

## New Criteria for Assessing the Accuracy of Blood Glucose Monitors Meeting, October 28, 2011

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### Abstract

Glucose meters (GMs) are routinely used for self-monitoring of blood glucose by patients and for point-of-care glucose monitoring by health care providers in outpatient and inpatient settings. Although widely assumed to be accurate, numerous reports of inaccuracies with resulting morbidity and mortality have been noted. Insulin dosing errors based on inaccurate GMs are most critical. On October 28, 2011, the Diabetes Technology Society invited 45 diabetes technology clinicians who were attending the 2011 Diabetes Technology Meeting to participate in a closed-door meeting entitled New Criteria for Assessing the Accuracy of Blood Glucose Monitors. This report reflects the opinions of most of the attendees of that meeting.

The Food and Drug Administration (FDA), the public, and several medical societies are currently in dialogue to establish a new standard for GM accuracy. This update to the FDA standard is driven by improved meter accuracy, technological advances (pumps, bolus calculators, continuous glucose monitors, and insulin pens), reports of hospital and outpatient deaths, consumer complaints about inaccuracy, and research studies showing that several approved GMs failed to meet FDA or International Organization for Standardization standards in post-approval testing. These circumstances mandate a set of new GM standards that appropriately match the GMs' analytical accuracy to the clinical accuracy required for their intended use, as well as ensuring their ongoing accuracy following approval. The attendees of the New Criteria for Assessing the Accuracy of Blood Glucose Monitors meeting proposed a graduated standard and other methods to improve GM performance, which are discussed in this meeting report.

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**Abbreviations:** (AACE) American Association of Clinical Endocrinologists, (ADA) American Diabetes Association, (BG) blood glucose, (CGM) continuous glucose monitoring, (FDA) Food and Drug Administration, (GM) glucose meter, (IGC) intensive glucose control, (ISO) International Organization for Standardization, (SMBG) self-monitoring of blood glucose, (TES) the Endocrine Society

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