

COMMENTS AND RESPONSES

Comparison of the Numerical and Clinical Accuracy of Four Continuous Glucose Monitors

Response to Brauker and
Matsubara

In their comments on our assessment of the accuracy of four continuous glucose monitoring (CGM) sensors, Brauker and Matsubara (1) correctly point out that our presented studies employed hyperinsulinemic-euglycemic and hypoglycemic clamps, which tested the four devices (Guardian, DexCom 3-day sensor, Navigator, and Glucoday) close to the limits of their stated glucose range. We agree that such a test goes beyond evaluation of the devices per their intended use under normal therapeutic conditions, and we have never claimed that the performance observed during our study should be directly translated to the field. Our goal was to subject the devices to extreme conditions and to investigate, specifically,

their performance at moderate hypoglycemia (target 2.2 mmol/l), which is of utmost clinical concern when occurring in the field. Testing any technical device at the limits of its performance is a standard engineering practice justified by the fact that devices tend to fail most frequently in extreme situations. Such testing is an established clinical method as well. For example, an exercise stress test or an oral glucose tolerance test reveals conditions that are difficult to recognize during daily life. In that sense, the clamp technique used in our study has provided a unique opportunity to observe the four CGM sensors during highly controlled standardized conditions at the limits of their intended use (2). In addition to the presented parallel assessment of sensor performance, such conditions allow for other analyses shedding light on the physiologic process of blood-to-interstitial glucose diffusion and its influence on sensor calibration and lag time (3). Thus, in parallel with field performance studies, we would advocate the continued use of laboratory assessments such as glucose clamps that test specific parameters of sensor response, which may remain unrecognized in field studies due to their less controlled nature or the infrequent occurrence of critical events.

BORIS KOVATCHEV, PHD¹
STACEY ANDERSON, MD¹

LUTZ HEINEMANN, PHD²
WILLIAM CLARKE, MD¹

From the ¹University of Virginia, Charlottesville, Virginia; and the ²Profil Institute for Metabolic Research, Neuss, Germany.

Corresponding author: Boris Kovatchev, boris@virginia.edu.

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References

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