

---

# Setting the Bar for Blood Glucose Meter Performance

Posted on [January 9, 2014](#) by [FDA Voice](#)

**By: Courtney Lias**



Many of the nearly 19 million Americans diagnosed with diabetes must monitor their blood glucose (sugar) frequently throughout the day using an at-home meter to make sure that their blood glucose is within a safe range. The ability to measure blood glucose at home has given people with this serious and chronic condition the ability to better control their blood sugar and thus avoid potential complications.

In the last 10 years there has been much advancement in the development of glucose meters. They are now smaller, require a smaller blood sample for each test and produce faster results. However, their accuracy has improved little.

At FDA's public meeting in March 2010 on this topic, the clinical and patient communities challenged the agency to improve performance of glucose meters. Feedback gathered from that meeting directly informed the creation of two draft guidance documents released this week. These documents set forth recommendations, which are justified to help ensure that these important devices are designed to be more accurate and reliable for the patients who need them. To address this need, this week we are proposing new recommendations for labeling, meter performance evaluation, manufacturing controls, and cleaning and disinfection procedures to help improve the accuracy and performance of blood glucose meters.

FDA recognized the need to optimize the safe use of blood glucose meters in two distinct settings: self-monitoring using devices purchased over-the-counter, and use in a clinical setting by health care professionals. FDA believes that by distinguishing where these devices are used, they can be better designed to meet the needs of their intended populations and

ensure greater safety and efficacy.

Historically, devices used in these two settings have been studied using the same methods and standards. However, it has become increasingly clear that meters used in these different settings have unique characteristics and different design specifications. For example, critically ill patients in health care settings may have physiological variables, like abnormal oxygen levels, that could interfere with the accuracy of the blood glucose meter. Patients who use over-the-counter glucose meters and test strips at home vary in age, how much they know about how to use blood glucose tests, and other critical factors that might affect the accurate use of the device.

To distinguish between FDA recommendations for blood glucose meters used in health-care facilities, and those intended for self-monitoring by lay-persons, the agency is issuing separate draft guidances for each one, that is:

- prescription-use blood glucose meters, for use in point-of-care professional health-care settings, and
- blood glucose devices purchased over-the-counter, intended for self-monitoring by lay-persons.

We believe that these recommendations will help ensure that glucose meters meet critical standards for accuracy in the hands of people with diabetes, who rely on them to manage their disease. Please help us in this effort by providing specific comments to these draft guidance documents to let us know if you agree with our recommendations or whether you have suggestions to further improve them.

Improving the quality of blood glucose meters will not solve all challenges for those who live with diabetes, but it may help millions of people to avoid complications and better achieve their health goals.

***Courtney Lias is Director of the Division of Chemistry and Toxicology Devices within the Office of In Vitro Diagnostics and Radiological Devices at FDA's Center for Devices and Radiological Health***



This entry was posted in [Innovation, Medical Devices / Radiation-Emitting Products](#) and tagged [blood](#), [CDRH](#), [Center for Devices and Radiological Health](#), [Courtney Lias](#), [Diabetes](#), [FDA](#), [glucose](#), [glucose meter](#), [medical devices](#), [public meeting](#), [U.S. Food and Drug Administration](#) by [FDA Voice](#). Bookmark the [permalink \[http://blogs.fda.gov/fdavoice/index.php/2014/01/setting-the-bar-for-blood-glucose-meter-performance/\]](http://blogs.fda.gov/fdavoice/index.php/2014/01/setting-the-bar-for-blood-glucose-meter-performance/) .

---