**Participant Information Sheet**
**Version 1.1 17.02.2024**

**Study Title**: Proof of concept study for the use of edge-based potassium sweat sensors integrated with the UltraLYNX™ power and communication platform.

**Short title:** EDGE

**MODREC Application No:** 2310/MODREC/24

**Name of Researchers**: Professor Andrew Richardson
Dr David Cheneler
Dr John Hardy
John Puddy
Helen Austin
Dr Christopher Gaffney
Dr Samuel Rust
Dr Samantha Moore

**Invitation to take part:**

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have. Talk to others about the study if you wish. Ask us if there is anything that is not clear.

**What is the purpose of the research?**

Our work is about improving the performance of soldiers and whether an existing computer worn by soldiers (UltraLYNX™) can be used for human performance monitoring. Potassium is a salt present in the body. How much potassium you produce can show how stressed your body is. (1) This study aims to demonstrate that a potassium sensor can reliably detect potassium levels in sweat when compared to blood. (2) The study will test whether caffeine will shift measurements in your body both at rest and during exercise to an extent that is detectable using the potassium sensor. (3) We will test whether data from the potassium sensor and heart rate monitor can be integrated and combined to generate a red, amber, or green (RAG) signal, that tells us how hard your body is working.

**Who is doing this research?**

This research is being undertaken by a team from Lancaster University and ULTRA PCS; the sponsor will be DSTL. ULTRA PCS are an engineering company that have designed and manufactured the UltraLYNX™ technology being used in this study. The work is funded by

the Ministry of Defence as part of DASA grant: ACC6042224. The money is used to pay for experimental running costs and analytical costs.

**Why have I been invited?**

You have been invited as you have expressed an interest following advertisement of the study. To participate, you must meet our inclusion criteria, and not meet any of our exclusion criteria below. Some of these will be determined on your fist visit to the Human Performance Lab. The study doctor will also be able to clarify/check your suitability to participate in the study.

**Inclusion criteria:**
Male or Female.
18-35 years old.
Pass UK military physical tests (details below).

**Exclusion criteria:**
An intolerance or avoidance of caffeine
Any prescribed medication.
Smokers (smoking defined as more than 100 cigarettes throughout lifetime)
Vaping defined as any use in last 7 days
Liquorice consumption within the last 7 days
Recreational drug use in the last month including, but not limited to, cannabis and cocaine
Any medical condition that would prevent entry into army, navy or air force.
Phobia to needles.
Allergy or insensitivity to materials used in the study (e.g adhesive)
Recent musculoskeletal injury (within the last 3 months).
Non-English speakers
Pregnancy
Atrial fibrillation
Any findings that the Clinical research fellow believes affect the integrity of study data or the safety to conduct tests

**Do I have to take part?**

No, participation is entirely voluntary. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. This would not affect your legal rights.

**What will happen to me if I take part?**

If you choose to take part, you will attend the Human Performance Lab at Lancaster University for three visits. We advise that you attend all visits, including the screening in comfortable clothing suitable for exercise.

For female participants: You will be asked to take a commercial urine-based pregnancy test at the screening visit and prior to each laboratory visit to confirm that you are not pregnant. You will then be asked to self-report the outcome of the test.

**Visit 1 (Screening)**

The first visit will involve taking your written consent before undertaking a medical screening. This will involve a questionnaire about your health, measuring your height, weight, blood pressure, and checking for an electrical abnormality in the heart called atrial fibrillation. We will then then confirm that you can meet the fitness requirements for the military. This will involve a seated medicine ball throw, a mid-thigh pull, and a 2km run. Seated medicine ball throw: Sitting with your back against a wall, you will throw a 4kg medicine ball as far as you can. Your best throw of three will count. You must throw at least 2.7m to be included. Mid-thigh pull: Standing in front of a bar set to mid-thigh height you will be asked to pull the bar upwards for 5 seconds then rest and repeat. Your best score of the two attempts will count. You must pull 50kg or more to be included. Your score will be taken from the best of your two attempts. 2km run: You will run 2km on a treadmill as fast as you can. You must complete this in under 11 minutes and 15 seconds to be included.

If at this point the tests indicate you are suitable to take part, we will arrange your second visit to participate in the testing. If the tests indicate you are not suitable, you will be unable to participate in any further visits. If we find anything about your health that your GP may like to know about, the study doctor will provide a letter that you can take to your GP.

**Visits 2 and 3**

When you attend the lab, you will consume a 200 mg caffeine pill or a placebo pill. This amount of caffeine is like two regular cups of coffee. The caffeine pill is a commercially available food supplement, and the placebo pill is a sugar pill. Neither you nor the investigators will know what each pill is at the time. After you've swallowed the pill with water, you will be monitored for 45 minutes, the time it takes caffeine to reach its peak effect.

