

Libre CGM Important Information

What are FreeStyle Libre 14 day system's contraindications?

- Remove the sensor prior to MRI, CT scan and direct exposure X-rays (see note below).

Note: The Abbott Diabetes Care engineering team has indicated that if the sensor is not 'exposed' directly to the X-ray, such as covering the sensor with a lead shield to avoid X-ray exposure, performance of the sensor should remain intact. Since the sensor is not directly exposed to the X-ray during a mammogram, it does not need to be removed when patients undergo this diagnostic. **The Diabetes Program recommends removing the sensors for these diagnostic procedures.**

What substances could interfere with the results generated by the FreeStyle Libre 14 day system?

- Salicylic Acid may interfere with the sensor readings. Doses of aspirin less than 650 mg did not appear to impact sensor glucose readings.
- Do not take high doses of vitamin C (more than 500 mg per day), as this may falsely raise your Sensor readings.

Has the FreeStyle Libre 14 day system been tested in (a) water and (b) sea water?

- a) Yes. Sensors can be worn while bathing, showering or swimming. Don't take sensors deeper than 3 feet or for longer than 30 minutes. b) No. The FreeStyle Libre 14 day system has not been tested in sea water.

Can the FreeStyle Libre 14 day system be prescribed for pregnant women with diabetes?

- No. The FreeStyle Libre 14 day system is not indicated for the management of diabetes in pregnant women.

Can the FreeStyle Libre 14 day system be used by dialysis patients?

- The FreeStyle Libre 14 day system has not been evaluated for use by persons on dialysis.

Can the FreeStyle Libre 14 day system be prescribed for children?

- No. The FreeStyle Libre 14 day system is indicated for the management of diabetes in people ages 18 and over.

How accurate is the FreeStyle Libre 14 day system at high and low values?

- The FreeStyle Libre 14 day system is accurate in the range between 40 to 500 mg/dL and only shows glucose values in this range. If "LO" appears on the reader, your reading is below 40 mg/dL; check your blood glucose again with a test strip. If "HI" appears in your reader, your reading is above 500 mg/dL; check

your blood glucose again with a test strip. If a second “LO” or “HI” result appears, contact your health care professional immediately.

What are the differences between interstitial fluid (ISF) and blood glucose (BG) readings?

- Interstitial fluid glucose measurements are taken from the fluid within tissue while blood glucose measurements are taken directly from the blood. Sensor glucose values, which are based on interstitial fluid glucose levels, can be different from blood glucose levels (finger sticks), particularly during times when your blood glucose is changing quickly. For example after eating, taking insulin, or exercising. When glucose levels are falling quickly, glucose readings from the Sensor may be higher than blood glucose levels. On the other hand, when glucose levels are rising quickly, glucose readings from the Sensor may be lower than blood glucose levels.



Interstitial fluid lags behind blood glucose by approximately 15 minutes. Readings will NEVER be exactly the same.

Will the difference in results between the FreeStyle Libre 14 day system and my blood glucose meter (BGM) impact my dosing decisions?

- Sensor glucose values, which are based on interstitial fluid glucose levels, can be different from blood glucose levels (finger sticks), particularly during times when your blood glucose is changing quickly. For example after eating, taking insulin, or exercising. When glucose levels are falling quickly, glucose readings from the Sensor may be higher than blood glucose levels. On the other hand, when glucose levels are rising quickly, glucose readings from the Sensor may be lower than blood glucose levels. If glucose is rising quickly or falling quickly, you will see the check glucose symbol. Whenever you see the check glucose symbol, do a blood glucose test and treat based on that result.

What will happen if a user scans frequently, for example, every 30 seconds?

- Users can scan as often as they want, but the reading will not update more frequently than every 60 seconds.

How frequently does the sensor capture and store glucose readings?

- The FreeStyle Libre 14 day sensor automatically captures 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.

Does this sensor require any special handling at the airport?

- Some airport full-body scanners include x-ray or millimeter radio-wave, which you cannot expose your System to. The effect of these scanners has not been evaluated and the exposure may damage the System or cause inaccurate results. To avoid removing your System, you may request another type of screening. If you do choose to go through a full-body scanner, you must remove your Sensor. The System can be exposed to common electrostatic (ESD) and electromagnetic interference (EMI), including airport metal detectors. You can keep your Reader on while going through these. You can safely use your System at all times while on an aircraft.

Does the FreeStyle Libre 14 day system require a prescription?

- Yes, a FreeStyle Libre 14 day reader and sensors require a valid prescription.

Is the FreeStyle LibreLink app approved by the FDA?

- Yes, the FreeStyle LibreLink app for iOS and Android is approved by the FDA as a compatible reading device and alternative primary display for the FreeStyle Libre System and FreeStyle Libre 14 day system.

What type of reports does the LibreView software generate?

- The software has many reports including Snapshot, Glucose Pattern Insights, Daily Log, Glucose Summary, and Daily Patterns.

What types of reports are available on the reader, if any?

- Many reports are available, including Average Glucose, Daily Patterns, Time-in Target, Low Glucose Events, Log Book, Daily Graph and Sensor Usage. For more detail please refer to your User's Manual.

What happens to the sensor if it is worn outside of the recommended temperature range?

- If the sensor stops working due to extreme temperature the reader will display an error message. The sensor will resume recording glucose readings again once it is within the temperature range again. The Operating temperature is between 50 °F to 113 °F.

How is the sensor applied to the body?

- The sensor is applied to the back of the upper arm with a simple, disposable device called an applicator. When the sensor is applied, a small (5mm) filament is inserted just under the skin, and held in place with a small adhesive pad.

Will the user feel the sensor while wearing it?

- In a study conducted by Abbott Diabetes Care, 93.4 %1 of patients surveyed (n=30) did not feel discomfort under the skin while wearing the sensor.