

FreeStyle offers the accuracy advantage

Accuracy of Four Blood Glucose Monitoring Systems

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Background: The minimum acceptable accuracy for results produced by a blood glucose monitoring system according to the current version of ISO 15197, created in 2002, is 95% of the individual glucose results shall fall within ± 15 mg/dL (± 85 mmol/L) of the results of the manufacturer's measurement procedure at glucose concentrations < 75 mg/dL (< 4.2 mmol/L) and within $\pm 20\%$ at glucose concentrations > 75 mg/dL (> 4.2 mmol/L). The ISO Standard is undergoing revision and tighter accuracy requirements are expected. In this report, we compare the accuracy of four latest models of blood glucose monitoring systems using the current standard and tighter criteria.

Methods: Accuracy of the four blood glucose monitoring systems for fingertip capillary blood testing was assessed at a diabetes clinic. A total of 100 diabetic subjects were included in the study. At the study site, the trained operator tested the subject's fingertip blood with the four systems and a YSI glucose analyzer, which served as the reference. Accuracy was evaluated using ISO 15197:2003, and by calculating the percentage of meter results falling within $\pm 15\%$, $\pm 10\%$ and $\pm 5\%$ of the reference value for glucose concentrations 100 mg/dL (5.6 mmol/L) or higher, and within ± 15 and ± 15 mg/dL (± 0.8 mmol/L), ± 0.28 , ± 0.56 and ± 0.85 mmol/L of the reference value for glucose concentrations below 100 mg/dL (< 5.6 mmol/L).

Results: All four blood glucose monitoring systems in this study met the minimum acceptable accuracy required by ISO 15197:2003. When evaluated with tighter accuracy criteria, the FreeStyle Freedom Lite[®] system had 99.7% of its results agreeing within $\pm 15\%$ of the reference, and 98.0% of the results agreeing with $\pm 10\%$ of the reference—a performance significantly ($p<0.001$) better than those of OneTouch[®] Ultra[®]2 and AccuChek[®] Contour[®]. The FreeStyle Freedom Lite system had 72.3% of its results agreeing within $\pm 5\%$ of the reference, significantly ($p<0.0001$) better than the Contour, OneTouch Ultra2 and AccuChek[®] Aviva.

Conclusions: Of the four latest models of blood glucose monitoring systems evaluated, the FreeStyle Freedom Lite system showed the highest level of accuracy. More accurate glucose results may help patients maintain their blood glucose levels with a higher degree of accuracy, and the more accurate glucose monitoring systems are more likely to meet any new ISO Standard and local regulatory requirements.

As much you might like to, you can't control how strictly your patients with diabetes stick to their diet and exercise plans. But you can ensure more accurate blood glucose monitoring with the FreeStyle meter. In a recent study evaluating the four latest models of blood glucose monitoring systems, the FreeStyle Freedom Lite system showed the highest level of accuracy.¹

See inside how our accurate monitors can help better manage your patients' glucose.



1360 South Loop Road
Alameda, CA 94502

Look inside to see how well our glucose meters measure up.



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Are your patients using the most accurate meter?

Study shows FreeStyle on top versus three leading meters.

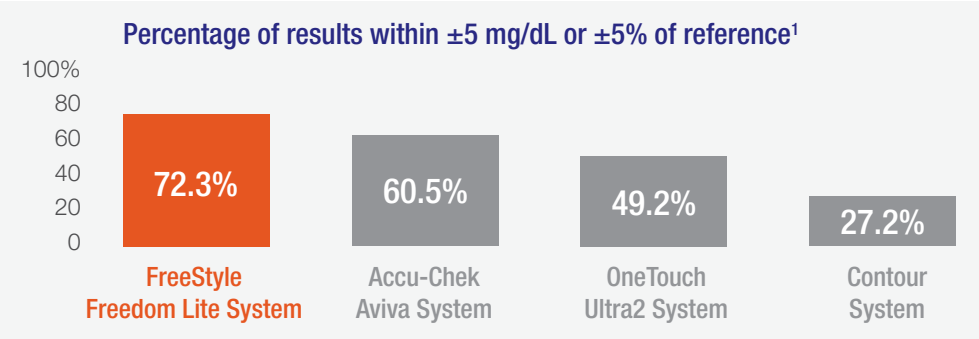
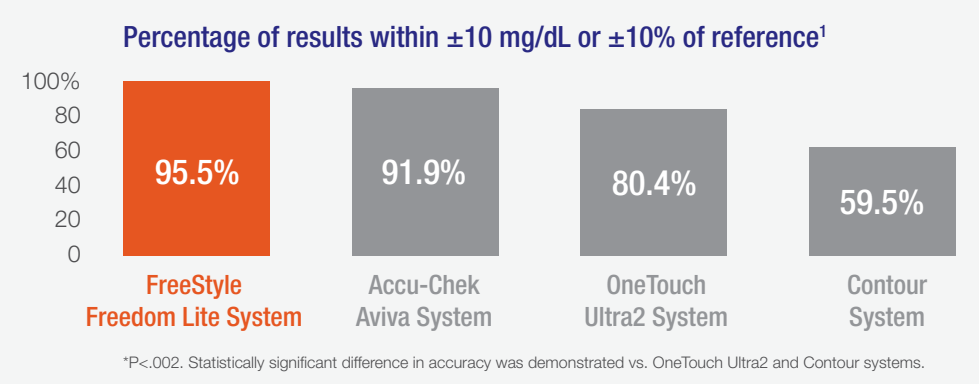


