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Products For Health Care

## Preparation and Value Assignment Process for Calibrator Solutions used with Medica's Instruments

International standards (ISO 17511) call for metrology traceability as shown in the attached chart.

There is no "primary calibrator" (item c) that matches Medica's unique formulation for calibrant A and Calibrant B for the ISE module Na/K/Cl/Li and EasyElectroLytes (EEL) Na/K/Cl/Li analyzers. Additionally, Medica has no access to a "primary reference measurement procedure" (item b) that will compare Medica's uniquely formulated solutions to a "primary calibrator" (item c) of different formulation.

Medica's traceability program starts with the preparation of "secondary calibrators" (item e). These calibrators utilize chemicals of the highest purity available in the market and have the same unique formulation as the ISE module and EEL calibrants A and calibrants B. Following a "manufacturer's (Medica's) selected measurement procedure" (item f) we release for use to our Manufacturing and Quality Control departments a "manufacturer's working calibrator" (item g). Manufacturing prepares and Quality Control tests the "manufacturer's product calibrator" (item i) following established "manufacturers standing measurement procedures" (item h).

Finally, the end-user measures a "routine sample" using the "end-user's routine measurement procedure" (item j), which is the Applications manual of the ISE module and the Operator's manual of the EEL analyzers.

The process described above may be used in place of a Traceability Certificate for the purpose of registering Medica's instruments, sensors, calibrants and other consumable items as needed.

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Title: Director of QA/RA  
Date: September 13, 2005

Signature: Photios Makris

### Traceability Matrix for Medica's calibrators

- QA Secondary calibrator (e): Use 99.9% pure salts (ACS grade) to match actual calibrator formulation. The active ingredients are NaCl, LiCl and KCl, which are dried at 105°C overnight and placed in a desiccator until use. Use analytical precision balance ( $\pm 0.0001$  gr) to weigh the salts into a class a volumetric flask. Add water half way into the flask, dissolve salts, and bring the DI water level to the line using a pipet.
- QA Measuring Procedure (f): Test new "secondary Calibrator" against a previous lot with an accuracy specification of  $\pm 0.5\%$  ( $\pm 1.0\%$  for Li). Analyze the two sets of calibrators ten times alternating between samples. Calculate the mean, standard deviation, and coefficient of variation (CV%) for each set. The calculated CV for Na, K, Cl shall be below 0.3% (0.5% for Li) and the difference in the calculated means shall be equal or less than 0.5% (1.0% for Li) of the nominal values for Na, K, and Cl.
- Mfg/QC Working Calibrator (g): If new secondary calibrator meets specifications, aliquot into small vials and label accordingly. Adapt as a working calibrator and transfer vials to Manufacturing and Quality Control for in-process use.
- Standing measuring procedure (h): Compare calibrators made by manufacturing to secondary calibrator with an accuracy specification of  $\pm 0.5\%$  ( $\pm 1.0\%$  for Li).
- Product Calibrator ((i): Fill Mfg. calibrator into reagent modules and test again by QC against the secondary calibrator with an accuracy specification of  $\pm 1.0\%$  ( $\pm 2.0\%$  for Li).

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## QC RESULTS

LAST CONTROL  
QC LEVEL 1  
FEB-06  
Na<sup>+</sup> 138.0  
K<sup>+</sup> 3.6  
Cl<sup>-</sup> 105.0  
FEB-06-23: 15:40

LAST CONTROL  
QC LEVEL 3  
FEB-06  
Na<sup>+</sup> 120.0  
K<sup>+</sup> 2.75  
Cl<sup>-</sup> 86.7  
FEB-06-23: 15:41

Qc-1 Na<sup>+</sup> → 134-144  
Range K<sup>+</sup> → 3.3-3.9  
Cl<sup>-</sup> → 97-107

Mean: Na<sup>+</sup> → 139 mmol/L  
K<sup>+</sup> → 3.6 mmol/L  
Cl<sup>-</sup> → 102 mmol/L

Qc-3 Na<sup>+</sup> → 114-124  
Range K<sup>+</sup> → 2.4-3.0  
Cl<sup>-</sup> → 77-89

Mean: Na<sup>+</sup> → 119 mmol/L  
K<sup>+</sup> → 2.7 mmol/L  
Cl<sup>-</sup> → 83 mmol/L

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EasyElectrolytes

CALIBRATION

SLOPES

Na <sup>+</sup>	58.72	nV/decade
K <sup>+</sup>	58.69	nV/decade
Cl <sup>-</sup>	51.95	nV/decade

\*CAL A MOVED\*

REAGENT MODULE  
STATUS

052%, 105 days

FEB-06-23; 08:37

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