

Health Legacy

Glucose Sensor Participant Information

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Please note, this information sheet should only be used alongside the latest version of the Health Legacy Participant Information Sheet when a glucose sensor is being used.



What is a glucose sensor and why is it needed?

One of the aims of the Health Legacy study is to understand the links between our genes and common diseases like diabetes. It is important to study genes as they can affect whether someone is more or less likely to get diabetes, and whether there might be particular approaches to diagnosing or treating the condition if someone develops it. Glucose sensors monitor a person's blood glucose (sugar) levels day and night continuously for up to 2 weeks. Using a glucose sensor can help tell us more about whether a person is at risk of diabetes and/or whether the tests that are used to diagnose the condition are accurate or not.

In the Health Legacy study, we would like some of our participants to wear a glucose sensor so that we can better understand the links between our genes, our blood glucose levels, and diabetes.

What kind of glucose sensor will I wear?

We would like you to wear a small glucose sensor on your arm called FreeStyle Libre Pro iQ, pictured below. This allows the Health Legacy team to monitor your glucose (sugar) levels for 24 hours a day over 14 days. Freestyle Libre glucose sensors are used commonly by the NHS for people living with diabetes, and they can be bought in pharmacies and online for people who want to do detailed health tracking (e.g. people who use the Zoe app). It is safe to wear the Freestyle Libre sensor.

The FreeStyle
Libre Pro iQ
continuous
glucose
monitoring
system



How long will I wear the sensor?

We would like you to wear the sensor for 14 days so that we can build an accurate picture of your glucose levels, day and night, before and after food.



Will I have to put the glucose sensor on by myself?

No, the research team will put the glucose sensor on your arm for you. This is a quick and painless procedure



Is it painful to wear the sensor?

The vast majority of people wearing the Freestyle Libre sensor do not find it painful. A study conducted by the sensor manufacturers and published in a scientific journal found that 93% of people wearing the sensor did not get any discomfort.



Is there a needle in the glucose sensor?

No. It contains a tiny plastic filament that is 0.4 millimetres thick that goes just 5 millimetres under the skin's surface.



Will I develop a skin reaction?

It is very unlikely you will get a skin reaction from wearing the glucose sensor. In the same study mentioned earlier, 95% of people wearing the sensor did not get any skin reaction, and 5% of people noticed itching or skin reddening around the sensor.

What if I notice pain or get a skin reaction while wearing the sensor?

Our experienced study team will talk to you and assess the problem. Sometimes there can be a simple solution to these problems that mean you can keep wearing the sensor. If the medical team think the sensor should be removed or replaced, we will arrange this. If you change your mind about wearing the sensor, you can contact the Health Legacy team and we can arrange to remove it.



What happens if it falls off during the study?

Sometimes the sensor falls off before the 14 days are complete. In some cases there may be enough information already collected to complete the study. In other cases where the sensor falls off very early the study team may invite you to wear a second sensor to complete the data collection. This second sensor is optional.

What should I do if it becomes loose or falls off?

Keep hold of the sensor and store it in a clean and dry container or bag. Contact the study team on <INSERT MOBILE NUMBER> or email: healthlegacy@qmul.ac.uk to discuss the next steps.



Can I wear it in the shower or swimming pool?

Yes. The sensor can be worn while bathing, showering, swimming or exercising. The sensor should not be taken below 1 meter of water (3 feet) and should not be submerged in water for more than 30 minutes. The adhesive is designed to keep the sensor securely and comfortably in place for up to 14 days.



Are there times when it should be removed?

Yes. The sensor should be removed prior to exposing it to strong magnetic or electromagnetic radiation, such as with an MRI (magnetic resonance imaging) or CT (computed tomography) scan. Additionally, if you suspect a strong allergic reaction or skin infection then the sensor should be removed immediately before medical seeking help.



How should I remove it at the end of the study?

You should pull up the edge of the adhesive that keeps the sensor attached to the skin, then slowly peel away from the skin in one motion. **DO NOT THROW THE SENSOR AWAY.** Please place the sensor in the clean and dry container we have given you and return it to the study team. We will tell you how to return the sensor to us at your first study visit, but if you are not sure, you can contact us. If you prefer not to take the sensor off yourself, our study team can do this for you when you return it.



Will I be able to review my blood glucose levels?

People who wear glucose sensors and see their daily glucose patterns often change their daily habits. During the study we want you to live your life as normal so that we can build an accurate picture of your normal glucose levels. For this reason the glucose sensor we give you will not allow you to look at your own glucose levels while you are wearing it. After you have returned your sensor, our medical team will review the information from it. If we see anything in your glucose levels that needs further review, e.g. high glucose levels consistent with having diabetes, we will contact you and your GP. If you would like to receive a copy of your glucose sensor report after the sensor is removed, you may request this.



Could the glucose sensor diagnose me with diabetes?

At your Health Legacy study visit, we will do blood tests including a standard diabetes check. The glucose sensor can also identify glucose patterns that are high and consistent with having diabetes. If either your blood test or glucose sensor results suggest you might have diabetes or any other health problem, we will discuss this with you and your GP.



What happens to the information from my glucose sensor?

When we set up your glucose sensor, we will link it to the LibreView Data Management System, hosted by Abbott, the manufacturer of the sensor. This is a cloud-based system that meets international data protection and privacy regulations and that is used in the NHS. We will not transfer any information that identifies you to the LibreView Data Management System.

Abbott may create, access, retain, use or disclose to third-party researchers, aggregated, anonymised, de-identified (or pseudonymised to the extent permitted by your law) data derived from the LibreView Data Management System for the purposes of research, to evaluate how the LibreView Data Management System is provided, to evaluate its use and its various components and equipment, to evaluate performance or impact on clinical staff or across clinics, to enhance the functioning of the LibreView Data Management System, the Readers and the FreeStyle Libre sensors, to validate LibreView Data Management System upgrades or for product development and quality and safety of medical devices. You agree that the licence herein permits Abbott to take any such actions subject to our compliance with any applicable data protection laws.

Once your sensor is removed, the study team will download the information from your sensor onto our secure, dedicated research database at Queen Mary University of London. The information will then be deleted from the cloud.