

# User performance evaluation of the FreeStyle Optium Blood Glucose Monitoring System

<b>Submission date</b> 16/07/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 17/08/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 15/08/2022	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

The FreeStyle Optium Blood Glucose Monitoring System is a system for measuring glucose levels and is freely available to buy on the market in the UK. The aim of the study is to evaluate whether at least 95% of FreeStyle Optium Blood Glucose Monitoring System results are required to be within  $\pm 0.83$  mmol/L (15mg/dL) / 15%.of the YSI reference measurement.

### Who can participate?

Patients with diabetes and aged at least 16 years.

### What does the study involve?

Participants first have an opportunity to familiarise themselves with the FreeStyle Optium System, before performing a blood glucose test from their fingertip. A capillary blood sample is collected to perform haemoglobin testing on the HemoCue analyser and a glucose reference test on the YSI analyser. This should take up no more than 30 minutes of each participants time.

### What are the possible benefits and 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 capillary blood sample collection, these are small but could include pain, bruising, local infection and fainting.

### Where is the study run from?

The Ipswich Hospital NHS Trust and Leeds Teaching Hospitals NHS Trust (UK)

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

July 2015 to October 2015

### Who is funding the study?

Abbott Diabetes Care Ltd (UK)

### Who is the main contact?

Dr Pamela Reid

## Contact information

**Type(s)**

Public

**Contact name**

Dr Pamela Reid

**Contact details**

Range Road  
Witney  
United Kingdom  
OX29 0YL

## Additional identifiers

**Protocol serial number**

ADC-UK-PES-15027

## Study information

**Scientific Title**

User performance evaluation of the FreeStyle Optium Blood Glucose Monitoring System: a multi-centre prospective single arm study

**Study objectives**

The aim of the study is to evaluate whether at least 95% of FreeStyle Optium Blood Glucose Monitoring System results are required to be within  $\pm 0.83$  mmol/L (15mg/dL) / 15%.of the YSI reference measurement.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

NRES Committee South Central - Berkshire B, 23/06/2015, ref: 15/SC/0395

**Study design**

Multi-centre prospective single arm

**Primary study design**

Interventional

**Study type(s)**

Prevention

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

Diabetes mellitus

**Interventions**

1. A participant will perform a blood glucose measurement on the FreeStyle Optium Blood Glucose Monitoring System

2. A capillary blood sample will be collected to perform haemoglobin testing on the HemoCue analyser and a glucose reference test on the YSI analyser

### **Intervention Type**

Device

### **Primary outcome(s)**

Accuracy analysis will be performed according to ISO 15197:2013 Section 8.2

The analysis will be performed when the study is complete. ISO 15197:20131 section 8.2 specifies that at least 95% of fingerstick blood glucose results are required to be within  $\pm 0.83$  mmol/L (15mg/dL) / 15% of the reference analyser (YSI). Regression analysis will also be performed and plots of the data will be generated.

### **Key secondary outcome(s)**

Linear regression and error grid analysis.

### **Completion date**

30/10/2015

## **Eligibility**

### **Key inclusion criteria**

1. Type 1 or Type 2 Diabetes
2. Age  $\geq$  16 years

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

### **Total final enrolment**

165

### **Key exclusion criteria**

1. Currently using the FreeStyle Optium, Boots or Optium Xceed Blood Glucose Monitoring System for routine testing at home (as pictured in the PIIC)
2. Known to be infected with hepatitis B virus (Hep B), hepatitis C virus (Hep C) or human immunodeficiency virus (HIV)
3. Be a member of the study staff
4. Already participated in this study

### **Date of first enrolment**

27/07/2015

**Date of final enrolment**

11/09/2015

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**The Ipswich Hospital NHS Trust**

Ipswich

United Kingdom

IP4 5PD

**Study participating centre**

**Leeds Teaching Hospitals NHS Trust**

Leeds

United Kingdom

LS9 7TF

## Sponsor information

**Organisation**

Abbott Diabetes Care

**ROR**

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

## Funder(s)

**Funder type**

Industry

**Funder Name**

Abbott Diabetes Care Ltd

# Results and Publications

## Individual participant data (IPD) sharing plan

Not provided at time of registration

## IPD sharing plan summary

Data sharing statement to be made available at a later date

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Funder report results</a>	Abbott white paper	01/01/2016	15/08/2022	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No