User Support Information

FreeStyle Libre 3 Plus Sensor

The FreeStyle Libre 3 Plus Sensor is authorized to work with partner systems. For more details, go to www.diabetescare.abbott/support/partnerships.html.

WARNING: Do not ignore symptoms that may be due to low or high blood glucose. If you have symptoms that do not match the sensor glucose 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.

Cautions and Important System Information

What the System has not been evaluated for:

- The sensor has not been evaluated for use with other implanted medical devices such as pacemakers.
- The sensor has not been evaluated for use in persons on dialysis.
- The sensor has not been evaluated for use with critically ill patients.
- The sensor has not been evaluated for use in persons less than 2 years of age.

Traveling by Air

You may use your sensor while on an aircraft, following any requests from the flight crew.

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

Sensor Specifications

Sensor glucose assay method: Amperometric electrochemical sensor
Sensor glucose reading range: 2.2 to 27.8 mmol/L (40 to 500 mg/dL)
Sensor size: 2.9 mm height and 21 mm diameter
Sensor weight: 1 gram
Sensor power source: One silver oxide battery
Sensor life and sensor memory: Up to 15 days (glucose readings stored every 5 minutes)
Operating temperature: 10°C to 45°C
Operating and storage relative humidity: 10-90%, non-condensing
Operating and storage altitude: -381 meters (-1,250 ft) to 3,048 meters (10,000 ft)
Radio Frequency: 2.402-2.480 GHz BLE; GFSK; 4.6 dBm EIRP

Electromagnetic Compatibility

Guidance and Manufacturer's Declaration – Electromagnetic Emissions
The sensor is intended for use in the electromagnetic environment specified in the following table. The customer or the user of the sensor should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	The sensor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The sensor is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity
The sensor is intended for use in the electromagnetic environment specified in the following table. The customer or the user of the sensor should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Power frequency (50/60 Hz); magnetic field; IEC 61000-4-8	30 A/m; 50 Hz or 60 Hz	30 A/m; 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical domestic, commercial, or hospital environment.
Radiated RF; IEC 61000-4-3	10 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz	10 V/m 80 MHz - 2.7 GHz 80% AM at 1 kHz	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the System, including cables specified by Abbott Diabetes Care. Otherwise, degradation of the performance of the System could result.
Proximity fields from RF wireless communications equipment IEC 61000-4-3	See following table	Compliance to the tested levels	

The table below lists the immunity levels at specific test frequencies for testing the effects of some wireless communications equipment. The frequencies and services listed in the table are representative examples in healthcare and various locations where the System may be used.

Test Frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
385	380 – 390	TETRA 400	Pulse modulation [b] 18 Hz	1.8	0.3	27
450	430 – 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0.2	0.3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0.3	28
870						
930						
1720	1700 – 1990	SM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0.3	28
1845						
1970						
2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0.3	28
5240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	0.3	9
5500						
5785						

[a] For some services, only the uplink frequencies are included.
[b] The carrier shall be modulated using a 50% duty cycle square wave signal.
[c] As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used, because while it does not represent actual modulation, it would be worst case.

Performance Characteristics: FreeStyle Libre 3 Plus Sensor

Note: Please consult your health care team on how to use this information.

Study Overview
We ran a controlled clinical study at seven centers to evaluate sensor performance. It included 285 subjects with diabetes. Each wore up to two sensors on the back of the upper arm. Subjects ages 6 and older came to a center up to 3 times to have their venous blood glucose tested. This was done with a YSI* analyzer. The youngest subjects (ages 2-5) were tested with a blood glucose meter.
* Yellow Springs Instrument Life Sciences 2300 STAT Plus™.

How to Understand the Data
We can tell how accurate the sensor is by comparing sensor readings to the reference blood glucose values. The tables below show the percentage of sensor readings that were within 20 mg/dL (1.1 mmol/L) or 20% of the reference.

Note: Relative difference (%) is used for values ≥80 mg/dL (4.4 mmol/L). The difference in mg/dL (mmol/L) is used for values below this.

What is MARD?
MARD stands for Mean Absolute Relative Difference. This is the average difference (%) between the sensor readings and the reference. A lower percent indicates that sensor readings are closer to blood glucose values.

Table 1. Overall Accuracy vs. Reference

Subject Group	Number of CGM – Reference Pairs	Number of Subjects	Percent Within ±20% / ±20 mg/dL (±1.1 mmol/L)	MARD (%) (Mean Absolute Relative Difference)
Overall*	27694	273	94.2%	8.2%
Adults	20619	149	94.2%	8.2%
Children (age 6-17)	7075	124	94.0%	8.1%
Children (age 2-5)†	477	12	86.6%	11.2%

* Includes only YSI data.
† No YSI data was obtained for ages 2-5. Sensor results were compared to blood glucose test data.

Table 2. Accuracy of Results vs. Reference

Subject Group	Glucose Concentrations <80 mg/dL (4.4 mmol/L) Within ±20 mg/dL (±1.1 mmol/L)	Glucose Concentrations ≥80 mg/dL (4.4 mmol/L) Within ±20%
Overall	97.9%	93.2%
Adults	97.9%	93.2%
Children (age 6-17)	97.6%	93.3%

Table 3. Accuracy Over the Wear vs. Reference

Subject Group	MARD (%) (Mean Absolute Relative Difference)			
	Beginning (days 1-3)	Early Middle (days 5-7)	Late Middle (days 9-11)	End (days 13-15)
Overall	9.7%	7.1%	7.5%	8.2%
Adults	10.0%	7.2%	7.7%	7.8%
Children (age 6-17)	9.0%	6.8%	6.9%	10.4%

Adverse Events
There were no device related serious adverse events. A small number of subjects (14 out of 293 or 4.8%) reported mild skin irritations at the sensor site. These included:

- Redness (16 instances)
- Bruising (3 instances)
- Rash (3 instances)

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