Figure: Picture of cannula in the inner elbow

A heart rate monitor will be fitted by a researcher using a plastic and elastic strap around your chest, and the potassium sensor will be fitted in a similar region to the heart rate strap.

This will be done behind a screen and can be self-fitted in private if you prefer. We will also place a small plastic tube known as a cannula on the inside of your elbow to take blood. You

may feel a sharp scratch when this is initially inserted (like a normal blood sample) but after this, you should not be aware of it. We may flush this tube occasionally with saline and when we do it may feel a little cold in the region. This will be done by a medical professional or someone with NHS training and certification in this procedure. The cannula will be in place throughout the study visit. We will take a maximum of 25ml blood per visit, which is the same as about 5 teaspoons of blood.

You will then undergo a series of tests on a laptop to measure your attention, memory, and reaction time skills. These tests will the less than 13 minutes and you will be made familiar with the tests in advance. At the same time, we will measure electrical activity on your skin surface, known as electrodermal activity. We will do this through placing two electrodes on the index and middle finger of your non-dominant hand. You will then sit on a machine which can measure your strength and you will complete some knee extension exercises, to test the maximum strength in your legs.

Figure: Image of a plate carrier vest

Once these tests are complete, you will then be fitted with a blue mask connected to a gas-analysis system. You will also be fitted with a 9.07kg weighted plate-carrier vest. You will step on to a treadmill and on the side, there will be yellow bars that measure changes in the way you walk or run. You will then walk for 20 minutes, walk for 40 minutes at a 1% gradient, before undergoing some sprint intervals at 11km/h of 9s duration with 11s rest in between. Once complete, the strength tests will be completed using knee extension exercises.

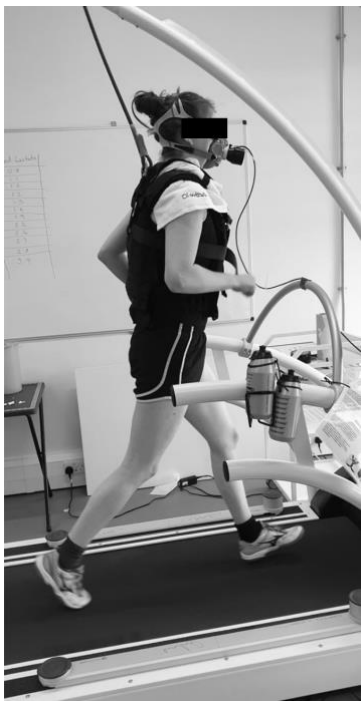

Figure: Participant running on a treadmill wearing the gas analysis equipment and weighted vest

**What is the device or procedure that is being tested?**

We are testing a potassium sensor that is worn on the skin and measures potassium in sweat. This will be secured using a see-through plaster. We are also testing whether this device can communicate effectively with the UltraLYNX™ vest-worn computer device. A picture of the sensor that will be taped to your lower back is shown in the Figure below.

*Figure: Sensor size*

**Are there any direct benefits to me of taking part?**

No, there are no direct benefits to you taking part.

**What are the possible disadvantages and risks of taking part?**

The exercise protocol involves running and sprinting whilst carrying a 9.07kg (20lb) load. This carries a small risk of injury, including slips, trips, falls and rubbing or chafing from the vest. Equipment will be fitted correctly by researchers to minimise these risks. The exercise could also make you feel ill and result in discomfort which may, in extreme cases, cause vomiting. This type of exercise has risks that we try to limit through giving you a health screening which includes checking your heart.

Caffeine will be administered as a single 200mg pill available commercially. Caffeine carries side effects can include a fast heart rate, dizziness, dehydration, restlessness, and anxiety. You may experience some or none of these symptoms and you will be monitored throughout testing for these symptoms. Cannulation carries a risk of bruising, unintended puncture of other blood vessels and infection. It can also cause discomfort. As we are testing a novel sensor there is a possibility of an adverse reaction with the skin, e.g. skin irritation or abrasion, though all materials are used routinely in skin-worn electronic products. All procedures are carried out by experienced personnel routinely within our research group.

You may experience some caffeine withdrawal symptoms in advance and on the day of study visits. Symptoms include headaches, low energy, and difficulty in concentrating.

If you do suffer any other symptoms or if you become in any way concerned during your current visit, prior to your next study visit, or after the study has finished, notify one of the investigators listed at the end of this sheet as soon as possible. Should you become unwell, you should seek medical attention if appropriate. If we uncover any health findings your GP may like to know about, the study doctor will give you a letter that you can take to your GP to inform them. You should note that none of the tests are diagnostic in nature, the tests are just for the research, so any findings will need to be followed up through your GP once you have notified them.

