

# FreeStyle Libre Flash Glucose Monitoring System FAQs

## **Do I need a separate blood glucose meter when using the FreeStyle Libre system?**

No. For convenience, there is a built-in FreeStyle Optium blood glucose and ketone meter within the reader that can be used for blood glucose and ketone readings.

## **Can I perform a blood ketone test with the FreeStyle Libre system?**

You can use the built-in meter to check your blood ketone levels using FreeStyle Optium b-ketone test strips. You should perform a blood ketone test on your fingertip only. Be sure to read the test strip instructions for use prior to using the built-in meter.

## **What is a Flash Glucose Monitoring System?**

Flash glucose monitoring is a new, user-friendly way to discreetly obtain glucose readings. A flash glucose monitoring system provides a complete picture showing the current glucose reading plus you can see how glucose levels are changing in a flash by just scanning the reader over the sensor.

What makes flash glucose monitoring system unique is that a quick scan of the reader over the sensor provides a complete picture of your glucose including the current glucose reading, 8 hour history and trend arrow showing if your glucose level is going up, down or staying steady.

## **What is the FreeStyle Libre flash glucose monitoring system?**

The FreeStyle Libre flash glucose monitoring system is the first product in the flash glucose monitoring category and is designed to liberate people with diabetes from many of the hassles of glucose monitoring, such as routine finger pricking. The FreeStyle Libre system contains two components:

**FreeStyle Libre sensor:** A small, disposable 14-day sensor that is worn on the back of the upper arm and automatically measures glucose levels and stores them for a period of 8 hours. Every time the user scans the reader over the sensor, the glucose data from sensor is transferred to the reader in 1 second.

**FreeStyle Libre reader:** A compact, handheld reader that displays glucose readings and stores up to 90 days of glucose data. When the reader is scanned over the sensor, it shows a current glucose reading, last 8-hours of data as well as a trend arrow (indicating if glucose is going up, down or staying steady). To obtain a glucose reading, simply perform a quick, 1-second scan of the reader over the sensor. This easy scan gives you more information than blood glucose monitoring without the need for routine finger pricks<sup>1</sup>.

<sup>1</sup> A finger prick test using a blood glucose meter is required during times of rapidly changing glucose levels when interstitial fluid glucose levels may not accurately reflect blood glucose levels or if hypoglycaemia or impending hypoglycaemia is reported by the system or when symptoms do not match the system readings.

## **What does 'Flash' mean?**

'Flash' reflects the fact that users can obtain glucose readings quickly by just scanning the reader over the sensor. Flash glucose monitoring also provides a flash of insight to people with diabetes and their healthcare professionals.

## **How does the FreeStyle Libre system work?**

To obtain a glucose reading, simply perform a quick 1-second scan of the reader over the sensor.

This easy scan gives you more information than a blood glucose test without the need for routine finger pricks<sup>1</sup>. The FreeStyle Libre system also offers software to generate concise reports that provide a clear analysis of your glucose data.

<sup>1</sup> A finger prick test using a blood glucose meter is required during times of rapidly changing glucose levels when interstitial fluid glucose levels may not accurately reflect blood glucose levels or if hypoglycaemia or impending hypoglycaemia is reported by the system or when symptoms do not match the system readings.

## **Does the FreeStyle Libre system need to be calibrated?**

No, the FreeStyle Libre sensor is calibrated during the manufacturing process so you don't have to. The sensor is activated by scanning and then, after a 1 hour warm up period, it starts to record glucose readings automatically.

## **Is FreeStyle Libre accurate?**

The FreeStyle Libre system is clinically proven to be accurate, stable and consistent over 14 days compared to blood glucose testing without the need for finger prick calibration

In a clinical study, the FreeStyle Libre system achieved 11.4% Mean Absolute Relative Difference (MARD) compared to blood glucose testing<sup>2</sup>

99.7% of glucose results fall within Zone A and Zone B of the Consensus Error Grid, when compared against blood glucose testing<sup>2</sup>

The measurement errors associated with these zones have no effect on clinical action and little or no effect on clinical outcomes<sup>3</sup>

<sup>2</sup> Bailey, T, et al. The Performance and Usability of a Factory-Calibrated Flash Glucose Monitoring System. *Diabetes Technology and Therapeutics* v17 n11 July 2015 (10.1089/dia.2014.0378)

<sup>3</sup> Parkes J, Slatin S, Pardo S, et al. A new consensus error grid to evaluate the clinical significance of inaccuracies in the measurement of blood glucose. *Diabetes Care*. 2000;23(8):1143-1148.

