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# StatStrip® Glucose- Setting *new Standards* *in Glucose POC meter testing?*

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# Outline of Presentation

- What is the current status of POC glucose meter testing in hospitals?
- StatStrip® Glucose: first point of care glucose meter to correct for interferences
- StatStrip® Glucose: improving the accuracy of glucose measurements

# Hospital Glucose testing

- Managing and maintaining glucose levels in critically ill hospitalised patients reduces mortality and morbidity rates as well as length of stay.
- Protocols for maintaining safe and effective glycaemic control are widely implemented
- Hospital glucose testing now widely established and is a high volume test parameter
- POC Glucose meters most commonly used procedure for measuring glucose values throughout a hospital.

# However

- Accurate results are required to manage glycemic control and insulin dosing.
- The blood sample composition of hospitalised patients will contain components that can influence the results of diagnostic tests.
- There is increasing awareness that the accuracy of most commonly used glucose meters are affected by HCT and interfering substances commonly present in hospitalised patients

# Many Factors affect Glucose meter measurements

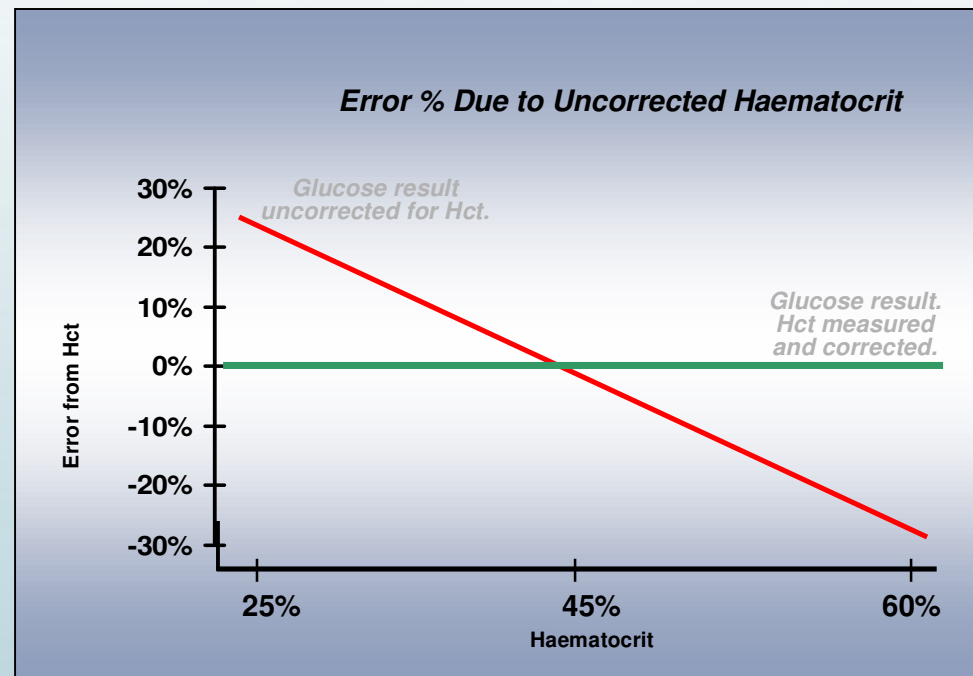
	Glucose oxidase	Glucose dehydrogenase
<b>Haematocrit</b>		
Low HCT	↑	↑
High HCT	↓	↓
<b>Oxygen concentration</b>		
Hypoxia	↑	—
Oxygen therapy	↓	—
<b>Therapeutic Agents</b>		
Ascorbic acid	↓	↑ / —
Acetaminophen	↓	↑
Dopamine	—	↓
Icodextrin / maltose	—	↑
Mannitol	↑	—

Dungan, K et al, Glucose Measurement: Confounding Issues in Setting Targets for Inpatient Management, Diabetes Care, Feb 2007

# Haematocrit Interference Effect

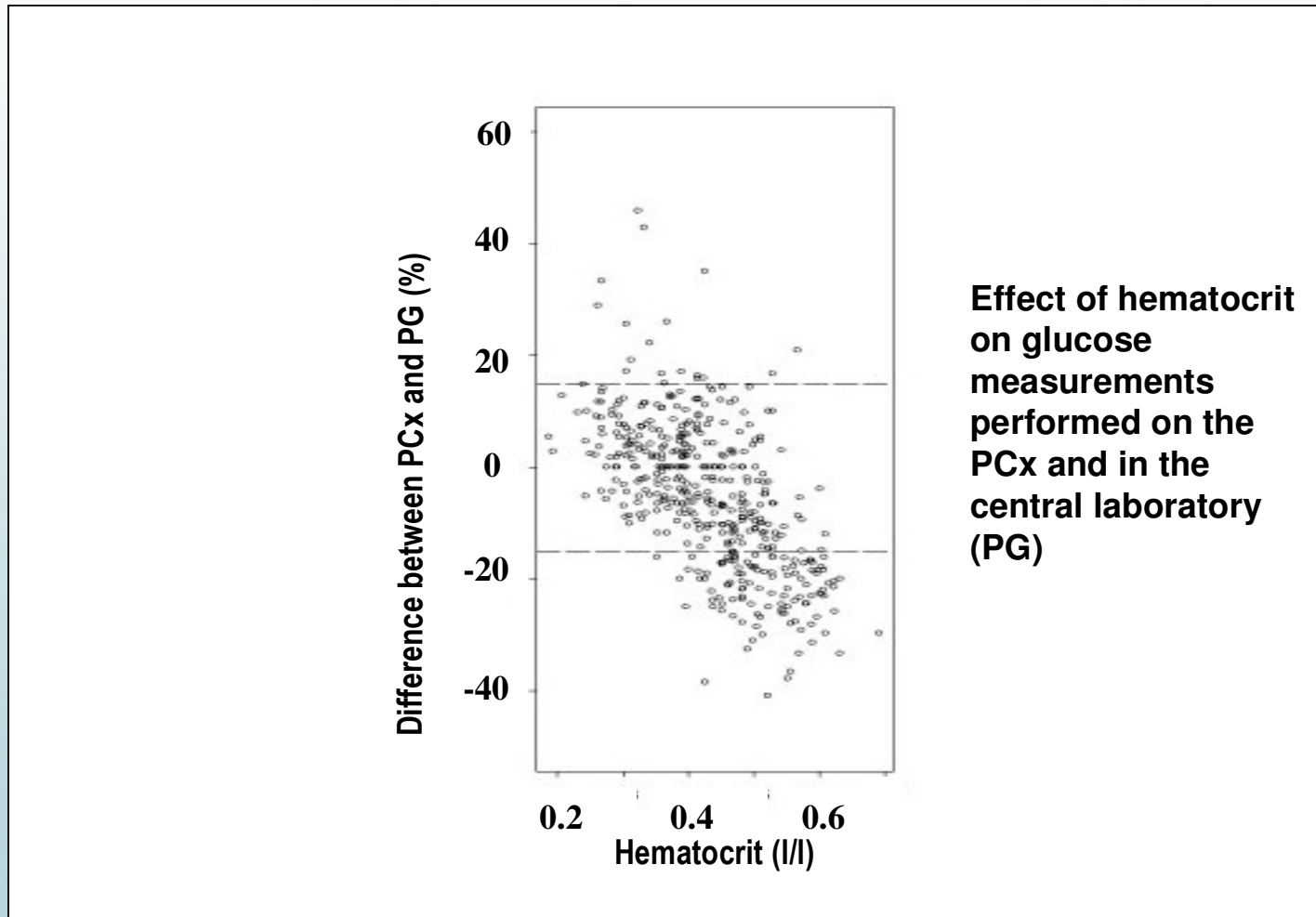
Severe haematocrit abnormalities are routinely found in critically ill patients