**Can I withdraw from the research and what will happen if I withdraw?**

Your participation is voluntary, and you are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw, then the information collected so far that has been anonymised cannot be erased and this information may still be used in the project analysis. Any identifiable data will be erased.

You may also be withdrawn from the study by the study team at any time. This may be because of factors that affect your safety, or the integrity of the scientific data collected.

**Will I receive any expenses or payments?**

You will receive a £100 inconvenience allowance upon completion of the study, which can be paid via BACs bank transfer. Payment will be pro-rata if you complete part of the study per test visit i.e. £33 for screening only, £66 for screening and one study visit, £100 for all three visits. Payment for research participation in the UK can affect tax obligations and benefit payments, so we recommend participants check this before participation.

**Will my taking part or not taking part affect my career or studies?**

Your participation will in no way affect your career or your academic studies at Lancaster University. The same applies if you choose not to take part, or if you withdraw part way through the study.

**What happens if I suffer any harm?**

If you suffer any harm as a direct result of taking part in this study, you can apply for compensation under the MOD's No-Fault Compensation Scheme.

**What will happen to any samples I give?**

We will analyse your fingertip blood samples within the Human Performance Lab at Lancaster University. This is a point of care test where blood will be immediately discarded. Blood taken from a cannula will be separated into serum, which will be stored at Lancaster University where we will later measure serum potassium levels. Any samples remaining after ethics has ended will be disposed of in accordance with the Human Tissue Authorities codes of practice.

**How will my records be managed?**

We will follow ethical and legal practice and all information about you will be handled accordance with all applicable regulations.

All personal identifiable data that is collected about you during the research will be kept **confidential**. There are limits to this, and if the researcher is concerned that you are at risk of harm, or there is a risk of harm to others, they may have to break confidentiality and speak to other members of the research team or relevant professionals.

The data collected about you during the course of the study may be looked at by authorised persons from Lancaster University, ULTRAPCS, and DSTL who are organising the research. It may also be looked at by other authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant.

Paper records will be stored in a secure and locked office on Lancaster University campus, and electronic records on a password protected database held on Lancaster University approved secure cloud storage servers, with access allowed only to those researchers taking part in the study.

Any information about the study that leaves the Research Unit will have your all-identifiable details removed, such as names and address and a unique code will be used (Pseudonymised). All reasonable steps will be taken to ensure anonymity. Once the data has been anonymised, it will not be possible to remove your anonymised data.

Lancaster University will be the data controller for any personal information collected as part of this study. Under the GDPR you have certain rights when personal data is collected about you. You have the right to access any personal data held about you, to object to the processing of your personal information, to rectify personal data if it is inaccurate, the right to

have data about you erased and, depending on the circumstances, the right to data portability. Please be aware that many of these rights are not absolute and only apply in

certain circumstances. If you would like to know more about your rights in relation to your personal data, please speak to the researcher on your particular study.

For further information about how Lancaster University processes personal data for research purposes and your data rights please visit our webpage:

www.lancaster.ac.uk/research/data-protection.

**Who has reviewed the study?**

This study has been reviewed and given favourable opinion by the Ministry of Defence Research Ethics Committee (MODREC).

**Who do I contact if I have any questions?**

Should you have any questions or would like more information, you can contact either the Clinical Research Fellow or the Chief Investigator:

Clinical Research Fellow: Dr Samantha Moore
Address: Health Innovation One, Lancaster University, Lancaster, LA1 4AT, UK
E-mail: samanthamoore2@nhs.net

Name: Dr Christopher Gaffney (Chief Investigator for Human Experimentation)
Address: A49 Health Innovation One, Lancaster University, Lancaster, LA1 4AT, UK
Tel No: +44 (0) 1524 593 602
E-mail: c.gaffney@lancaster.ac.uk

Name: Dr Cliff Shelton (Independent Medical Officer)
Address: Health Innovation One, Lancaster University, Lancaster, LA1 4AT, UK
Email: c.shelton@lancaster.ac.uk

**Who do I contact if I have a complaint?**

Should you have any concerns about the way this study has been conducted, or you wish to make a complaint, then you can discuss this with the researchers listed above. Should you wish to discuss your concerns with someone outside of the research team you can contact:

Name: Helen Brace, Acting Head of Research Quality and Policy
Address: Research Enterprise Services, Lancaster University, Lancaster, LA1 4YW
E-mail: sponsorship@lancaster.ac.uk

**Compliance with the Declaration of Helsinki**

This study will be conducted in accordance with the principles defined in the Declaration of Helsinki as adopted at the 64th WMA General Assembly at Fortaleza, Brazil in October 2013.