## **Is interstitial fluid an adequate replacement to blood glucose testing?**

Interstitial fluid-based glucose readings are a reliable indicator of blood glucose levels<sup>4</sup>

The physiological lag in ISF glucose, with respect to changes in blood glucose, is about 5-10 minutes<sup>4</sup>

The average lag time of the FreeStyle Libre system is approximately 5 minutes, which is unlikely to impact routine day-to-day treatment decisions<sup>3, 4</sup>

<sup>3</sup> Parkes J, Slatin S, Pardo S, et al. A new consensus error grid to evaluate the clinical significance of inaccuracies in the measurement of blood glucose. *Diabetes Care*. 2000;23(8):1143-1148.

<sup>4</sup> Rebrin K, Sheppard NF Jr, Steil GM. Use of subcutaneous interstitial fluid glucose to estimate blood glucose: revisiting delay and sensor offset. *J Diabetes Sci Technol*. 2010;4(5):1087-1098.

## **How is Flash Glucose Monitoring different to Blood Glucose Monitoring (BGM)?**

Traditional blood glucose monitoring provides users with glucose readings that represent distinct points in time. Users do not get information regarding how their glucose levels have been changing, nor do they get information about where their glucose levels are heading. Without such information, it can be easy to miss significant glucose fluctuations - the ups and downs. The FreeStyle Libre system is a new way to obtain glucose readings. It allows the user to get their current glucose reading by just scanning the reader over the sensor, and also provides a complete picture of glucose variations.

### **Can the FreeStyle Libre system be used by children?**

The FreeStyle Libre Flash Glucose Monitoring System is indicated for measuring interstitial fluid glucose levels in people (age 4 and older) with insulin-dependent diabetes mellitus. The indication for children (age 4 - 17) is limited to those who are supervised by a caregiver who is at least 18 years of age. The caregiver is responsible for managing or assisting the child to manage the FreeStyle Libre Flash Glucose Monitoring System and also for interpreting or assisting the child to interpret FreeStyle Libre readings.

### **Can the FreeStyle Libre system calculate a mealtime insulin dose?**

Yes, the system can calculate a suggested mealtime insulin dose when using the built-in blood glucose meter since it has a built-in insulin dose calculator function.

Please note that this feature only works when using the blood glucose test strip port and needs to be activated by a healthcare professional.

### **How does the FreeStyle Libre system calculate an insulin dose?**

The insulin calculator utilises settings entered into the insulin calculator during one of two setup modes (Easy or Advanced); this feature requires an understanding of the use of insulin and must be set up by a healthcare professional. Using the settings they enter, the glucose reading from the built-in blood glucose meter and carbohydrate information (in grams or servings) the user provides, the insulin calculator software in the reader calculates a suggested insulin dose.

### **Does the insulin calculator work with any type of insulin?**

No, the insulin calculator can assist you with calculating rapid-acting (meal-time or short-acting) insulin doses only. The insulin calculator must be set up by a healthcare professional.

### **What's the difference between the Easy and Advanced setup for insulin calculator?**

'Easy setup' is for users who use a fixed dose of rapid-acting insulin before meals. 'Advanced setup' is for users who count carbohydrates (in grams or servings) and/or use a correction factor to adjust doses of rapid-acting insulin at meals. The insulin calculator must be set up by a healthcare professional.

### **How do you discard the disposable components, for example sensor pack and applicator?**

This product should be disposed of in accordance with all applicable local regulations related to the disposal of electronic equipment, batteries, sharps, and materials potentially exposed to body fluids.

This means the used applicator and sensor pack should be disposed of in a Biohazard Sharps bin - Clinical waste referral is required from the district nurse or GP, but the majority of people with diabetes will already have the necessary arrangements in place.

### **How should the FreeStyle Libre system be stored?**

Both the reader and the sensor should be stored between 4 and 25°C.

### **What is a Trend Arrow? How does it work? And what does it tell me?**

The FreeStyle Libre Flash Glucose Monitoring System offers a Trend Arrow with each glucose reading which tells you which way and how quickly glucose levels are changing. So, at any given time, you not only know what your glucose level is currently, but also which way it is heading.

Depending on the direction of Trend Arrow, you can find out if your glucose levels are going up, down or staying steady, facilitating better decision-making.

**Why does the system require a 1 hour warm up period?**

Abbott Diabetes Care is committed to making its products safe for the user. After the insertion, the sensor and the body need to equilibrate (or settle). We have found through our research that it is not always easy to accurately measure glucose in the body until this equilibration happens. Therefore, we let the system equilibrate for 1 hour to make sure that it is providing accurate glucose readings.

**Can my healthcare professional access my reports remotely e.g. over the internet or cloud?**

No, the reports are available only when the reader is connected to a computer. However, you can send the pdf version of your reports to your healthcare professional via e-mail (with your healthcare professional's permission).