- NICU patients
- Open heart surgery
- Dialysis patients
- Oncology patients
- Trauma patients
- Severely anaemic patients
- Elderly patients



# Hematocrit Interference Effect

Hamilton Health Sciences Study, Hamilton, Ontario, Canada



Balion C et al. Screening for hypoglycemia at the bedside in the neonatal intensive care unit (NICU) with the Abbott PCx glucose meter. *BMC Pediatr.* 2006 Nov 3;6:28.

# Accuracy of Current meters

Meter	Hematocrit Interference	Maltose Interference	Other Interference	Reference
AccuChek Aviva	Yes	Yes	Ascorbate	Britta F et al Analytical performance of an interference-resistant glucose meter. Poster presentation 22nd International AACC CPOCT Barcelona 17-20 September 2008
AccuChek Active	Yes	Yes	Ascorbate	Germagnolit L et al Suitability Assessment of a New Bedside Interference Free Glucose System for Use in Critical Care when Compared to Current Technology. Poster presentation 22nd International AACC CPOCT Barcelona 17-20 September 2008
AccuChek Inform	Yes	Yes	Ascorbate	Karon BS et al. Evaluation of the Impact of Hematocrit and Other Interference on the Accuracy of Hospital-Based Glucose Meters. Diabetes Technology & Therapeutics, Vol10, No 2, 2008
AccuChek Advantage	Yes	Yes		Thomas A et al An evaluation of the analytical performance of a new generation hospital based glucose meter and an assessment of its clinical reliability in a neonatal care unit..Poster presentation 22nd International AACC CPOCT Barcelona 17-20 September 2008

# Accuracy of Current meters continued

Meter	Hematocrit Interference	Other Interference	Reference
Precision Freestyle	Yes	Ascorbate and Maltose	Britta F et al Analytical performance of an interference-resistant glucose meter. Poster presentation 22nd International AACC CPOCT Barcelona 17-20 September 2008
Precision Xtra	Yes	Ascorbate	Germagnolit L et al Suitability Assessment of a New Bedside Interference Free Glucose System for Use in Critical Care when Compared to Current Technology. Poster presentation 22nd International AACC CPOCT Barcelona 17-20 September 2008
Precision PCx	Yes	Ascorbate	Karon BS et al. Evaluation of the Impact of Hematocrit and Other Interference on the Accuracy of Hospital-Based Glucose Meters. Diabetes Technology & Therapeutics, Vol10, No 2, 2008
Optium Xceed	Yes		Thomas A et al An evaluation of the analytical performance of a new generation hospital based glucose meter and an assessment of its clinical reliability in a neonatal care unit..Poster presentation 22nd International AACC CPOCT Barcelona 17-20 September 2008

# Accuracy of Current meters continued

Meter	Hematocrit Interference	Other Interference	Reference
<b>Ascensia Contour</b>	<b>Yes</b>	<b>Ascorbate</b>	Britta F et al Analytical performance of an interference-resistant glucose meter. Poster presentation 22nd International AACC CPOCT Barcelona 17-20 September 2008
<b>Ascensia Breeze 2</b>	<b>Yes</b>	<b>Ascorbate</b>	Germagnolit L et al Suitability Assessment of a New Bedside Interference Free Glucose System for Use in Critical Care when Compared to Current Technology. Poster presentation 22nd International AACC CPOCT Barcelona 17-20 September 2008
<b>Ascensia Elite XL</b>	<b>Yes</b>		Bewley B et al An evaluation of the analytical specificity and clinical application of a new generation hospital based glucose meter in a dialysis setting..Poster presentation 22nd International AACC CPOCT Barcelona 17-20 September 2008
<b>SureStepFlexx</b>	<b>Yes</b>	<b>Ascorbate</b>	Holtzinger C et al Evaluation of a New POCT Bedside Glucose Meter and Strip With Hematocrit and Interference Corrections Point of Care & Volume 7, Number 1, March 2008

# Poor accuracy Leads To Insulin Dosing Error

Clinical Chemistry 47:2  
209-214 (2001)

Evidence-based  
Laboratory Medicine  
and Test Utilization

## Quality Specifications for Glucose Meters: Assessment by Simulation Modeling of Errors in Insulin Dose

JAMES C. BOYD\* and DAVID E. BRUNS

**Background:** Proposed quality specifications for glucose meters allow results to be in error by 5-10% or more of the "true" concentration. Because meters are used as aids in the adjustment of insulin doses, we aimed to characterize the quantitative effect of meter error on the ability to identify the insulin dose appropriate for the true glucose concentration.

