

# Performance review for FreeStyle Libre Glucose Monitoring Systems

<b>Submission date</b> 13/05/2021	<b>Recruitment status</b> Recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 28/06/2021	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 25/06/2021	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Diabetes is a lifelong condition where the amount of sugar in the blood is too high. The aim of this study is to collect glucose data using the FreeStyle Libre Glucose Monitoring System from adults.

### Who can participate?

Anyone aged 18 without diabetes or with type 1 or type 2 diabetes

### What does the study involve?

Participants will wear up to four sensors for up to 14 days, after which sensors will be removed, and data uploaded. Each study event aims to recruit between 18 and 72 participants. Once a study event is complete another one commences, on a continuing basis. Each participant is in the study for up to 15 days.

### What are the possible benefits & risks of participating?

There is no direct benefit to the participant by taking part in this study. The only risks associated with the study are from obtaining capillary blood samples, these are small but could include pain, bruising, local infection and fainting.

### Where is the study run from?

Abbott Diabetes Care (UK)

### When is the study starting and how long is it expected to run for?

May 2020 to December 2031

### Who is funding the study?

Abbott Diabetes Care (UK)

### Who is the main contact?

Dr Pamela Reid

## Contact information

**Type(s)**

Public

**Contact name**

Dr Pamela Reid

**Contact details**

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## **Additional identifiers**

**Clinical Trials Information System (CTIS)**

Nil known

**Integrated Research Application System (IRAS)**

292446

**ClinicalTrials.gov (NCT)**

Nil known

**Protocol serial number**

ADC-UK-PMS-20048, IRAS 292446

## **Study information**

**Scientific Title**

Sensor accuracy performance review for FreeStyle Libre Glucose Monitoring Systems

**Study objectives**

Accuracy of FreeStyle Libre Glucose Monitoring Systems compared to capillary fingerstick blood glucose values using the consensus error grid.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 12/04/2021, West Midlands - South Birmingham Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; +44 (0)207 104 8345, +44 (0)207 104 8107, +44 (0)207 104 8388; southbirmingham.rec@hra.nhs.uk), REC ref: 21/WM/0064

**Study design**

Prospective single-arm single-centre study

**Primary study design**

Observational

**Study type(s)**

Other

**Health condition(s) or problem(s) studied**

Diabetes mellitus

**Interventions**

Participants will wear up to four FreeStyle Libre Sensors for up to 14 days. There is no follow-up period unless the participant experiences an unanticipated adverse device effect (UADE).

**Intervention Type**

Device

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

FreeStyle Libre Sensors

**Primary outcome(s)**

Accuracy of the FreeStyle Libre Glucose Monitoring Systems compared to capillary fingerstick blood glucose values (FreeStyle Optium blood glucose test strips) using the consensus error grid at the end of the sensor wear period

**Key secondary outcome(s)**

There are no secondary outcome measures

**Completion date**

31/12/2031

## **Eligibility**

**Key inclusion criteria**

1. Aged 18 years or over
2. Has type 1 or type 2 diabetes or has not been diagnosed as having diabetes
3. Be willing and able to test their blood glucose levels at least four times a day

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Has another form of diabetes e.g. maturity-onset diabetes of the young (MODY)
2. Have a known (or suspected) allergy to medical grade adhesive
3. Have a skin abnormality at the application sites
4. Have a pacemaker or any other neurostimulators
5. Have concomitant medical condition which in the participant's opinion could interfere with the study or present a risk to their safety or welfare, or that of the study team

**Date of first enrolment**

01/05/2021

**Date of final enrolment**

16/12/2031

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

Abbott Diabetes Care Ltd

Range Road

witney

United Kingdom

OX29 0YL

**Sponsor information****Organisation**

Abbott (United Kingdom)

**ROR**

<https://ror.org/03wnay029>

**Funder(s)****Funder type**

Industry

**Funder Name**

Abbott Diabetes Care

**Alternative Name(s)****Funding Body Type**

Private sector organisation

**Funding Body Subtype**

For-profit companies (industry)

**Location**

United States of America

## Results and Publications

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are not expected to be made available due to lack of consent to share. All data will be held by Abbott Diabetes Care and used as part of a post-market surveillance program.

**IPD sharing plan summary**

Not expected to be made available

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes