MEDICA

IVD CE

EASYELECTROLYTES $Na^+/K^+/Li^+$ REAGENT PACK
REF 4103

INTENDED USE

The EasyElectrolytes $Na^+/K^+/Li^+$ Reagent Module is intended for the quantitative determination of sodium (Na^+), potassium (K^+) and lithium (Li^+) in human serum, plasma, whole blood and urine (urine results for Na^+ and K^+ only) using the MEDICA EasyElectrolytes™ Analyzer.

For professional use only. For *in vitro* diagnostic use only.

SUMMARY AND EXPLANATION

Electrolyte measurements in biological fluids were traditionally performed using flame photometry. The development of selective organic compounds for sodium, potassium, lithium and other electrolytes has permitted the development of sensors capable of the direct measurement of biological fluids throughout the physiological range. These sensors are known as ion-selective sensors.

Sodium is the major cation in extracellular fluid and has a major effect on osmotic pressure and water distribution between cells, plasma and interstitial fluid. Low sodium imbalance (Hyponatremia) is associated with diarrhea, server polyuria, metabolic acidosis, Addison's disease and renal tubular disease. High sodium imbalance (Hypernatremia) is associated with hyperadrenalism, severe dehydration, brain injury, diabetic coma and excess treatment with sodium salts.

Potassium is a major cation in intracellular liquid. Potassium imbalance has a direct effect on muscle irritability, myocardial function and respiration. Some conditions that effect potassium levels in blood include hypoaldosternism, diarrhea, vomiting and therapy with diuretics for hypertension or cardiac disease. Unlike sodium, there is no mechanism to maintain a threshold potassium level in the body.

Lithium is not present in healthy people and it is not metabolized. However it is administered in the form of a carbonate salt to control manic-depressive disorders. It is believed that lithium medications affect the central nervous system neurotransmitters, as well as the kidneys. Excessive levels of lithium may cause lithium toxicity.

PRINCIPLE OF THE PROCEDURE

The EasyElectrolytes analyzer measures sodium, potassium and lithium in human serum, plasma, whole blood and urine (urine results for Na^+ and K^+ only) using ion-selective electrode technology. The flow-through sodium electrode uses a selective membrane that is specially formulated to be sensitive to sodium ions. The potassium and lithium electrodes employ a similar design with appropriate selective membrane materials. The potential of each electrode is measured relative to a fixed and stable voltage that is established by the double-junction silver/silver chloride reference electrode. An ion-selective electrode develops a voltage that varies with the concentration of the ion to which it responds. The relationship between the voltage developed and the concentration of the sensed ion is logarithmic, as expressed by the Nerst equation:

$$E = E^{o} + \frac{RT}{nF} \text{Log (g C)}$$

where: E = The potential of the electrode in sample solution
E^o = The potential developed under standard conditions
RT/nF = A temperature dependent “constant”, termed the slope(s)
n = 1 for sodium, potassium, lithium
Log = Base ten logarithm function
g = Activity coefficient of the measured ion in the solution
C = Concentration of the measured ion in the solution

REAGENTS

Na/K/Li Reagent Module (REF 4103)

Calibrant A Solution, 960mL
140.0 mmol/L Na^+
4.0 mmol/L K^+
1.00 mmol/L Li^+
Buffer
Preservative
Wetting Agent

Calibrant B Solution, 500mL
70.0 mmol/L Na^+
8.0 mmol/L K^+
0.41 mmol/L Li^+
Buffer
Preservative
Wetting Agent

Waste Container

PRECAUTIONARY STATEMENTS

When used, the Reagent Module contains human body fluids and is considered biohazardous. Handle and dispose of the Reagent Module using the same precautions as with any biohazardous material. Discard according to local regulations.

