

Clinical Studies

Glucose monitoring during OGTT

Summary of the Clinical Study

For the performance of Probe's MicroEye[®] device with online sensor to be compared to the current gold-standard approach, blood was withdrawn every 30 minutes from a venous catheter during the baseline period, and every 10 minutes after an Oral Glucose Tolerance Test (OGTT), which started 5 hours into the study. Whole venous blood glucose was measured using an approved reference method (points shown as red dots in Figure 1).

A MicroEye[®] device sitting within a standard blood cannula, connected to an online glucose sensor unit, generated data points every few seconds, using online measurement, without blood loss, manual input or operator manipulation. For comparison, values reported at the time blood was withdrawn are shown below (blue squares) without further correction (i.e. the data is in real-time).

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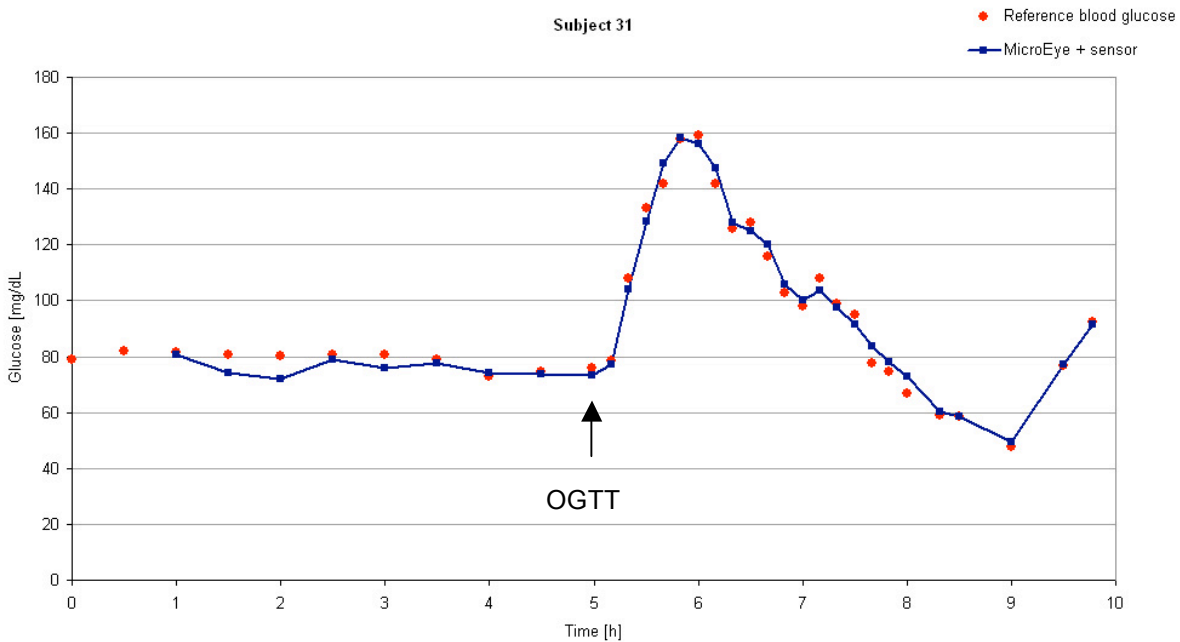


Figure 1 exemplary temporal glucose profile of a healthy volunteer during an OGTT

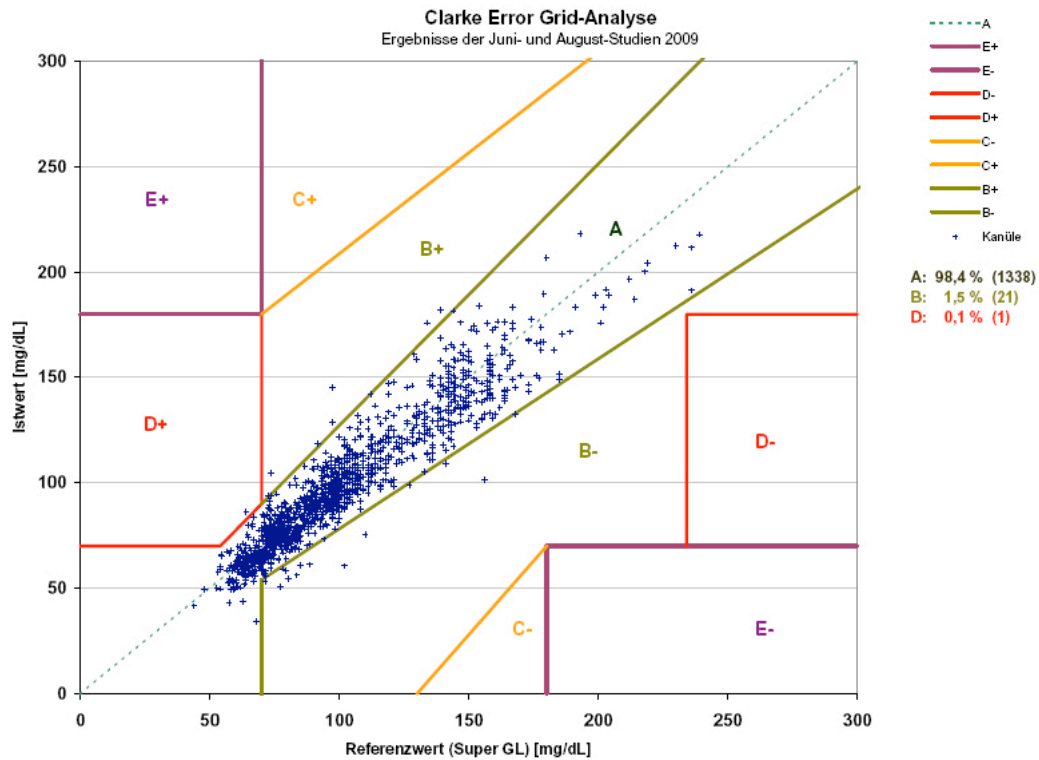


Figure 2 Clarke Error Grid Analysis.

Users of Probe's MicroEye[®] device with online sensor are convinced of the advantages and benefits of this system in comparison to existing and next generation products currently in development. Many companies claim to provide continuous glucose monitoring but none, currently on the market, provide true BLOOD glucose measurements. Existing system presently provide a glucose measurement, typically in subcutaneous and try to relate this to the blood concentration. During periods when blood glucose is changing rapidly the subcutaneous measurement can be significantly different from that of the blood and the subcutaneous levels can lag behind the blood concentration by 15 – 60 minutes in most cases. Furthermore, because these tissue implanted devices cause injury during insertion, what is measured is further confused by the scarring / healing process. In addition, many systems require a stabilisation period following device insertion that can be as long as 4 – 6 hours, whereas the MicroEye[®] device with online sensor system as use in recent trials was able to provide meaningful data within the first few minutes after deployment.