Accuracy of the Sof-Sensor Glucose Sensor with the *i*Pro Calibration Algorithm

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Performance characteristics of devices that measure interstitial fluid glucose concentrations continue to improve. The overall accuracy of continuous glucose monitoring (CGM) systems depends on the sensor, the reference blood glucose concentrations used for calibration, and the calibration algorithm. We examined the accuracy of the *i*Pro calibration algorithm when applied retrospectively to data collected with Sof-sensor CGM sensors.

A total of 768 sensors were worn by 71 adults (ages 19–72) and 61 children (ages 7–17) with type 1 diabetes. Sensor data from the first 3 days of wear, along with contemporaneous blood glucose (BG) concentrations measured by the Paradigm Link BG monitor, were supplied to the *i*Pro algorithm to generate a data set of sensor glucose (SG) concentrations. The mean absolute relative difference (MARD) between SG and BG concentrations, the SG:BG agreement rate, and Clarke error grid analysis of paired SG and BG values were used to estimate the overall accuracy of the SG data.

The MARD was 9.9% in adults and 10.1% in children, and were lowest in the 240–400 mg/dl range (6.8% in adults, 6.3% in children). The SG:BG agreement rate (i.e., the percentage of SG values within 20% of the reference BG value or the percentage within 20 mg/dl for reference values <80 mg/dl) was 89.1% for adults and 88.7% for children. The highest agreement rates were seen in the 240–400 mg/dl range (94.9% in adults, 95.2% in children). For values in the 40–80 mg/dl range, 88.7% of adult and 85.5% of pediatric SG values were within 20 mg/dl of the reference value, and for values in the 80–120 mg/dl range, 83.3% of adult and 81.2% of pediatric SG values were within 20% of the reference value. Clarke error grid analysis (**Figure 1**) showed that 99.0% (4849 of 4897) of adult and 98.4% (4116 of 4181) of pediatric-paired values were within zones A and B.

The *i*Pro algorithm is at the heart of the *i*Pro Professional CGM system, which is used by clinicians to gain insights that are not apparent with finger stick and hemoglobin A1c testing alone. A CGM sensor and an attached *i*Pro recording device are worn by the patient for 3 days, and four BG values are measured each day. Data from the BG meter and recording device are then uploaded for report generation and analysis. Therapy adjustments based on retrospectively-generated glycemic profiles have been shown to reduce the duration of hypoglycemia compared with therapy adjustments guided by BG values alone.[1] Retrospective CGM was found to be well tolerated and beneficial in children[2] and has been used to demonstrate frequent hypoglycemia in adults with poor control.[3] It may be especially useful for those with hypoglycemia unawareness, for those with postprandial hyperglycemia, or during therapy regimen adjustments.[4]

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Abbreviations: (BG) blood glucose, (CGM) continuous glucose monitoring, (MARD) mean absolute relative difference, (SG) sensor glucose

Keywords: calibration algorithm, Clarke error grid, continuous glucose monitoring, *i*Pro retrospective analysis, sensor accuracy

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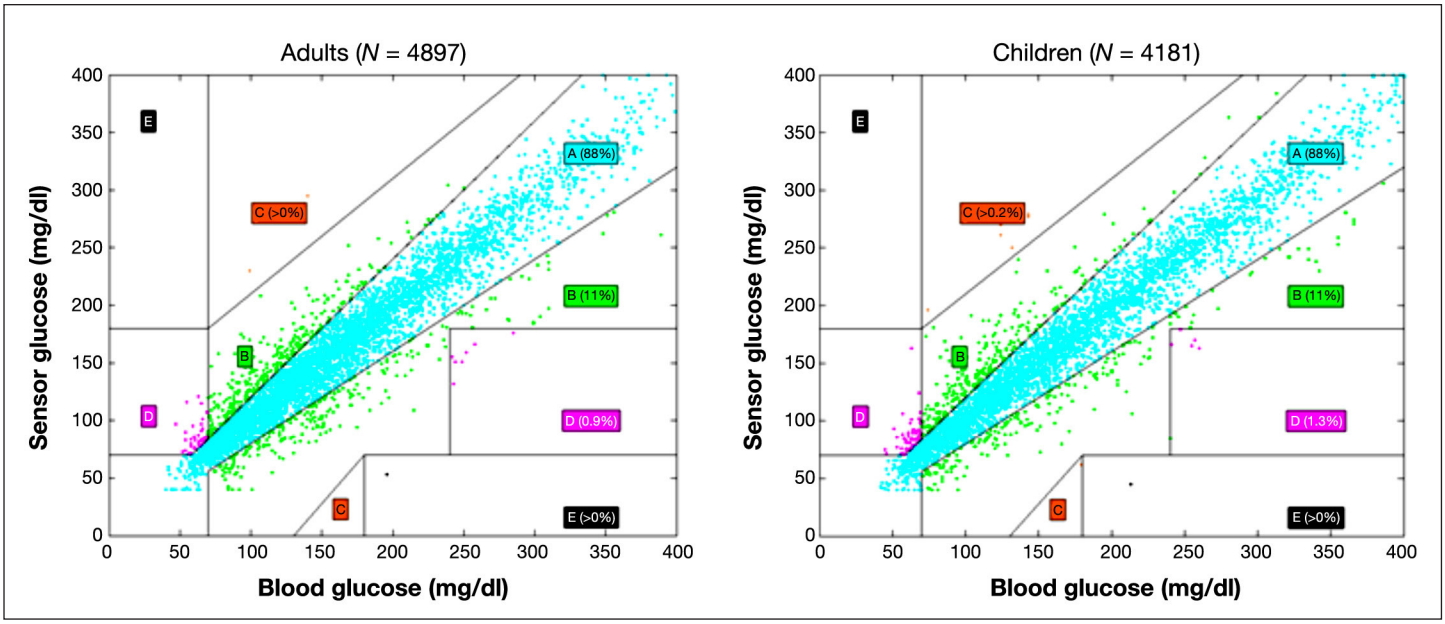

Figure 1. Clarke error grid analysis of paired SG and BG values from adults and children.

The *i*Pro algorithm provides SG readings that are in good agreement with respect to home BG meter readings when used in conjunction with Sof-sensor CGM sensors. The accuracy is maintained in both adults and children for at least 3 days.

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*i*Pro, Sof-sensor, and Paradigm Link are trademarks of Medtronic MiniMed, Inc., Northridge, CA.

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