The Impact of Blood Glucose Monitoring System Accuracy on Diabetes Management

KEY POINTS:

- For people with diabetes, the ability to maintain their blood glucose within a predefined range depends in part on their ability to obtain accurate readings of their glucose levels.[1]
- Blood glucose monitor readings are utilized to detect hypoglycemia and hyperglycemia, titrate insulin doses, calibrate continuous glucose monitoring devices, and adjust diet and exercise.[2]
- The American Diabetes Association considers self-monitoring of blood glucose to be an integral part of diabetes management for patients with both Type 1 and Type 2 diabetes.[2]

The accuracy of blood glucose measurements depends on both the blood glucose monitoring system (BGMS) and the user. Although many patients and their health care providers assume all BGMS are equally accurate, substantial differences in accuracy exist between and within brands. Both clinicians and their patients may be unaware of these differences.[1]

Current industry standards proposed by the International Organization for Standardization (ISO) in 2013 state that BGMS accuracy must be within ±15% of the reference measurement for samples with glucose concentrations ≥100 mg/dL, and ±15 mg/dL when glucose concentrations are <100 mg/dL.[3] The Food and Drug Administration's (FDA's) 2014 draft guidance states that 95% of results should be within ±15% and 99% of results within ±20% of reference values across the entire glycemic range.[4] Currently there may be meters still on the market with only a ±20% level of accuracy, as allowed per ISO's 2003 standards.[5] The 2003 standards were recognized by the FDA until January 2014.[4]

At ±20%, a single blood sample could potentially provide a fairly broad range of blood glucose readings. For example, an actual blood glucose level (that is, the reading that would be obtained under ideal laboratory conditions) of 360 mg/dL could appear as low as 288 mg/dL using a meter with -20% error margin, and as high as 432 mg/dL at an error margin of +20%. Therefore, a ±20% margin of error could potentially lead a patient to take the wrong course of action to correct his/her blood sugar.[6]

Research has demonstrated that the higher the margin of error of the BGMS, the greater the predicted risk that hypoglycemic events could be missed—and thus inadequately treated. For example, fewer than 1 in 100 hypoglycemic events may be missed via self-monitoring of blood glucose at 10% system error level.[6] At 15% system error level, the predicted risk increases 4-fold, to 4 in 100 hypoglycemic events missed, and when the system error increases to 20%, the predicted risk of missing a hypoglycemic event rises sharply, to 1 in 10.[6]

References:

1. Walsh J, Roberts R, Vigersky RA, et al. New criteria for assessing the accuracy of blood glucose monitors meeting, October 28, 2011. *J Diabetes Sci Technol.* 2012;6(2):466-474. **2.** American Diabetes Association. Standards of medical care in diabetes—2015. Diabetes Care. 2015;38(suppl 1):S1-S92. **3.** International Organization for Standardization. In vitro diagnostic test systems—requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus. ISO 15197:2013. Geneva: International Organization for Standardization; 2013. **4.** Food and Drug Administration. Self-monitoring blood glucose test systems for over-the-counter use. Draft guidance for industry and Food and Drug Administration staff. Available from http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM380327.pdf. Accessed February 22, 2016. **5.** ISO. In vitro diagnostic test systems—requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus. ISO 15197:2003. Geneva: International Organization for Standardization; 2003. **6.** Breton MD, Kovatchev BP. Impact of blood glucose self-monitoring errors on glucose variability, risk for hypoglycemia, and average glucose control in type 1 diabetes: an *in silico* study. *J Diabetes Sci Technol*. 2010;4(3):562-570. **7.** Bernstein R, Parkes JL, Goldy A, et al. A new test strip technology platform for self-monitoring of blood glucose. *J Diabetes Sci Technol.* 2013;7(5):1386-1399. **8.** Harrison B, Dunne N. Accuracy and precision evaluation of the CONTOUR®NEXT blood glucose monitoring system. Poster presented at: 12th Annual Meeting of the Diabetes Technology Society; November 8-10, 2012; Bethesda, MD. **9.** Harrison B, Brown D, Warchal-Windham ME, et al. Accuracy evaluation of a new platform of blood glucose monitoring systems with the CONTOUR®NEXT test strip. Poster presented at: 12th Annual Meeting of the Diabetes Technology Society; November 8-10, 2012; Bethesda, MD. **10.** Simmons DA. How should blood glucose meter system analytical performance be assessed? *J Diabetes Sci Technol.* 2015;10(1):178-184.

