

# An evaluation of the accuracy of a flash glucose monitoring system in children with diabetes in comparison with venous blood glucose

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**Introduction and objectives:** Venous BG should also be compared when evaluating the accuracy and performance of the CGM [1-4]. There were no data on comparison of the sensor results and venous values. Furthermore, the China Food and Drug Administration (CFDA) has not approved this system for use in Chinese children and adolescents. We first evaluated the performance and usability of a factory-calibrated flash glucose monitoring system against venous BG in a Chinese paediatric diabetes population.

**Methods:** A total of 13 hospitalized participants newly diagnosed with type 1 diabetes, aged 1~14 years old, were involved in the study. Sensor glucose measurements on days 2, 3, 6, 7, 12 and 13 of wear were compared with venous BG. During these days, the venous BG results were obtained either 4 or 7 times per day.

**Results and Conclusions:** The accuracy was evaluated against venous BG, with 469 of 469 (100.0%) sensor and venous BG pairs within consensus error grid zones A and B, including 94.7% in zone A. The overall mean absolute relative difference (MARD) was 11.67%. The MARD of blood glucose lower than 4.0 mmol/L (MARD=16.89%) was higher than blood glucose between 4 to 10 mmol/L (MARD=11.58%) and blood glucose higher than 10 mmol/L (MARD=7.79%). Compared to venous BG, the MARDs of wear days 2, 3, 6, 7, 12 and 13 were 11.53%, 9.66%, 11.79%, 10.89%, 13.18% and 13.92%, respectively, with no statistically significant difference ( $P=0.25$ ). The median ARD was highest when the glucose decreased  $>0.11$  mmol/L/min (20.27%), and lower than 10.00% when the glucose changing between 0.06 and 0.11 mmol/L/min, changing  $<0.06$  mmol/L/min and increasing  $>0.11$  mmol/L/min. The accuracy of the system is good and remains stable over 14 days of wear; however, the accuracy depends on the glucose level and rates of glucose concentration changes.

## References:

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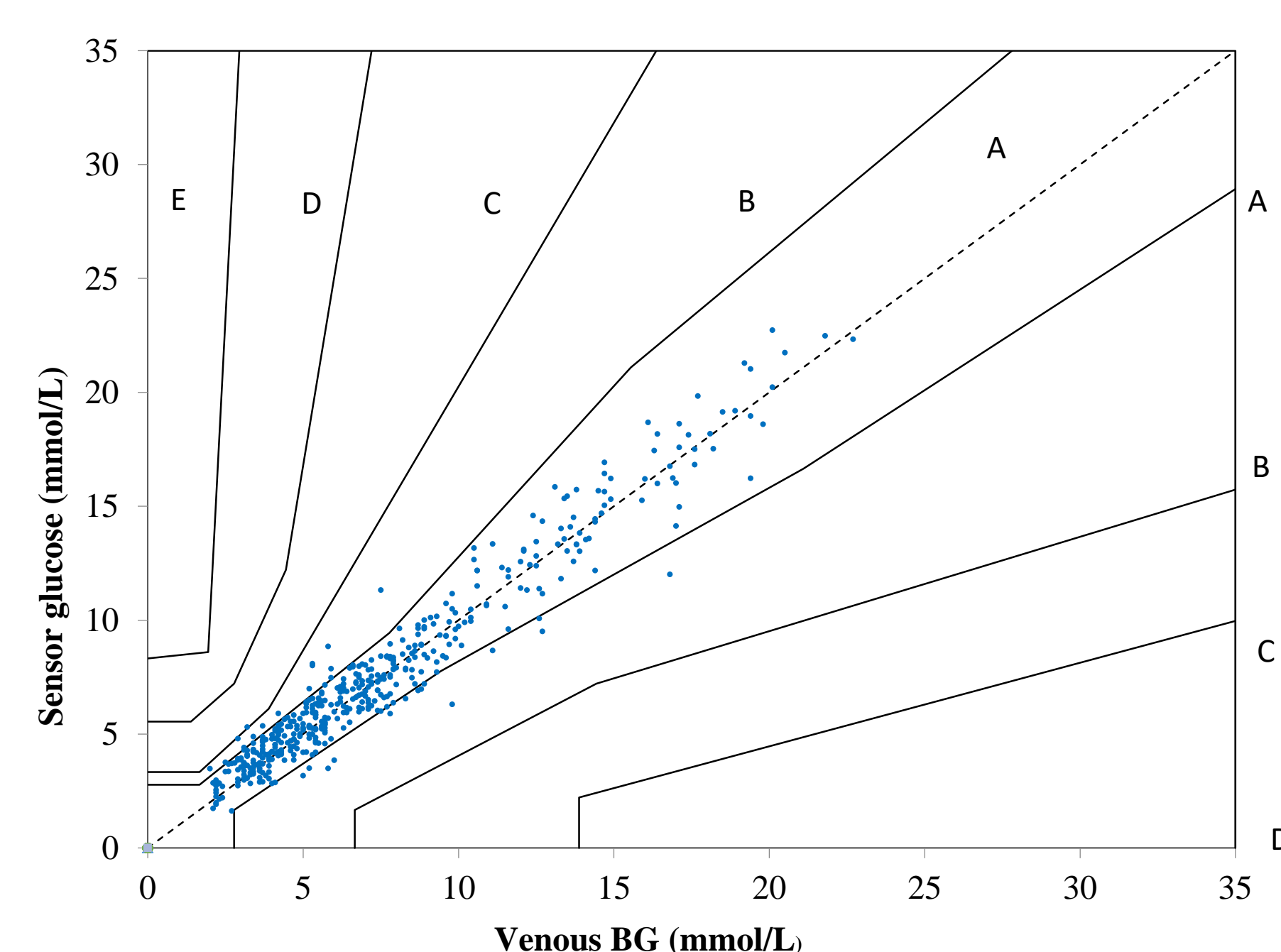