**Methods:** Using Monte Carlo simulation, we generated random "true" glucose values within defined intervals. These values were converted to "measured" glucose values using mathematical models of glucose meters having defined imprecision (CV) and bias. For each combination of bias and imprecision, 10 000-20 000 true and measured glucose concentrations were matched with the corresponding insulin doses specified by selected insulin-dosing regimens. Discrepancies in prescribed doses were counted and their frequencies plotted in relation to bias and imprecision.

**Results:** For meters with a total analytical error of 5%, dosage errors occurred in ~8-23% of insulin doses. At 10% total error, 16-45% of doses were in error. Large errors of insulin dose (two-step or greater) occurred >5% of the time when the CV and/or bias exceeded 10-15%. Total dosage error rates were affected only slightly by choices of sliding scale among insulin dosage rules or by the range of blood glucose. To provide the intended insulin dosage 95% of the time required that both the bias and the CV of the glucose meter be <1% or <2%, depending on mean glucose concentrations and the rules for insulin dosing.

**Conclusions:** Glucose meters that meet current quality specifications allow a large fraction of administered insulin doses to differ from the intended doses. The

effects of such dosage errors on blood glucose and on patient outcomes require study.

© 2001 American Association for Clinical Chemistry

Glucose meters and glucose sensors play a central role in the modern management of diabetes. The Food and Drug Administration has approved >25 glucose meters, but quality specifications (or analytical goals) for glucose meters are controversial (1-3). Performance goals for the meters are critically important for clinicians, manufacturers, and most importantly, for patients who wish to achieve optimal control of blood glucose for improved clinical outcomes.

Fraser and Petersen (4) have proposed a hierarchy of criteria for quality specification for analytical methods. For most methods, key determinants of quality specifications are the within-person and person-to-person biological variation of the analyte (4). As Fraser and Petersen state (4), however: "Ideally, quality specifications should be derived objectively from an analysis of medical needs". An important medical use of glucose meters is in adjustments of insulin dose, with higher doses given at higher glucose concentrations according to predetermined rules for each patient and setting. We felt that it could be useful to explore the possibility of relating quality specifications for glucose meters to this clinical use.

In this study, we asked the question: What is the effect of analytical performance on the ability to correctly direct the administration of the dose of insulin intended for the patient's ("true") glucose concentration? We reasoned that a method with high imprecision or bias would frequently yield results sufficiently different from the patient's true glucose that the insulin dose would differ from the intended dose. To assess this effect, we used

Total  
Analytical  
Error (cv%  
and bias)

Insulin  
Dosage  
Error Rate

5%

8-23%

10%

16-45%

15%

>5% chance  
of  
2-Step  
Dosing Error

# Safe and Effective Glycemic Management Demands Improved Glucose Strip Performance

*US Army Institute of Surgical Research, 2008.*

## Average Percent Error for POC Glucose Meters Versus Reference Laboratory Value<sup>1</sup>

Meter	N	Average Percent Error	Error Range, min to max %
SureStep Flexx	196	16.0*	-6.07 to 36.2
Accu-Chek Inform	187	16.0*	-3.9 to 37.1
Accu-Chek Advantage	196	16.9*	-5.4 to 35.9
Precision PCx	108	18.7*	-11.4 to 59.0

**\*Large errors of insulin dose (two-step or greater) occur >5% of the time when average percent error of method exceeds 15%**

<sup>1</sup>Mann EA et al. Error Rates Resulting from Anemia Can be Corrected in Multiple Commonly Used Point of Care Glucometers. US Army Institute of Surgical Research, 2008.

# Safe and Effective Glycemic Management Demands Improved Glucose Strip Performance

*US Army Institute of Surgical Research, 2008.*

## Average Percent Error for POC Glucose Meters Versus Reference Laboratory Value<sup>1</sup>

<b>Meter</b>	<b>Average Percent Error @ Hct &lt; 25%</b>	<b>Error Range, min to max %</b>
SureStep Flexx	<b>20.6%</b>	<b>-6.07 to 36.2</b>
Accu-Chek Inform	<b>15.4%</b>	<b>-3.9 to 37.1</b>
Accu-Chek Advantage	<b>17.1%</b>	<b>-5.4 to 35.9</b>
Precision PCx	<b>22.3%</b>	<b>-11.4 to 59.0</b>

**\*Large errors of insulin dose (two-step or greater) occur >5% of the time when average percent error of method exceeds 15%**

<sup>1</sup>Mann EA et al. Error Rates Resulting from Anemia Can be Corrected in Multiple Commonly Used Point of Care Glucometers. US Army Institute of Surgical Research, 2008.

