University's data protection policy governing the use of personal data by the University can be found on its website (<https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page>).

This Participant Information Sheet tells you what data will be collected for this project and whether this includes any personal data. Please ask the research team if you have any questions or are unclear what data is being collected about you.

Our privacy notice for research participants provides more information on how the University of Southampton collects and uses your personal data when you take part in one of our research projects and can be found at <http://www.southampton.ac.uk/assets/sharepoint/intranet/Is/Public/Research%20and%20Integrity%20Privacy%20Notice/Privacy%20Notice%20for%20Research%20Participants.pdf>

Any personal data we collect in this study will be used only for the purposes of carrying out our research and will be handled according to the University's policies in line with data protection law. If any personal data is used from which you can be identified directly, it will not be disclosed to anyone else without your consent unless the University of Southampton is required by law to disclose it.

Data protection law requires us to have a valid legal reason ('lawful basis') to process and use your Personal data. The lawful basis for processing personal information in this research study is for the performance of a task carried out in the public interest. Personal data collected for research will not be used for any other purpose.

For the purposes of data protection law, the University of Southampton is the 'Data Controller' for this study, which means that we are responsible for looking after your information and using it properly. The University of Southampton will keep identifiable information about you for 10 years after the study has finished after which time any link between you and your information will be removed.

To safeguard your rights, we will use the minimum personal data necessary to achieve our research study objectives. Your data protection rights – such as to access, change, or transfer such information - may be limited, however, in order for the research output to be reliable and accurate. The University will not do anything with your personal data that you would not reasonably expect.

If you have any questions about how your personal data is used, or wish to exercise any of your rights, please consult the University's data protection webpage (<https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page>) where you can make a request using our online form. If you need further assistance, please contact the University's Data Protection Officer (data.protection@soton.ac.uk).

Thank you.