



Important Safety Information

The information contained herein is available within the FreeStyle Libre Flash Glucose Monitoring System User Manual. Please read the User Manual prior to use.

Indications for Use

The FreeStyle Libre Flash Glucose Monitoring System is indicated for measuring interstitial fluid glucose levels in people (age 4 and older) with 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. It is designed to replace blood glucose testing in the self-management of diabetes with the exceptions listed below. Under the following circumstances, use a blood glucose meter to check the current glucose readings from the FreeStyle Libre Flash Glucose Monitoring System Sensor:

- » During times of rapidly changing glucose levels, interstitial glucose levels as measured by the Sensor and reported as current may not accurately reflect blood glucose levels. When glucose levels are falling rapidly, glucose readings from the Sensor may be higher than blood glucose levels. Conversely when glucose levels are rising rapidly, glucose readings from the Sensor may be lower than blood glucose levels.
- » In order to confirm hypoglycaemia or impending hypoglycaemia as reported by the Sensor.
- » If symptoms do not match the FreeStyle Libre Flash Glucose Monitoring System reading. Do not ignore symptoms that may be due to low blood glucose or high blood glucose.

Contraindications

The FreeStyle Libre Flash Glucose Monitoring System must be removed prior to Magnetic Resonance Imaging (MRI).

Warnings

- » The FreeStyle Libre Flash Glucose Monitoring System Sensor is only intended to be used by patients (aged 4 years and older) with insulin dependent diabetes mellitus.
- » Health care professionals and consumers should be aware about the limitations of available scientific evidence for use of this device in any other groups of patients who require diabetes management.
- » The FreeStyle Libre Flash Glucose Monitoring System contains small parts that may be dangerous if swallowed.
- » During times of rapidly changing glucose (more than 0.1 mmol/L per minute), interstitial fluid glucose levels as measured by the FreeStyle Libre Flash Glucose Monitoring System Sensor may not accurately reflect blood glucose levels. Under these circumstances, check the Sensor glucose readings by conducting a fingerstick test using a blood glucose meter.
- » In order to confirm hypoglycaemia or impending hypoglycaemia as reported by the FreeStyle Libre Flash Glucose Monitoring System Sensor, conduct a fingerstick test using a blood glucose meter.
- » Do not ignore symptoms that may be due to low or high blood glucose. If you have symptoms that do not match the FreeStyle Libre Flash Glucose Monitoring System reading or suspect that your reading may be inaccurate, check the reading by conducting a fingerstick test using a blood glucose meter. If you are experiencing symptoms that are not consistent with your glucose readings, consult your health care professional.



Important Safety Information *continued*

Cautions

- » On rare occasions, you may get inaccurate Sensor glucose readings. If you believe your glucose readings are not correct or are inconsistent with how you feel, perform a blood glucose test on your finger to confirm your glucose. If the problem continues, remove the current Sensor and apply a new one.
- » Performance of the System when used with other implanted medical devices, such as pacemakers, has not been evaluated.
- » The Reader is for use by a single person. It must not be used on more than one person including other family members due to the risk of spreading infection. All parts of the Reader are considered biohazardous and can potentially transmit infectious diseases, even after performing the cleaning procedure.
- » Some individuals may be sensitive to the adhesive that keeps the Sensor attached to the skin. If you notice significant skin irritation around or under your Sensor, remove the Sensor and stop using the FreeStyle Libre system. Contact your health care professional before continuing to use the FreeStyle Libre system.

System-Related Information

- » The FreeStyle Libre Flash Glucose Monitoring System is designed to be used only with FreeStyle Optium blood glucose and blood ketone test strips and Optium control solution.
- » Avoid getting dust, dirt, blood, control solution, water or other substances in the Reader's USB and test strips ports.
- » Physiologic differences between the interstitial fluid and capillary blood may result in differences in glucose readings. Differences in glucose readings between interstitial fluid and capillary blood may be observed during times of rapid change in blood glucose, such as after eating, dosing insulin or exercising.
- » Severe dehydration and excessive water loss may cause inaccurate results. If you believe you are suffering from dehydration, consult your health care professional **immediately**.
- » Store the Sensor Kit between 4°C-25°C. While you don't need to keep your Sensor Kit in a refrigerator, you can as long as the refrigerator is between 4°C-25°C.
- » If you have a medical appointment that includes strong magnetic or electromagnetic radiation, for example an X-ray, MRI (Magnetic Resonance Imaging), or CT (Computed Tomography) scan, remove the Sensor you are wearing and apply a new one after the appointment. The effect of these types of procedures on the performance of the system has not been evaluated.
- » The FreeStyle Libre Flash Glucose Monitoring System has not been evaluated for use in pregnant women, persons on dialysis, or people less than 4 years of age.