Figure 1 Consensus error grid (CEG) analysis comparing FreeStyle Libre sensor and venous blood glucose (BG) results.

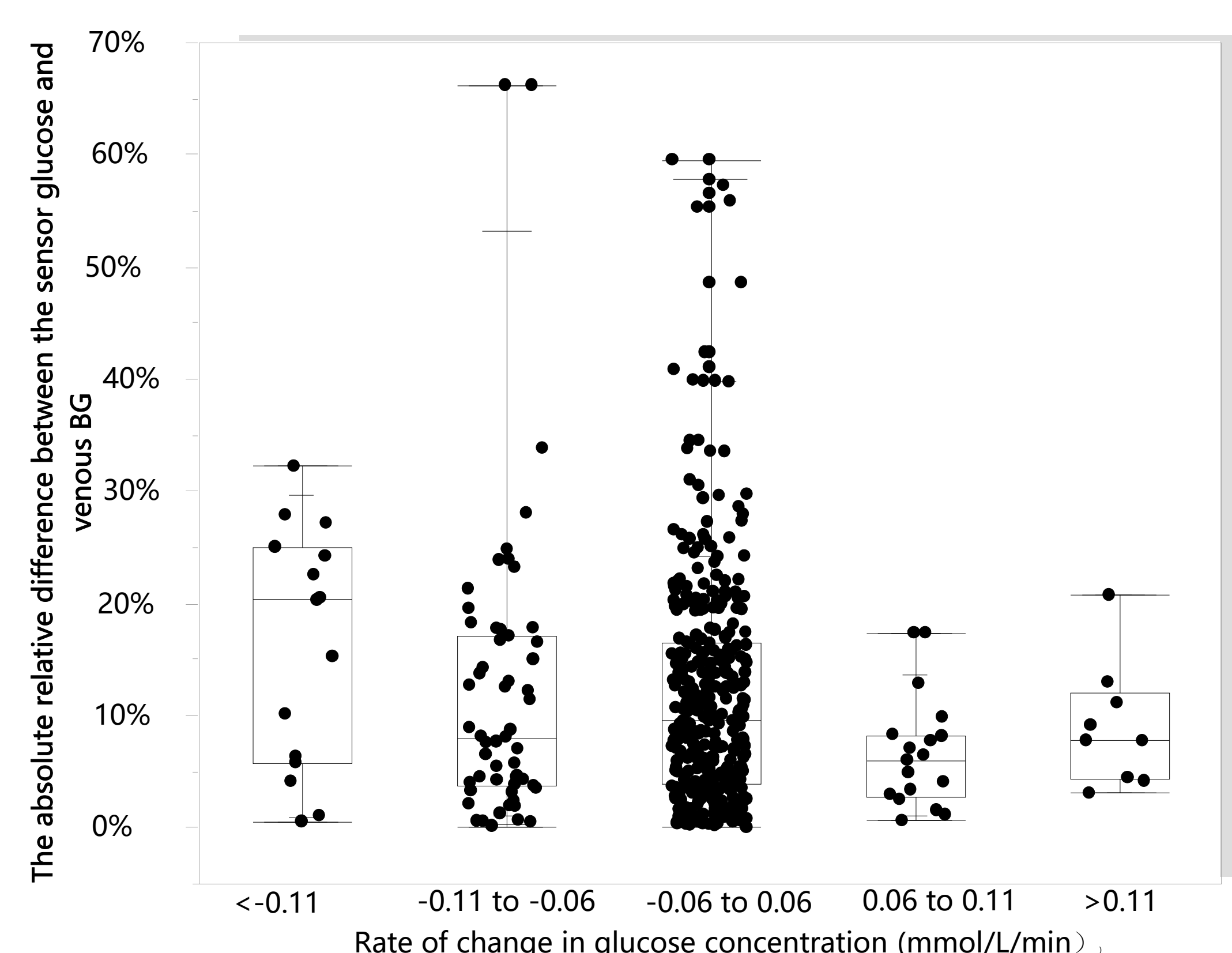


Figure 2 The absolute relative difference between the sensor glucose and venous BG results at different rates of glucose concentration changes