



FreeStyle
Libre Pro
FLASH GLUCOSE MONITORING SYSTEM

The FreeStyle Libre Pro System: A clinical overview of accuracy



Evaluating the accuracy of the FreeStyle Libre Pro System¹⁻³

Study overview

A multicenter, prospective study evaluated the accuracy of the FreeStyle Libre Pro system, a factory calibrated continuous glucose monitoring (CGM) device, compared to fingerstick capillary samples and venous blood glucose measurements.

Study population

- 72 patients (18 and older) at 4 centers*

Demographic	% (n) by subtype	
Sex	Female: 50% (36)	Male: 50% (36)
Race	White: 90.3% (65) Asian: 2.8% (2)	Black/African American: 2.8% (2) Other†: 4.2% (3)
Type of diabetes	Type 1: 81.9% (59)	Type 2: 18.1% (13)
Insulin pump use	Yes: 54.2% (39)	No: 45.8% (33)

*All patients were using insulin pump or multiple daily injections for at least 6 months prior to enrollment.

†Race was reported as “Black or African, White” by 1 patient and “Hispanic” by 2 patients.

Blood glucose measurements

- Patients wore 2 sensors on the back of each upper arm for 14 days. Blood glucose was also measured using FreeStyle Precision meter (BG) and Yellow Spring Instrument (YSI) references
 - No fingerstick calibration was required for the reader
 - >12,000 results paired with both BG and YSI references

	Day 1	Day 14
Measurements	Sensor	Automatically captured interstitial glucose data every 15 minutes
	BG	8 capillary BG tests per day (Preferably upon waking, before each meal, an hour after each meal, and at bedtime)
	YSI	3 scheduled in-clinic visits (Venous blood samples were collected every 15 minutes over an 8-hour period)

Evaluations included

- Percent of results within YSI reference
 - YSI is the recognized standard for laboratory analysis of blood glucose
- Mean absolute relative difference (MARD)
 - Average relative error of all sensor readings
- Consensus Error Grid analysis
 - Evaluates sensor readings in regard to clinically accurate treatment decisions

The FreeStyle Libre Pro System delivers clinically proven accuracy¹⁻³

Mean absolute relative difference (MARD) demonstrates agreement between the FreeStyle Libre Pro system and YSI

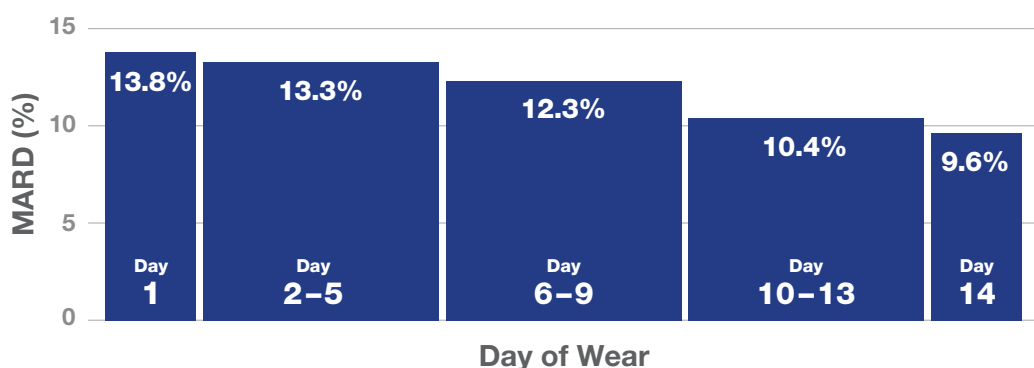
Reference glucose level (mg/dL)	YSI reference		
	# of FreeStyle Libre Pro system reference pairs	Median absolute relative difference (%)	Mean absolute relative difference (%)
Overall	12323	10.1	12.3
40–50 [†]	30	14.2	15.8
51–80 [†]	505	12.5	15.5
81–180	7373	10.7	12.9
181–300	4115	8.7	10.1
301–400	286	7.8	8.8
401–500	14	4.2	7.2

[†]For reference values ≤ 80 mg/dL, the mean and median absolute differences (mg/dL) are presented instead of mean and median absolute relative differences (%).