FreeStyle



Choose FreeStyle

Greater Accuracy Compared with OneTouch Ultra2, Accu-Chek Aviva, and Contour Systems¹



For In Vitro Diagnostic Use.

FreeStyle Lite blood glucose test strips are intended to be used with FreeStyle Lite and FreeStyle Freedom Lite meters only.

1. Study conducted in October-November 2009. Data on file, Abbott Diabetes Care Inc. Study results show: (a) the FreeStyle Freedom Lite system (meter and FreeStyle Lite test strips with ZipWik tabs) had 72.3% of the results within $\pm 5\%$ of the reference value, or ± 5 mg/dL at glucose concentrations below 100 mg/dL, significantly ($p < 0.002$) more than Accu-Chek Aviva system (60.5%), OneTouch Ultra2 system with OneTouch Ultra Blue test strip (49.2%) and Contour system (27.2%); and (b) the four systems were similar in accuracy when based on percentage of meter results within $\pm 20\%$ of the reference value at ≥ 75 mg/dL, or ± 15 mg/dL at glucose concentrations below 75 mg/dL, the current standard used by the U.S. Food and Drug Administration (FDA). Per ISO 15197, all comparisons were made by trained operators using fingertip samples for both test meters and the reference. The FreeStyle Freedom Lite and FreeStyle Lite meters, using GDH-FAD based FreeStyle Lite test strips, were cleared together by the FDA and share performance specifications including accuracy; these two meters use the same coulometric biosensor technology to measure glucose.

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Features, accuracy, and support your patients can count on

FreeStyle Lite Meter

Small and fast for testing on-the-go



FreeStyle Freedom Lite Meter

Simplicity and accuracy in an easy-to-hold, easy-to-read meter



Both meters work with FreeStyle Lite test strips.

- Easy to use
- Proven accuracy
- Fewer wasted test strips²

2. Versus OneTouch Ultra2 and Contour. Study conducted in October–November 2008. Data on file, Abbott Diabetes Care Inc. Home use study among lay user diabetic subjects who routinely monitored blood glucose at home but had no prior experience with any of the study meters. Subjects used both the FreeStyle Freedom Lite meter with ZipWik tab strips and their current system and tested with each system at least 4 times/day for 7 days; subjects during separate week used the LifeScan OneTouch Ultra2 meter with Ultra test strips or the Bayer Contour system, plus their current system, and tested with each system at least 4 times/day. Claims based on subject-recorded strip usage.

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The FreeStyle Promise Program

A free membership program that provides your patients with knowledge and support to help them better manage their diabetes:

- Ongoing co-pay savings on test strips³
- A free Certified Diabetes Educator helpline⁴
- Free meter and battery replacements⁵
- 24/7 tech support



Co-pay assistance is not valid for prescriptions reimbursed under Medicare, Medicaid, or similar federal or state programs or in Massachusetts. Eligible patients are responsible for the first \$15 of each co-pay under their insurance coverage; patients on high co-pay plans may have additional responsibility. Uninsured patients are also eligible in most situations. Void where prohibited. Abbott can modify or rescind this offer without notice.

3. Residents of Massachusetts and Medicare or Medicaid beneficiaries (including beneficiaries of Medicare Advantage, Part D, or managed Medicaid plans) are not eligible for co-pay assistance. Eligible patients are responsible for a co-pay equal to the amount of the co-pay for the "preferred" glucose test strips under their insurance plan. A prescription is required in order to redeem co-pay savings. Eligible patients may redeem savings every 25 days. Cash paying patients are also eligible for savings in most cases. Void where prohibited. Abbott may modify or rescind this offer without notice.

4. The information provided by the team of Diabetes Educators is for general background purposes and is not intended as a substitute for medical diagnosis or treatment by a trained professional. You should always consult your physician about any healthcare questions you may have, especially before trying a new medication, diet, fitness program, or approach to healthcare issues.

5. Product provided as a free sample shall not be resold or submitted to any third-party payer for reimbursement. Meter replacement requires enrollment in FreeStyle Promise program and use of patient's Abbott-brand meter for at least three years. Choice of replacement meter made by Abbott. Void where prohibited. Abbott may modify or rescind this offer without notice.