The CONTOUR®NEXT Meter Portfolio: Accuracy You Can Trust

The CONTOUR®NEXT meter portfolio has demonstrated **highly accurate** blood glucose results within 10% of laboratory reference values.[7-9]

	Blood glucose (BG) concentrations	Percentage of BG readings within specified error limits of ±15 mg/dL or ±15%	Percentage of BG readings within specified error limits of ±10 mg/dL or ±10%
 Contour next EZ	<100 mg/dL	100%	98.4%
	≥100 mg/dL	100%	99.5%
 Contour next	<100 mg/dL	100%	99.4%
	≥100 mg/dL	99.8%	98.1%
 Contour next USB	<100 mg/dL	100%	100%
	≥100 mg/dL	100%	98.1%
 Contour next link	<100 mg/dL	100%	99.5%
	≥100 mg/dL	100%	99.5%

Radar plots, such as the one for the CONTOUR®NEXT meter pictured in Figure 1 on the right, are a new method of visualizing the accuracy and precision of a BGMS.[10] Radar plots include multiple representations of analytical performance—accuracy (in terms of average error and based on ISO criteria[3]) and precision (consistency of readings)—in a single graphic.[10] Although other types of data plots may provide some of the same information, radar plots simplify the presentation of BGMS performance. Because a radar plot resembles a target, a tight clustering of data points in the center of the plot intuitively represents higher accuracy and precision.[10]

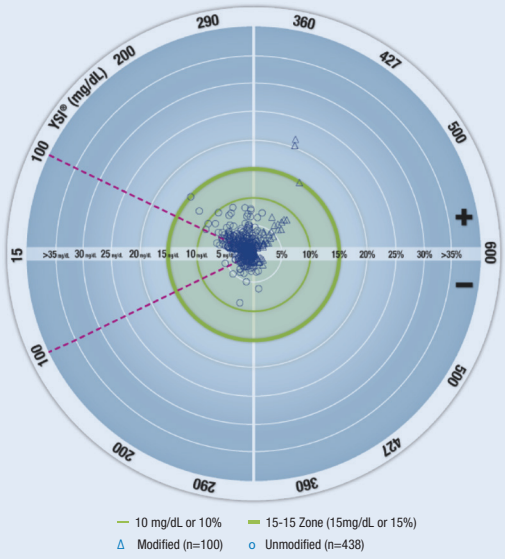
In addition to accuracy, all CONTOUR®NEXT portfolio meters offer the same easy-to-use features:

- Second-Chance™ sampling, which allows patients to apply more blood to help prevent wasted test strips and save money
- No Coding™ technology, which eliminates errors due to user miscoding
- Fast test time (5-second countdown)
- Small blood sample (0.6 µL)

All CONTOUR®NEXT meters use the same CONTOUR®NEXT test strip.

Figure 1.

CONTOUR®NEXT Meter Radar Plot



Each data point on the radar plot represents the error of a meter system result. The distance from the center of the plot to a data point indicates the magnitude of the meter system error. The direction of a line connecting the point to the center indicates the value of the laboratory reference measurement. When the point is above the horizontal midline, the error is positive (that is, the meter overestimated the laboratory reference blood glucose value). If the point is below the horizontal midline, the error is negative (that is, the meter underestimated the laboratory reference blood glucose value).[10]

This radar plot demonstrates the tight correlation between laboratory values and values obtained using the CONTOUR®NEXT blood glucose monitoring system.

The company that brings you CONTOUR®NEXT products has a new name. Introducing Ascensia Diabetes Care.

Established in 2016 through the acquisition of Bayer Diabetes Care by Panasonic Healthcare Holdings, Ascensia Diabetes Care is a global company dedicated to improving the health and lives of people with diabetes. Already including the world renowned CONTOUR® range of blood glucose monitoring systems, we are committed to adding more innovative and life-changing products to our portfolio.

For more information, go to www.contournextpro.com

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