FreeStyle Navigator Continuous Glucose Monitoring System with TRUstart Algorithm, a 1-Hour Warm-Up Time

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Abstract

Background:

The first-generation FreeStyle Navigator® Continuous Glucose Monitoring System (FreeStyle Navigator CGM) requires a 10 h warm-up period to avoid inaccurate glucose readings caused by sensor insertion trauma and wound-healing processes. The performance of a second-generation FreeStyle Navigator CGM that begins reporting glucose 1 h after sensor insertion is described.

Methods:

Second-generation FreeStyle Navigator CGM performance was evaluated in an in-clinic study using the YSI Model 2300 STATPlus Glucose Analyzer as reference with 47 subjects with type 1 diabetes. The reference readings were taken at 15 min intervals, and the study was designed to emphasize the first 10 h of use.

Results:

The second-generation FreeStyle Navigator CGM exhibited continuous glucose error grid analysis ratings of 93.7% "clinically accurate," 3.6% "benign errors," and 2.8% "clinical errors" and a mean and median absolute relative difference of 14.5% and 10.7%, respectively. The second-generation algorithm detected signal instability in the first 10 h of use and suspended the reporting of 14.1% of first day continuous glucose readings. The clinical accuracy of the second-generation FreeStyle Navigator CGM was similar for the first 10 h versus subsequent hours, with 92.6% and 94.2% "clinically accurate" readings, respectively.

Conclusion:

The warm-up period for the second-generation FreeStyle Navigator CGM was reduced from 10 to 1 h, with minimal interruption of glucose reporting and without sacrificing clinical performance.

J Diabetes Sci Technol 2011;5(1):99-106

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Abbreviations: (ARD) absolute relative difference, (BG) blood glucose, (CGM) continuous glucose monitoring, (CG-EGA) continuous glucose error grid analysis, (EGA) error grid analysis, (ISO) International Standards Organization, (PIV) postinsertion variability, (SMBG) self-monitoring of blood glucose

Keywords: accuracy, calibration, clinical performance, continuous glucose monitor

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