UNIVERSITY OF LIMERICK
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Education and Health Sciences

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UNIVERSITY OF LIMERICK RESEARCH ETHICS COMMITTEE

RISK ASSESSMENT FORM – PROCEDURES INVOLVING HUMAN SUBJECTS

Procedure No	2023_11_06_RA
Title of Procedure	The Use of a Continuous Glucose Monitor (Abbott Libre Sense Glucose Sport Biosensor) in the Sport and Exercise Sciences
Name of Assessor(s)	Professor Phil Jakeman
Assessment Date	03/10/ 2023
Does this procedure already have ethical approval? (Delete as appropriate)	~~YES~~/NO
If **YES**, enter ethical number and expiry date	**Approval No:** **Expiry Date:** 3 / 10 / 33

1 Please provide a brief description of the procedure

The Abbott Libre Sense Glucose Sport Biosensor ('biosensor') is designed for glucose sport use only and offers streaming glucose data with a dynamic range of 55 – 200 mg/dL (3-12 mmol/L) for athletes to monitor their glucose levels. It is specifically designed for sports use. The biosensor has a CE Mark (Conformité Européenne) in Europe, where it is a consumer over-the-counter product that provides glucose monitoring via a mobile application to athletes performing sports such as cycling, running, and swimming, to understand the efficacy of their nutrition choices on training and competition. It is not considered a medical device and is not intended for the diagnosis, treatment, or management of disease.

The biosensor is applied by the subject to the back of the upper arm with the aid of the biosensor applicator. The applicator contains a u-shaped sharp that is equivalent in diameter to a 23-gauge (0.64 mm) needle that is spring-loaded to introduce a flexible filament into the subcutaneous tissue. The sharp retracts back into the applicator after application leaving only the 5mm filament just under the skin held in place with an adhesive pad. The sensor may be worn for a period of up to 14 days.

The biosensor is paired to a compatible smartphone app. To obtain glucose readings, users simply start a biosensor with a quick scan of the smartphone over the biosensor. After a 1-hour warm up period, users will start to automatically receive streaming glucose data every minute on their compatible smartphone app. The biosensor automatically reports the glucose concentration in the interstitial fluid every minute. It also automatically records the glucose concentration every 15 minutes, storing that data in a rolling 8-hour log.

The biosensor is designed to provide a glucose monitoring experience that will enable athletes to understand the efficacy of their nutrition choices during training and competition. It will therefore inform athletes about how to fuel appropriately, to fill their glycogen stores prior to a race and to know when to replenish during a race to maintain athletic performance.[1] Analogous to the instruction of heart rate monitors, smart watches, etc., that provide biofeedback of a person's somatic response(s), there is a requirement to validate their use in practice[2].

[1] Moore, D. 2015. Nutrition to Support Recovery from Endurance Exercise: Optimal Carbohydrate and Protein Replacement. *American College of Sports Medicine.* 14(4), pp. 294-300.
[2] Bowler, A. M., Whitfield, J., Marshall, L., Coffey, V. G., Burke, L. M., & Cox, G. R. (2023). The Use of Continuous Glucose Monitors in Sport: Possible Applications and Considerations. *International Journal of Sport Nutrition and Exercise Metabolism*, *33*(2), 121-132.

2 Location in which the procedure may take place

√	PG050 Teaching Laboratory
√	PG047 Project Laboratory

Others, please specify

√	During normal habitual living
√	During physical activity

3 Eligibility of subject(s) to be used

√	University Student
√	University Staff or Personnel
√	Members of the general public engaged in research projects granted ethical approval.

4 Potential risks. To be explained <u>before</u> obtaining consent

√	None, or minimal discomfort only

If the risks are other than trivial please provide a brief description.

The subject should **not participate** in the test if there is a recent history of illness, recurrent injury or medication. These are identified in the pre-test questionnaire.

5 Action to be taken in the event of a foreseeable emergency

Please provide a clear statement of appropriate action including contact names and telephone numbers.

For example:
1. Remove the biosensor from the subject.
2. Seek medical attention, if required.

6 Level of supervision required for procedure

√	lecturing/research staff
√	postgraduate researcher

Others, please specify

√	Undergraduate/postgraduate taught project student under supervision of Faculty or Research Staff

7 Other documentation required for this assessment?

√	Subject information sheet
√	Standard Operating Procedure

Others, please specify

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FOR COMPLETION BY HEAD OF DEPARTMENT

RISK ASSESSMENT FORM – PROCEDURES INVOLVING HUMAN SUBJECTS

In the Department of Physical Education and Sport Sciences

Procedure No	

Title of Procedure	The Use of a Continuous Glucose Monitor (Abbott Libre Sense Glucose Sport Biosensor**)** in the Sport and Exercise Sciences

Name of Assessor(s)	Professor Phil Jakeman	**Assessment Date**	03/10/ 2023

8 Approval of procedure

	Granted
	Subject to conditions (see below)

Others, please specify

	Refer to Medical Ethics

Comments/conditions

Informed consent must be completed.

Signed: _____ Date: ____24/10/2023_____

(Head of Department)