# Consequences of using Inaccurate Meters

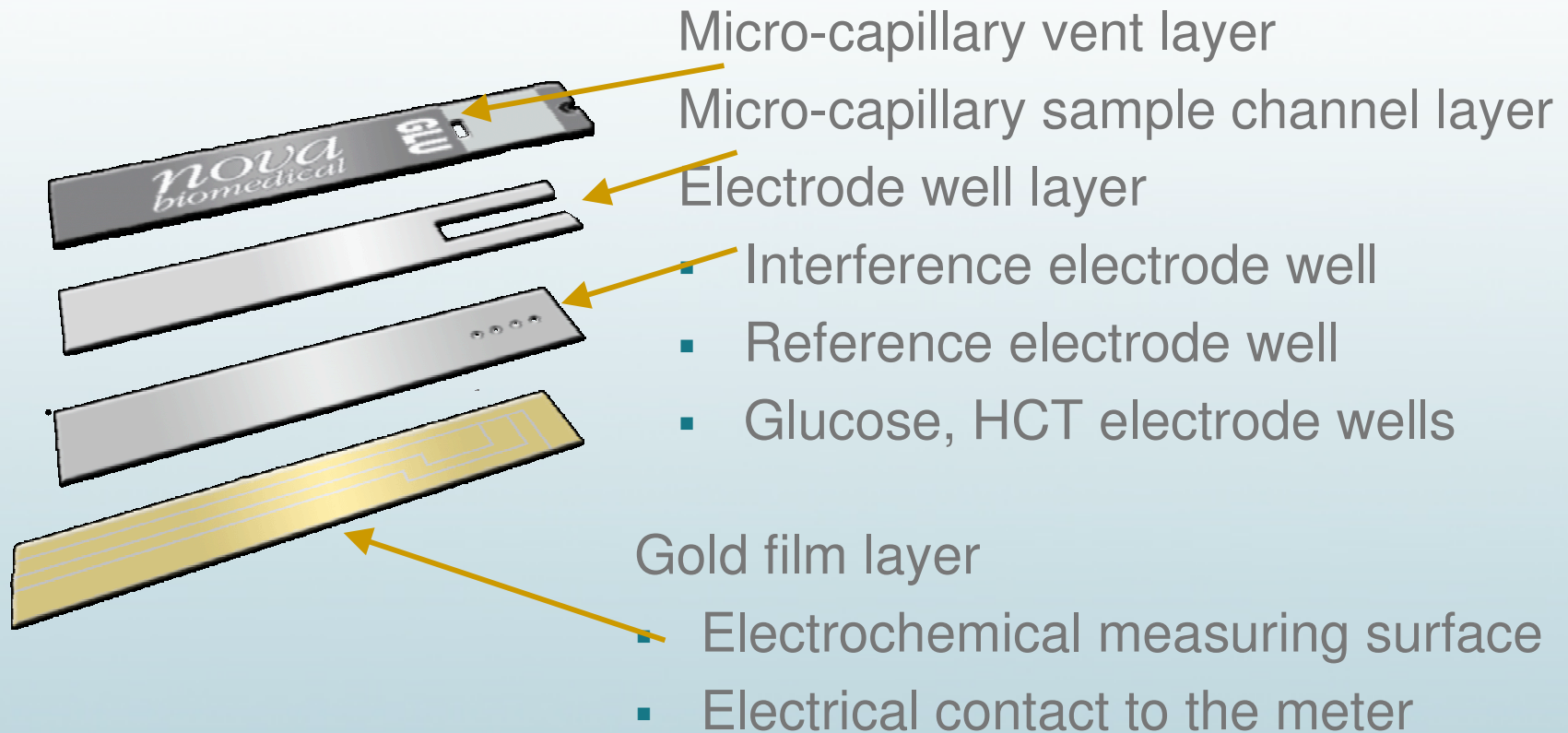
- Mis-dosing of Insulin
- Failure to maintain safe and effective glycaemic control
- Increased risk of hypoglycemia
- Increased hospital mortality
- Increased hospital morbidity
- Increased length of hospital stay
- Increased cost of patient care



## StatStrip® Glucose

First Point-of-Care Whole Blood  
Glucose Meter correcting for  
interference

# StatStrip<sup>®</sup> Glucose Strip Design



Sample volume = 1.2  $\mu$ L

Measurement time = 6 seconds

Patent 6,326,451

# Novel strip technology provides basis for;

- Measuring and correcting for hematocrit
- Correcting for assay interference factors
- Batch to batch production consistency – no need for batch to batch calibration
- Robust and stable strips

# Accuracy of StatStrip Glucose

Meter	Hematocrit Interference	Maltose Interference	Other Interferences
StatStrip Glucose	No	No	None

## References

- Germagnoli L et al Suitability Assessment of a New Bedside Interference Free Glucose System for Use in Critical Care when Compared to Current Technology. Poster presentation 22nd International AACC CPOCT Barcelona 17-20 September 2008
- Karon BS et al. Evaluation of the Impact of Haematocrit and Other Interference on the Accuracy of Hospital-Based Glucose Meters. Diabetes Technology & Therapeutics, Vol10, No 2, 2008
- Thomas A et al An evaluation of the analytical performance of a new generation hospital based glucose meter and an assessment of its clinical reliability in a neonatal care unit..Poster presentation 22nd International AACC CPOCT Barcelona 17-20 September 2008
- Britta F et al Analytical performance of an interference-resistant glucose meter. Poster presentation 22nd International AACC CPOCT Barcelona 17-20 September 2008
- Bewley B et al An evaluation of the analytical specificity and clinical application of a new generation hospital based glucose meter in a dialysis setting..Poster presentation 22nd International AACC CPOCT Barcelona 17-20 September 2008
- Holtzinger C et al Evaluation of a New POCT Bedside Glucose Meter and Strip With Haematocrit and Interference Corrections Point of Care & Volume 7, Number 1, March 2008