Accuracy was measured by comparing the absolute relative difference, which measures the average percent disagreement between the FreeStyle Libre Pro system and YSI reference.

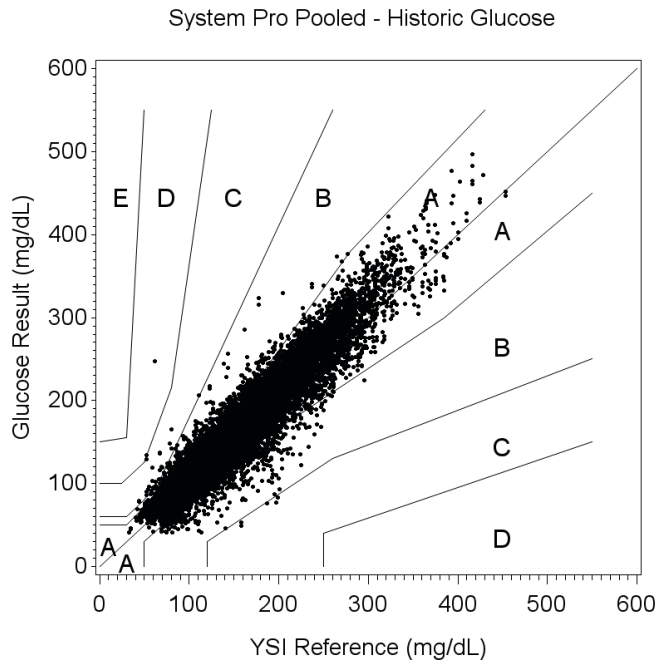
- Median absolute relative difference showed that half of the time the FreeStyle Libre Pro system was within 10.1% of YSI
- MARD, which indicates the average percent disagreement between the FreeStyle Libre Pro system and YSI, was low at 12.3%

MARD was stable over the 14-day wear period



99.9% of glucose results were in Zones A and B of the Consensus Error Grid^{2,3}

With the FreeStyle Libre Pro system, there was a high degree of agreement between sensor readings and YSI reference



Consensus Error Grid is a tool for evaluating accuracy and can be useful for assessing clinical performance. CGM errors are translated into the potential clinical consequences of the errors. Data are plotted vs YSI reference in the scatterplot, and the error grid is divided into zones, with Zone A representing the greatest accuracy:

Zone A: No effect on clinical action (considered clinically accurate)

Zone B: Altered clinical action, but no or little effect on clinical outcome

Zone C: Altered clinical action—likely to affect clinical outcome

Zone D: Altered clinical action—could have significant medical risk

Zone E: Altered clinical action—could have dangerous consequences

- 99.9% of glucose results were in Zones A and B, 89.6% of glucose results were in Zone A

Study results showed a high percentage of sensor readings were within $\pm 20\%$ of the YSI reference[§]

YSI glucose level (mg/dL)	# of FreeStyle Libre Pro system reference pairs	Within $\pm 15\%$ / ± 15 mg/dL	Within $\pm 20\%$ / ± 20 mg/dL	Within $\pm 30\%$ / ± 30 mg/dL	Within $\pm 40\%$ / ± 40 mg/dL	Outside $\pm 40\%$ / ± 40 mg/dL
Overall	12323	71.8	83.8	95.2	98.5	1.5
40–50	30	53.3	83.3	93.3	100.0	0.0
51–80	505	58.4	73.3	89.1	96.0	4.0
81–180	7373	68.3	80.2	93.7	98.0	2.0
181–300	4115	79.0	90.4	98.3	99.5	0.5
301–400	286	84.6	96.5	99.7	100.0	0.0
401–500	14	85.7	100.0	100.0	100.0	0.0

[§]The results of the clinical study conducted for this device showed that 40% of the time when the device indicated that user sensor glucose values were at or below 60 mg/dL, user glucose values were actually in the range of 81–160 mg/dL.

