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# The Clinical Research Tool: A High-Performance Microdialysis-Based System for Reliably Measuring Interstitial Fluid Glucose Concentration

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## Abstract

### *Background:*

A novel microdialysis-based continuous glucose monitoring system, the so-called Clinical Research Tool (CRT), is presented. The CRT was designed exclusively for investigational use to offer high analytical accuracy and reliability. The CRT was built to avoid signal artifacts due to catheter clogging, flow obstruction by air bubbles, and flow variation caused by inconstant pumping. For differentiation between physiological events and system artifacts, the sensor current, counter electrode and polarization voltage, battery voltage, sensor temperature, and flow rate are recorded at a rate of 1 Hz.

### *Method:*

*In vitro* characterization with buffered glucose solutions ($c_{glucose}$ = 0 - 26 x $10^{-3}$ mol liter$^{-1}$) over 120 h yielded a mean absolute relative error (MARE) of 2.9 ± 0.9% and a recorded mean flow rate of 330 ± 48 nl/min with periodic flow rate variation amounting to 24 ± 7%. The first 120 h *in vivo* testing was conducted with five type 1 diabetes subjects wearing two systems each. A mean flow rate of 350 ± 59 nl/min and a periodic variation of 22 ± 6% were recorded.

### *Results:*

Utilizing 3 blood glucose measurements per day and a physical lag time of 1980 s, retrospective calibration of the 10 *in vivo* experiments yielded a MARE value of 12.4 ± 5.7. Clarke error grid analysis resulted in 81.0%, 16.6%, 0.8%, 1.6%, and 0% in regions A, B, C, D, and E, respectively.

### *Conclusion:*

The CRT demonstrates exceptional reliability of system operation and very good measurement performance. The ability to differentiate between artifacts and physiological effects suggests the use of the CRT as a reference tool in clinical investigations.

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**Abbreviations:** (BG) blood glucose, (CRT) clinical research tool, (EGA) error grid analysis, (MARE) mean absolute relative error, (PAES) polyarylethersulphone, (PC) personal computer, (PRESS) predictive error sum of squares, (SCGM) subcutaneous continuous glucose monitoring, (SMBG) self-monitoring of blood glucose

**Keywords:** biosensor, clinical investigation, continuous monitoring, flow rate sensor, glucose, microdialysis

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