# Assessment of Accuracy

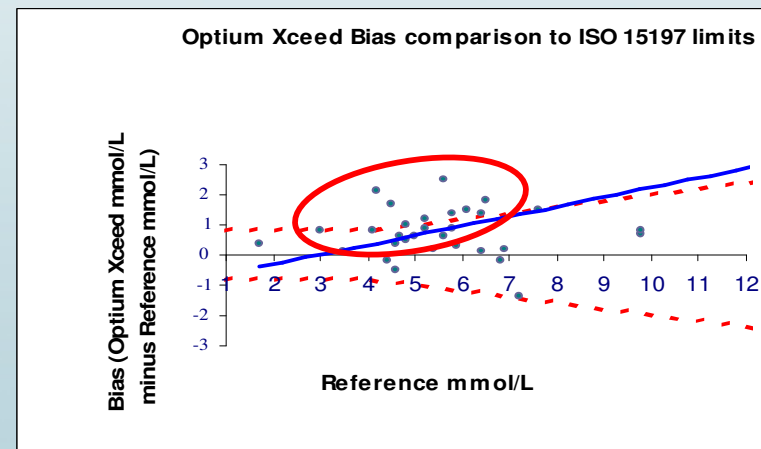
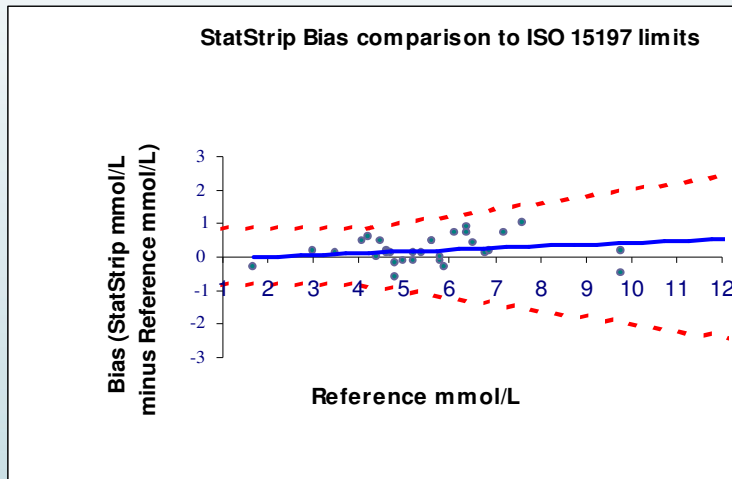
## ISO 15197 criteria

95% of glucose values should fall within 0.83 mmol/L of reference values at a glucose concentration <4.2 mmol/L or 20% of reference values at glucose concentration =4.2 mmol/L.

## TNO Quality guidelines

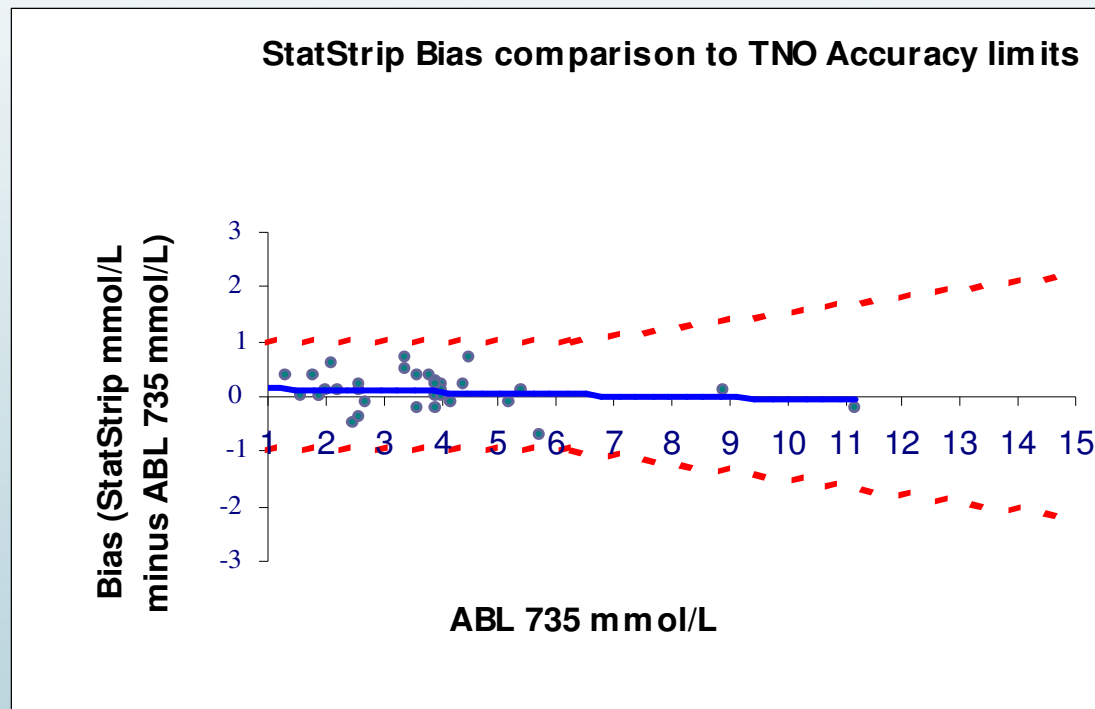
95% of glucose values should fall within 1.0 mmol/L of reference values at a glucose concentration <6.5 mmol/L or 15% of reference values at glucose concentration =6.5 mmol/L. 95% of glucose values

# Accuracy Assessment - NICU patients



Malic A et al Multiste evaluation of point of care glucose  
Evaluation of the Impact of Hematocrit and Other  
Interference on the Accuracy of meters in a neonatal  
intensive care unit. Poster presentation 23<sup>rd</sup> International  
Intensive Care meeting Milan 18-19 October 2008 .

