Post-market surveillance of 18 blood glucose monitoring systems' accuracy based on ISO 15197:2013

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BACKGROUND AND AIMS: High quality blood glucose monitoring systems are required for adequate self-monitoring of blood glucose 3 80 (SMBG). In this study, system accuracy of 18 \(\frac{1}{5} \) 60 current-generation SMBG systems from different manufacturers was evaluated based on the international standard ISO 15197:2013 with 1 lot each. Manufacturers were selected by their respective market share in Europe and had the opportunity to comment on system selection (including alternative proposals) in a manufacturer request prior to study start. SMBG systems were independently purchased on the market by the investigators.

MATERIALS AND METHODS: Each test strip lot was tested on 100 capillary blood samples from different subjects and compliance with accuracy criterion A stipulated in ISO 15197 (at least 95% of results within ±15% or ±15 mg/dL of the method's results comparison concentrations above or below 100 mg/dL, respectively) was assessed. Glucose oxidase (GOD) or hexokinase (HK) was used as g-20 comparison method (GOD: YSI 2300 STAT 9-40 Plus, YSI Incorporated, OH, USA; HK: Cobas 💆 60 Integra® 400 plus, Roche Instrument Center, 🖫 📶 Switzerland) depending on the manufacturer's measurement method.

RESULTS: In total, 14 out of 18 systems had ≥95% of results within ±15% or ±15 mg/dL of the result obtained with the respective manufacturer's measurement method (FIGURE = 80 1). Individual systems showed 89 to 100% of results within these limits. Results within ±10% or ±10 mg/dL of the respective comparison method results ranged from 71 to 99.5% with 3 systems showing ≥95% of results within these more stringent limits.

Conclusion: In this evaluation, 14 out of 18 \(\varphi\)-60 systems met the minimum system accuracy criterion A of ISO 15197 with the tested lot. only current-generation systems available on the market were used, more than 20% of systems did not meet ISO 15197 accuracy criteria with the tested lot.

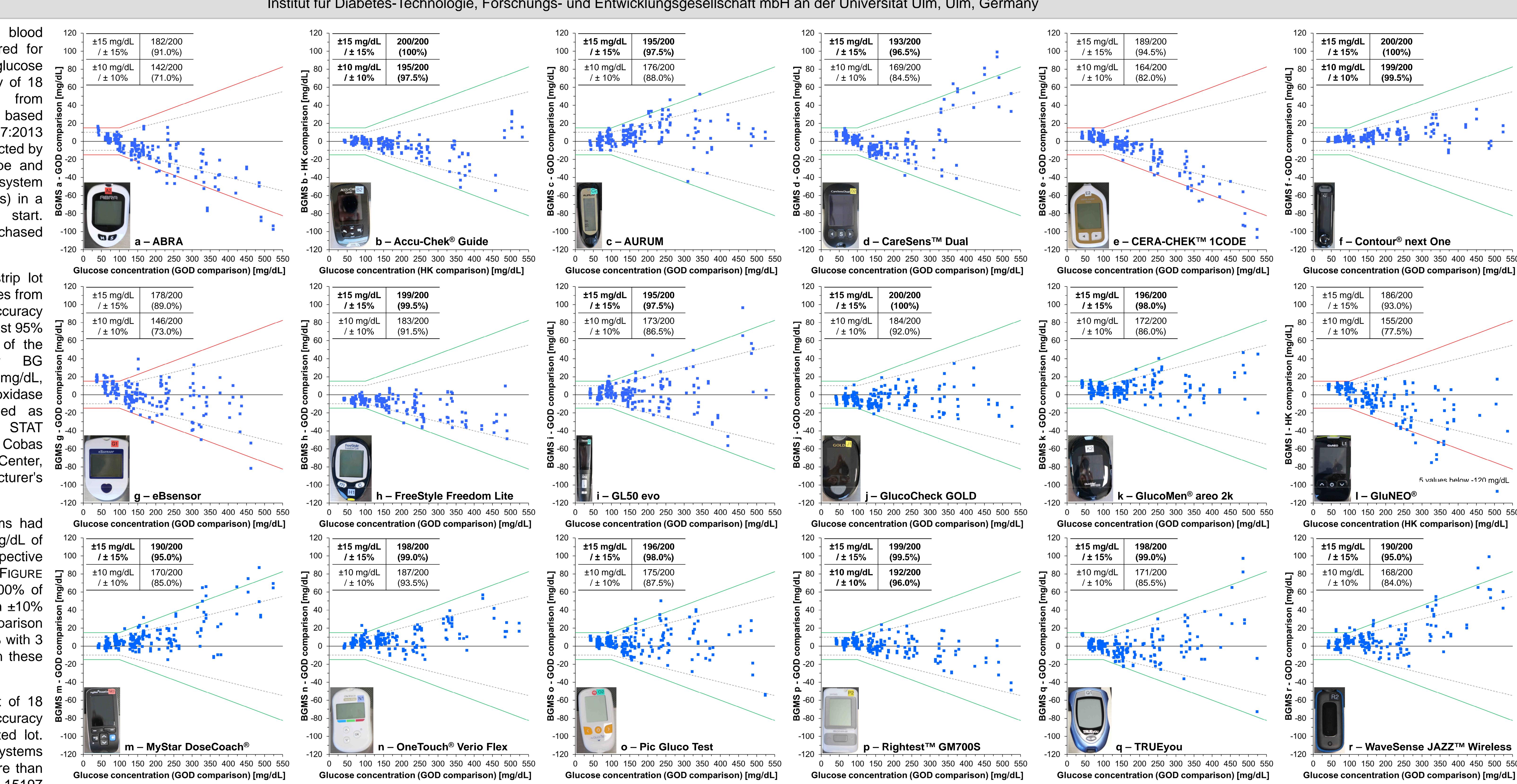


FIGURE 1: Difference plots of the 18 investigated blood glucose monitoring systems (in alphabetical order). Red/green solid lines: system accuracy criterion A (at least 95% of results within ±15% or ±15 mg/dL, respectively) in accordance to ISO 15197:2013. Green lines if criterion A is fulfilled, red lines if criterion A is not fulfilled. Grey dashed lines: accuracy limits of ±10 mg/dL / ± 10%. Tables show the absolute number of results and the percentage of results fulfilling accuracy criterion A.