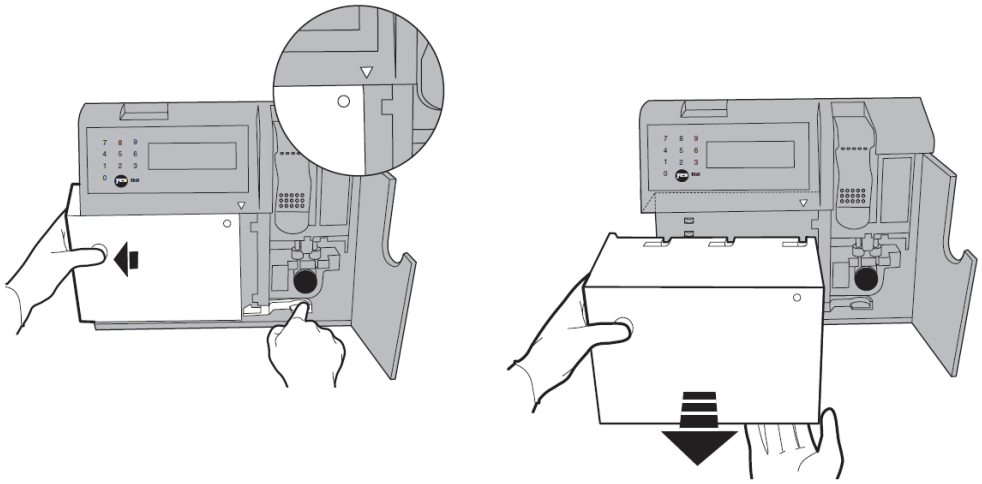
INSTRUCTIONS FOR REAGENT MODULE HANDLING, STORAGE AND STABILITY

The Reagent Module is ready to use as supplied. The unopened Reagent Module is stable until the install-by date listed on the label if stored at 4–25°C. After installation, the Reagent Module is stable on-board the EasyElectrolytes analyzer for 140 days. DO NOT FREEZE.

REMOVAL OF USED REAGENT MODULE

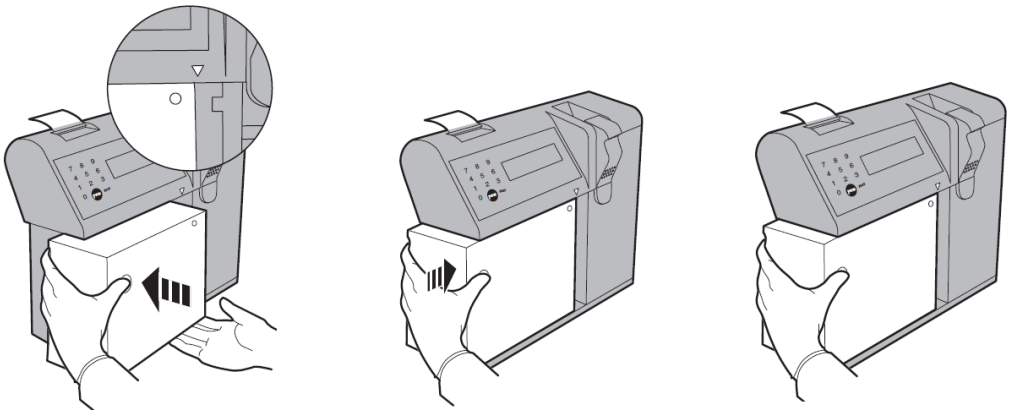
Follow standard laboratory precautions when removing a used Reagent Module.

To replace the Reagent Module, go to the **SECOND MENU** and press yes to **REPLACE COMPONENTS?**, then press yes to **REAGENT MODULE**. Fluid is automatically purged from the sample flow path. Open the access door and push in the reagent module release lever while holding the Reagent Module on the left side. Pull the module to the left. When the guide arrow points to the right edge of the Reagent Module, pull the module straight out from the front of the EasyElectrolytes analyzer. Dispose of the used Reagent Module according to local regulations.



INSTALLATION OF NEW REAGENT MODULE

Remove the new Reagent Module from the shipping container. Place the new Reagent Module into the front of the analyzer. The guide arrow must point to the right edge of the Reagent Module. Push the module straight back, then firmly to the right to lock it into place against the valve module until you hear a click. Press yes to **REPLACEMENT COMPLETE?**. The reagents are automatically primed from the Reagent Module. When priming is complete, the display indicates the detection of each fluid with **PASS**, then automatically returns to the **REPLACE COMPONENTS** screen.



The Reagent Module contains encoded information, which is read by the analyzer upon installation of the Reagent Module. This information includes: reagent Na^+, K^+ and Li^+ values and the install-by date of the reagent module.

ADDITIONAL INFORMATION

See EasyElectrolytes Operator's Manual for detailed information and performance data.

Medica Corporation, 5 Oak Park Drive
Bedford, MA 01730-1413 USA

EC REP Emergo Europe, Prinsessegracht 20
2514 AP The Hague, The Netherlands