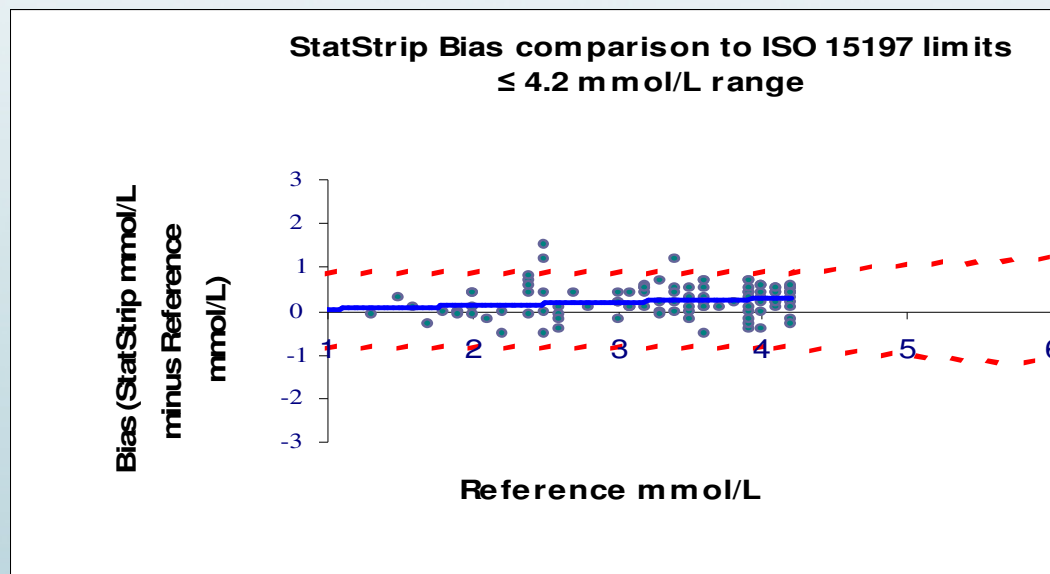
# NICU patient study– Comparison with TNO criteria



Slingerland R et al The Nova Statstrip Blood Glucose Meter Evaluation: Hematocrit Dependency, Method Comparison, Interfering Substances and Neonatal Samples. Poster presentation 22nd International AACC CPOCT Barcelona 17-20 September 2008

# NICU patient study – Comparison with ISO15197 criteria at low glucose range

Multi-site Study – UK, Holland, Canada

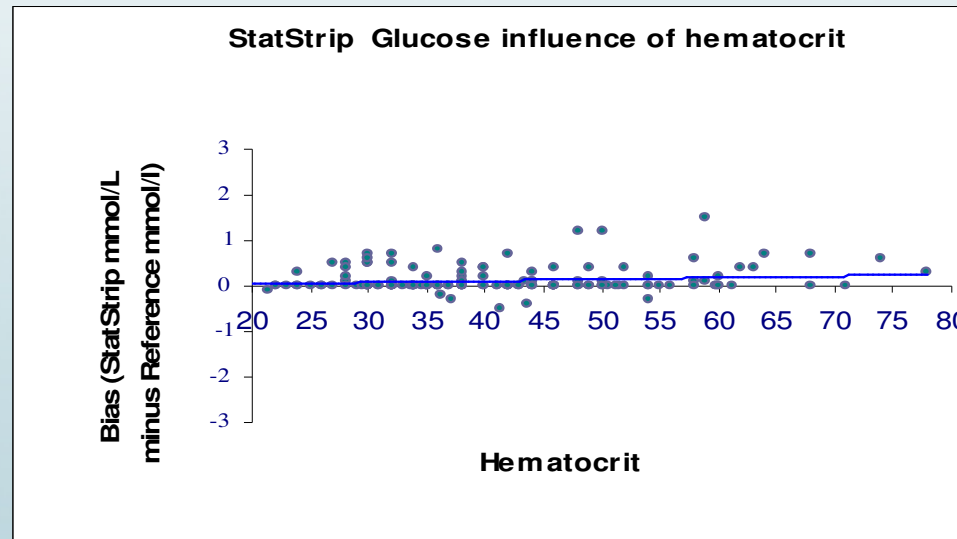


97.2 % concordance with ISO 15197 criteria

Malic A et al Multiste evaluation of point of care glucose Evaluation of the Impact of Hematocrit and Other Interference on the Accuracy of meters in a neonatal intensive care unit. Poster presentation 23<sup>rd</sup> International Intensive Care meeting Milan 18-19 October 2008 .

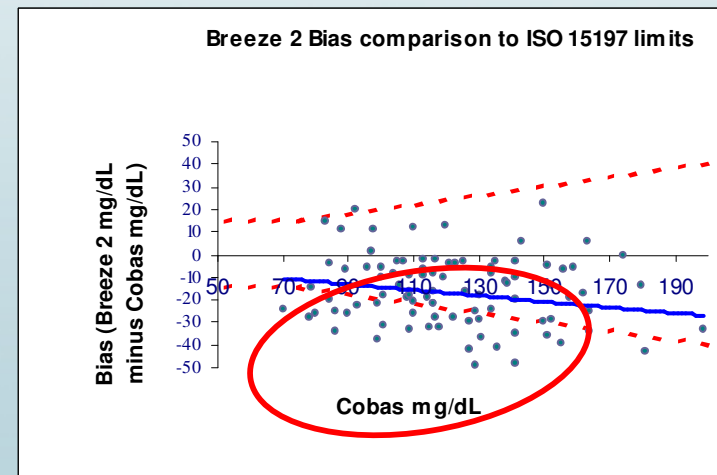
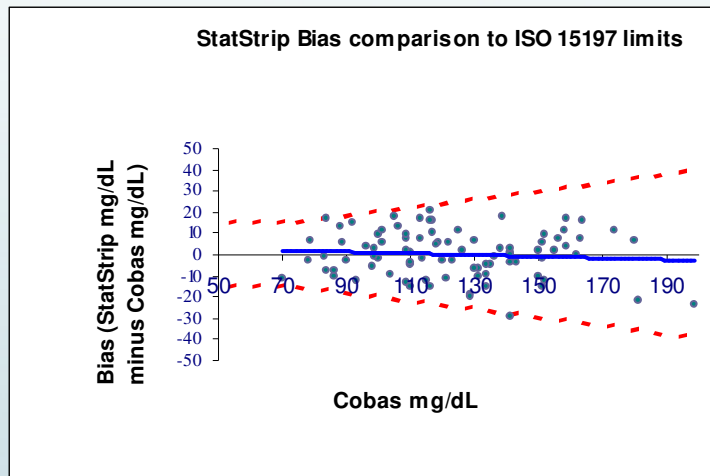
# NICU patient study – Assessment of hematocrit influence at low glucose range

