PRODUCT MONOGRAPH

FreeStyle Libre

Flash Continuous Glucose Monitor (CGM)

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PART I: HEALTH PROFESSIONAL INFORMATION

SUMMARY PRODUCT INFORMATION

Subdermal continuous glucose monitoring system

DESCRIPTION

The FreeStyle Libre system is a continuous glucose monitoring system designed specifically to eliminate routine fingersticks in measuring blood glucose levels. The system includes a sensor worn in the upper arm and a handheld reader. It is intended for patients 18 and older.

INDICATIONS AND CLINICAL USE

For the monitoring of blood glucose levels in diabetes mellitus patients. The FreeStyle Libre system is intended to provide accurate glucose measurements to enable the calculation of appropriate insulin dosages. The system is also used to track glucose patterns to better prevent hypoglycemic and hyperglycemic occurrences, and enable medical professionals to make both immediate and long-term adjustments to patient therapies. The system is prescription-only and is meant for single-patient use.

CONTRAINDICATIONS

The FreeStyle Libre system is contraindicated in patients who are allergic to the sensor filament.

The FreeStyle Libre Flash Glucose Monitoring System must be removed prior to X-Rays, Magnetic Resonance Imaging (MRI), Computed Tomography (CT) scan, or high-frequency electrical heat (diathermy) treatment.
The effects of these events on system performance has not been evaluated. The exposure may damage or impact proper function of the devices, which could cause inaccurate glucose readings.

WARNINGS AND PRECAUTIONS

Ignoring symptoms of hyperglycemia or hypoglycemia is dangerous. Do not ignore symptoms even if sensor readings are in target. Verify with a fingerstick using blood glucose meter if you are unsure, and treat as directed by your designated health care professional.

Perform a finger stick test in the following situations and conditions, and do not rely on the sensor readings:

If you have symptoms of hyperglycemia or hypoglycemia.
If your symptoms do not correlate appropriately with FreeStyle sensor readings.
If your blood sugar is changing quickly (>2 mg/dL per minute). The sensor may be less accurate during these times, as interstitial fluid glucose—which the sensor measures—has a delay compared with capillary blood glucose. Rapid glucose changes may occur after meals, boluses, or exercise.
If the sensor display does not indicate a Current Glucose number or a Trend Arrow.
If you see the Check Blood Glucose symbol. This means the sensor may not be accurate enough to make a treatment decision.

Hypoglycemic Unawareness:
The FreeStyle Libre system has not been assessed for use by individuals with hypoglycemic unawareness. It will not alert you, and you may not scan the sensor early enough to prevent a surprise hypoglycemic event.

Choking Hazard:
The FreeStyle Libre System has small parts that can be harmful if swallowed. Keep the system and its components away from small children and pets.

Alarms:
There are NO alarms or alerts for either low or high blood sugars. The system will not alert the user of glucose events without performing a sensor scan. This can be especially problematic for patients with hypoglycemia unawareness.

The following people should NOT use the FreeStyle Libre CGM system:

Patients under 18 year old. The system has not been evaluated or approved for this age range, and CGMs are typically less accurate in minors than adults.
Patients who are critically ill. Sensor readings may be inaccurate, and the effects of these patients' conditions and treatments on the system have not been documented.
Pregnant women, dialysis patients, and patients with other implanted medical devices, sch as pacemakers. The system has not been evaluated in these populations.

STORAGE AND HANDLING

The sensors should be stored between 39°F and 77°F (3.8°C and 25°C), and avoid freezing. Store the sensors in 10-90% non-condensing humidity.

PART II: SCIENTIFIC INFORMATION

CLINICAL TRIAL

Seventy-two of the 75 clinical trial participants are included in the study results.

Sensor data was collected for 99.2% (25,834/26,045) of total sensor scans. A total of 13,195 BG reference tests were matched with sensor results.

Twenty-eight pairs were excluded because the reference glucose result was outside the BG system's range of 20–500 mg/dL, and 114 pairs were excluded because the sensor result was outside the FreeStyle Libre system's range of 40–500 mg/dL.

Continuous glucose versus venous reference showed 96.5% (11,232/11,640) of the data was clinically accurate, and an additional 2.4% (274/11,640) were benign errors.

Sensor results were highly correlated with capillary BG. There was no significant variation in sensor sensitivity between left- or right-arm insertion sites.

Performance of the System was stable across 14 days of wear after the first day. The percentage of readings within Consensus Error Grid Zone A (BG reference) after averaging Days 2, 7, and 14 was 81.45.

After insertion, the mean time to initial glucose results was 61 min (n=168). All sensors provided interstitial glucose results within 70 min after insertion.

Factors like body mass index (BMI), age, type of diabetes, insulin administration, or hemoglobin A1c did not affect the accuracy of the sensors.

On Days 1 and 15, participants completed a study questionnaire and rated their experience with the FreeStyle Libre system on a scale of 0 (strongly agree) to 4 (strongly disagree) in several subjective categories.
On Day 1, the questionnaire included seven statements about usability, pain when compared to traditional fingersticks, packaging information, and pain or bleeding during sensor application.
On Day 15, the questionnaire included nine statements about the comfort of wearing the sensor, ease of wearing the sensor, if the sensor affected performing daily activities, pain when compared to traditional fingersticks, ease compared to traditional fingersticks, and erythema or edema (redness or fluid buildup) after removing the sensor.
Scores of 0, 1, or 2 were considered positive statements.
At Day 1, most participants (≥97.2%) reported positive responses in all seven statements.
At Day 15 the majority of respondents (≥94.4%) reported positive responses for all nine statements.