

Blood glucose meter accuracy unclear at low glycemic range

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Photo: U.S. National Kidney and Urologic Diseases Information Clearinghouse

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(HealthDay)—The accuracy of blood glucose meters (BGMs) in the low glycemic range is questionable, according to an observation letter published online July 15 in *Diabetes Care*.

Noting that the U.S. Food and Drug Administration draft guidance for over-the-counter BGMs requires ≥ 95 percent of results within ± 15 percent and ≥ 99 percent of results within ± 20 percent across the whole glycemic range, Lutz Heinemann, Ph.D., from Science & Co. in Düsseldorf, Germany, and colleagues examined whether current BGMs fulfill these criteria. The authors also queried the use of predefined

hypoglycemia thresholds when a BGM cannot reliably differentiate between 50, 60, and 70 mg/dL.

The authors note that these questions are relevant from a safety perspective when patients measure their BG concentration, and are important when BGMs are used in clinical trials. In assessments of current BGMs, considerable differences were seen in performance in the low glucose range. This may explain why the FDA does not accept BG measurement data as evidence for the efficacy of antidiabetic drugs with regard to hypoglycemia reduction. This raises the question of whether BGMs can be used in clinical trials that aim to show a benefit in terms of [hypoglycemia](#) risk.

"We wonder whether, from a clinical point of view, greater interest should be displayed in the performance of BGMs in the low glycemic range," the authors write.

Several authors disclosed financial ties to the pharmaceutical and medical device industries.

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