Multi-site Study – UK, Holland, Canada



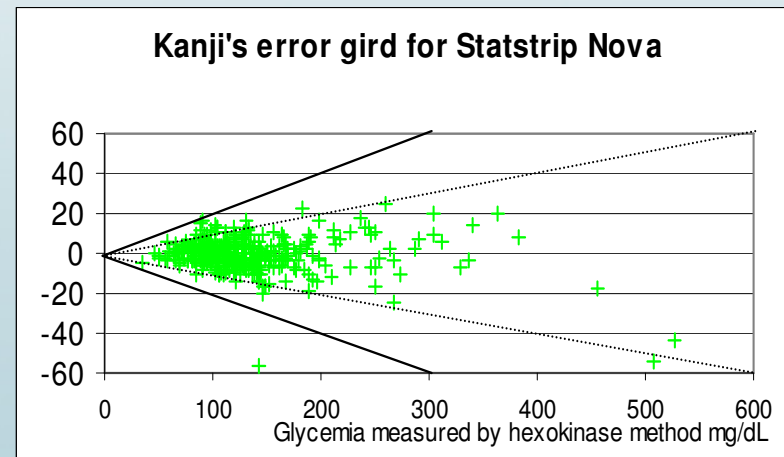
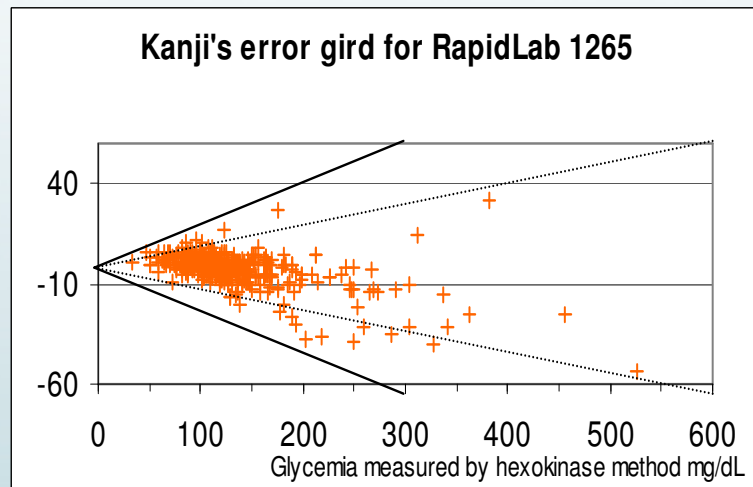
Malic A et al Multisite evaluation of point of care glucose  
Evaluation of the Impact of Hematocrit and Other  
Interference on the Accuracy of meters in a neonatal  
intensive care unit. Poster presentation 23<sup>rd</sup> International  
Intensive Care meeting Milan 18-19 October 2008 .

# ICU patient study – Comparison with ISO15197 criteria



Germagnoli L et al Suitability Assessment of a New Bedside Interference Free Glucose System for Use in Critical Care when Compared to Current Technology. Poster presentation 22nd International AACC CPOCT Barcelona 17-20 September 2008

# Accuracy Assessment - ICU patients



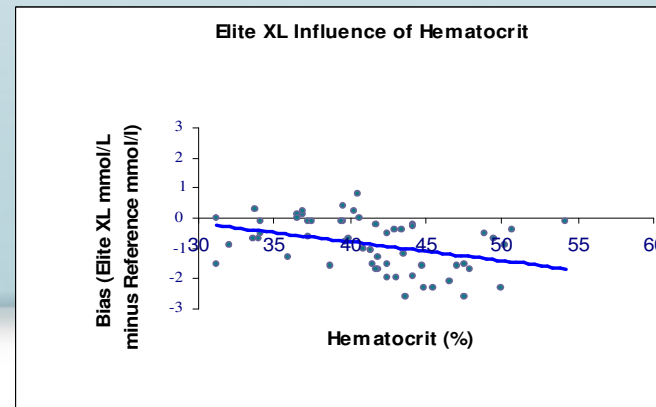
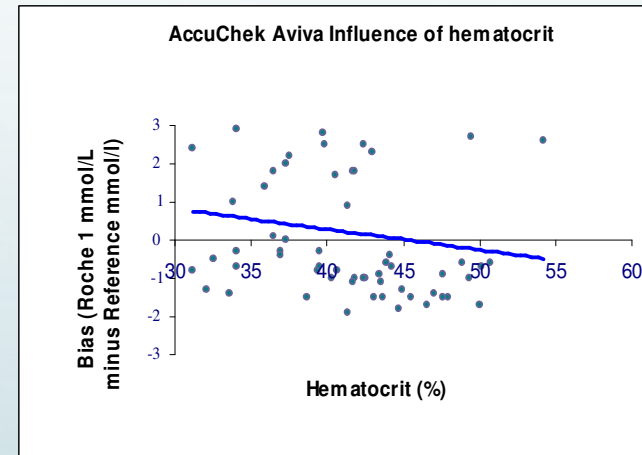
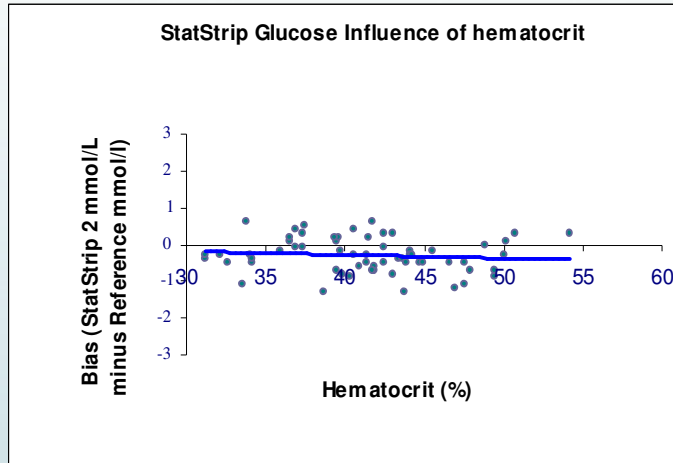
Roman A Comparison of accuracy of a glucometer and a blood gas analyser in an adult ICU: *The StatStrip NovaBiomedical fulfils TGC requirements.*  
Poster presentation 22nd International AACC CPOCT  
Barcelona 17-20 September 2008

