

Accuracy in Blood Glucose Measurement: What Will a Tightening of Requirements Yield?

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Abstract

Nowadays, almost all persons with diabetes—at least those using antidiabetic drug therapy—use one of a plethora of meters commercially available for self-monitoring of blood glucose. The accuracy of blood glucose (BG) measurement using these meters has been presumed to be adequate; that is, the accuracy of these devices was not usually questioned until recently. Health authorities in the United States (Food and Drug Administration) and in other countries are currently endeavoring to tighten the requirements for the accuracy of these meters above the level that is currently stated in the standard ISO 15197. At first glance, this does not appear to be a problem and is hardly worth further consideration, but a closer look reveals a considerable range of critical aspects that will be discussed in this commentary. In summary, one could say that as a result of modern production methods and ongoing technical advances, the demands placed on the quality of measurement results obtained with BG meters can be increased to a certain degree. One should also take into consideration that the system accuracy (which covers many more aspects as the analytical accuracy) required to make correct therapeutical decisions certainly varies for different types of therapy. At the end, in addition to analytical accuracy, thorough and systematic training of patients and regular refresher training is important to minimize errors. Only under such circumstances will patients make appropriate therapeutic interventions to optimize and maintain metabolic control.

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Abbreviations: (BG) blood glucose, (CGM) continuous glucose monitoring, (FDA) Food and Drug Administration, (ICU) intensive care unit, (ISO) International Organization for Standardization, (PD) percentage difference, (SMBG) self-monitoring of blood glucose, (TSA) total system accuracy

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