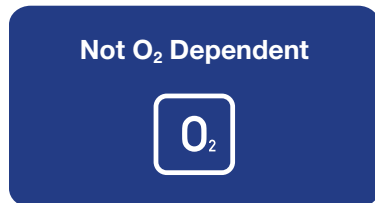
The FreeStyle Libre Pro System is the only CGM system with a factory calibrated sensor platform

Unique Wired Enzyme technology and proprietary manufacturing process to ensure accurate, stable, and consistent glucose readings



- A stable signal, with minimal sensor drift over time⁴
 - Sensor is calibrated in the factory—no further user calibrations required to maintain accuracy
- Other CGM systems may require the patient to perform regular fingerstick calibrations (2 or more a day) to compensate for sensor drift

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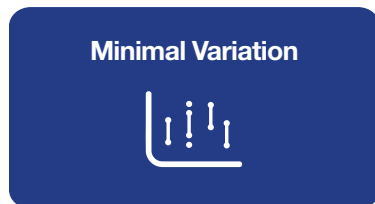
- Osmium mediator is used for transferring electrons from the enzymes to the electrode
- Other CGM sensors use oxygen to transfer the electrons from the enzyme to the electrode

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- A low measurement potential for osmium mediator decreases the chance of picking up electrons from other electrochemically active substances, such as acetaminophen and uric acid
- Other CGM systems, dependent on hydrogen peroxide, require a higher measurement potential
 - Can pick up electrons from electrochemically active substances, resulting in less accurate glucose readings

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- Manufactured with minimal sensor-to-sensor variation
 - A study and validation testing showed there was no difference in the average sensor sensitivity between subjects (n=28, $P=0.069$)⁴
 - Sensor response is stable over a 14-day wear period

The FreeStyle Libre Pro System is clinically proven to be accurate¹⁻³

The FreeStyle Libre Pro system offers:

- Accuracy, stability, and consistency over 14 days to reveal hidden glucose patterns and trends
- Small and discreet sensor
- One reader device starts multiple patients



Consider the FreeStyle Libre Pro System
for more of your patients with diabetes
Learn more at www.FreeStyleLibrePro.us

Indications and Important Safety Information

The FreeStyle Libre Pro Flash Glucose Monitoring System is a professional continuous glucose monitoring (CGM) device indicated for detecting trends and tracking patterns and glucose level excursions above or below the desired range, facilitating therapy adjustments in persons (age 18 and older) with diabetes. The system is intended for use by health care professionals and requires a prescription.

IMPORTANT: The device may inaccurately indicate hypoglycemia. The results of the clinical study conducted for this device showed that 40% of the time when the device indicated that user sensor glucose values were at or below 60 mg/dL, user glucose values were actually in the range of 81–160 mg/dL. Therefore, interpretation of the FreeStyle Libre Pro Flash Glucose Monitoring System readings should only be based on the trends and patterns analyzed through time using the reports available per the intended use.

CONTRAINDICATIONS: Remove the Sensor before MRI, CT scan, X-ray, or diathermy treatment. **WARNINGS/LIMITATIONS:** The FreeStyle Libre Pro system does not provide real-time results and patients should adhere to their blood glucose monitoring routine while using the system. If a sensor breaks, contact physician and call Customer Service. Patients with high levels of ascorbic acid (Vitamin C) or salicylic acid (used in Aspirin) or severe dehydration or excessive water loss or medications containing acetaminophen (Tylenol) may experience inaccurate results with this system. The FreeStyle Libre Pro system is not approved for pregnant women, persons on dialysis, or recommended for critically ill population. Sensor placement is not approved for sites other than the back of the arm and standard precautions for transmission of blood borne pathogens should be taken.

Review all product information before use or contact Abbott toll-free (855-632-5297) or visit www.FreeStyleLibrePro.us for detailed indications for use and safety information.

References: 1. FreeStyle Libre Pro Operator's Manual. 2. Bailey T, Bode BW, Christiansen MP, Klaff LJ, Alva S. The performance and usability of a factory-calibrated flash glucose monitoring system. *Diabetes Technol Ther.* 2015;17:787-794. 3. Data on file. Abbott Diabetes Care.

4. Hoss U, Budiman ES, Liu H, Christiansen MP. Feasibility of factory calibration for subcutaneous glucose sensors in subjects with diabetes. *J Diabetes Sci Technol.* 2014;8:89-94.

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