# ICU patient study – Discrepancy analysis compared to lab method

Point-of-care method	number	Bias ( mg/dL)	SD	number of > 10 % discrepancies	number of > 20 % discrepancies
<b>RapidLab 1265</b>	369	-3.1	10	25 ( 6,8% )	1 ( 0,3% )
<b>StatStrip Novabiomedical</b>	369	-0.4	8	24 ( 6,5% )	1 ( 0,3% )

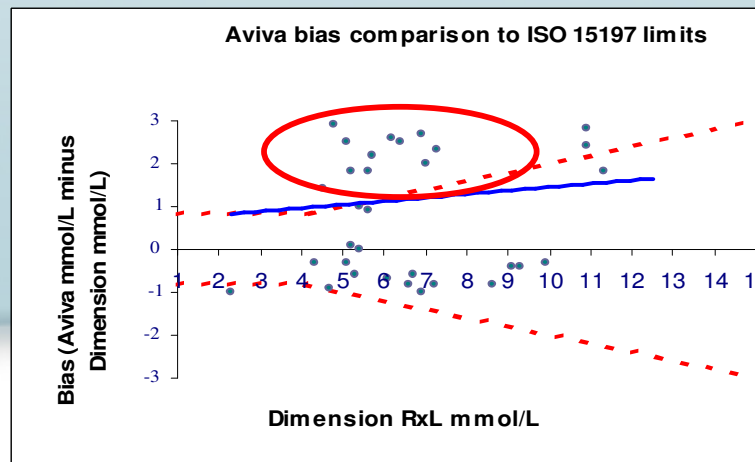
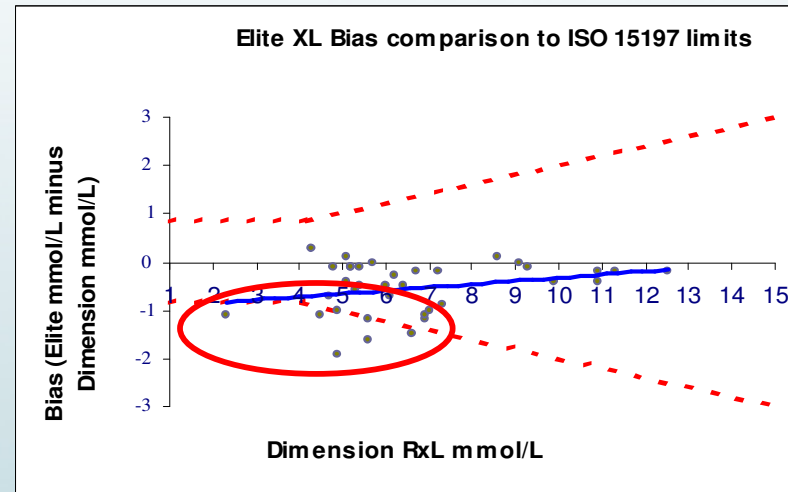
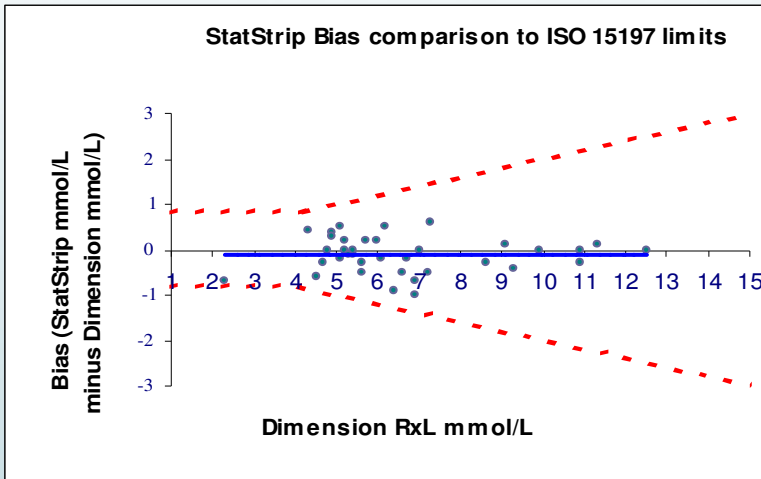
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Barcelona 17-20 September 2008

# Haematocrit - Dialysis patients



Bewley B et al An evaluation of the analytical specificity and clinical application of a new generation hospital based glucose meter in a dialysis setting..Poster presentation 22nd International AACC CPOCT Barcelona 17-20 September 2008

# Accuracy Assessment - Peritoneal Dialysis patients



Bewley B et al An evaluation of the analytical specificity and clinical application of a new generation hospital based glucose meter in a dialysis setting..Poster presentation 22nd International AACC CPOCT Barcelona 17-20 September 2008

## Dialysis patient study - Comparison against ISO 15197 criteria

Glucose Meter	n	Meeting ISO 15197 criteria
StatStrip lot 1	36	Yes
StatStrip lot 2	36	Yes
Ascencia Elite XL lot 1	36	No
Ascencia Elite XL lot 2	36	No
AccuChek Aviva lot 1	36	No
AccuChek Aviva lot 2	36	No
Reference method	36	Yes

Bewley B et al An evaluation of the analytical specificity and clinical application of a new generation hospital based glucose meter in a dialysis setting..Poster presentation 22nd International AACC CPOCT Barcelona 17-20 September 2008

# Summary

StatStrip® Glucose' multi-well technology addresses the requirements for improved accuracy and precision

- Clinical accuracy validated in >20 studies worldwide
- Good accuracy for measuring glucose in all hospital settings including NICU, ICU, dialysis
- Elimination of glucose reading errors due to haematocrit and other common interfering substances
- No calibration codes required