



Biosen studies and evaluations

Title	Is there a suitable point-of-care glucose meter for tight glycemic control? Evaluation of one home-use and four hospital-use meters in an intensive care unit	Precision and accuracy of blood glucose measurements using three different instruments	Validation of BIOSEN C-Line glucose/lactate analyser versus HITACHI 917	Clinical evaluation of Biosen C-Line analyzer manufactured by EKF Diagnostics for testing of glucose concentration in whole blood, plasma and serum
Date of publication	2012	2011	2006	2007
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Organisation	Department of Clinical Chemistry and Hematology Meander Medical Center, Amersfoort, The Netherlands	Institute for Clinical Diabetology, German Diabetes Center, Leibniz Institute for Diabetes Research at Heinrich Heine University, Dusseldorf, Germany	Otto-Von-Guericke University Magdeburg Faculty of Medicine Institute of Clinical Chemistry and PathoBiochemistry	Sofia Medical University Department of Clinical Laboratory and Clinical Immunology
Analyte	Glucose	Glucose	Glucose and Lactate	Glucose
Comparator	Roche Accu-Check Inform II System, HemoCue Glu201DM, Nova StatStrip, Abbott Precision Xceed Pro, Menarini GlucoCard Memory PC, RapidLab 1265 (Siemens Realtbcare Diagnostics, Sysmex XE-2100 (Sysmex) and Beckman Coulter DxC-800.	YSI 2300 STAT plus and Beckman Glucose analyzer II	HITACHI 917	Analox GL5
Method	Accuracy and precision	Accuracy and precision	Accuracy and precision	Accuracy and precision
Results	Precision SD 0.478 CV 5.9% Accuracy 0.973 coefficient of correlation mean glucose 8.1 mmol/L ±2.1 against reference method mean glucose value of 8.1 mmol/L ±2.0	Precision Plasma 0.83% CV Whole blood 1.26% CV Accuracy/Bias 3.0mmol/L ±3.5% vs BGM	Precision Glucose Plasma 0.8% of the total sample volume had a difference greater than 10% Whole blood 6.7% of the total sample volume had an difference greater than 10% Accuracy/Bias Glucose Plasma 0.998 coefficient of correlation Whole blood 0.997 coefficient of correlation Lactate Plasma 0.99 coefficient of correlation	Precision Whole blood Normal 7.7% CV High 6.3% CV Intra-run QC Normal 3.6% CV High 5.3% CV Inter-run QC Normal 4.3% CV High 5.3% CV Accuracy 0.984 coefficient of correlation in the range 0.6-24.3 mmol/L
Conclusion	The already in house laboratory method Biosen C-Line Clinic fulfilled all ISO 15197, TNO and NACB/ADA criteria compared to the reference method.	The EKF instrument is comparable regarding accuracy and precision to the reference method BMG and can be used in metabolic tests, while the YSI showed a systematic shift at higher glucose concentrations. Based on these results we decided to replace BMG with EKF instrument in metabolic tests.	Glucose values, measured with the BIOSEN C-Line, are identical to HITACHI 917. The BIOSEN C-Line, was more accurate was for Lactate doe samples above 15.5 mmol/L.	Biosen C-Line is distinguished for its high analytical reliability, - reproducibility and accuracy which meet the up to date regulations. BIOSEN C-Line glucose analyzer is simple and easy to operate and requires no additional handling.
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