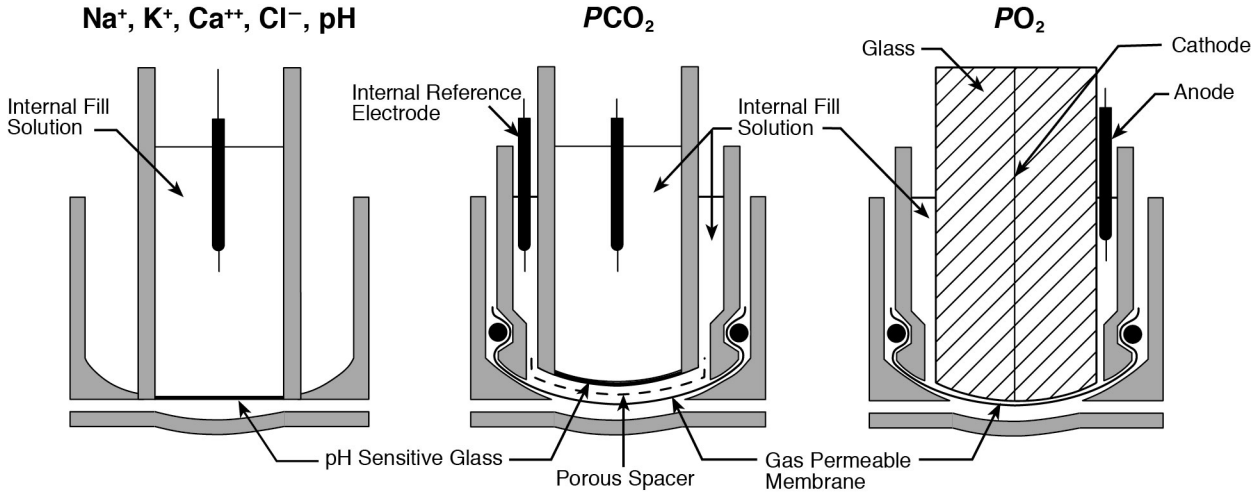
MEDICA

IVD CE

EASYSTAT REAGENT MODULE
REF 7101

INTENDED USE
The EasyStat Reagent Module is intended for the quantitative determination of pH (hydrogen ion activity), PCO_2 (partial pressure carbon dioxide) and PO_2 (partial pressure oxygen), hematocrit (Hct), sodium (Na^+), potassium (K^+), calcium (Ca^{++}) and chloride (Cl^-) on whole blood samples using the MEDICA EasyStat® Analyzer.

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



Note: pH Sensitive Glass not used on Na^+, K^+, Ca^{++} and Cl^- electrodes.

High levels of pH (metabolic alkalosis) are caused by gastrointestinal loss of hydrogen ions, Bartter's syndrome, cystic fibrosis and other extracellular fluid volume disorders. Low levels of pH (metabolic acidosis) are caused by lower levels of bicarbonate concentration (primary bicarbonate deficit) associated with an overproduction of organic acids such as lactic acidosis, diabetic ketoacidosis and alcoholic ketoacidosis.

High levels of PCO_2 (respiratory acidosis) are associated with decreased alveolar ventilation, hypoventilation and other pulmonary disorders. Low levels of PCO_2 (respiratory alkalosis) are associated with encephalitis, anxiety, hypoxia as well as other disorder that increase stimulation of the respiratory system.

High levels of PO_2 are associated with inhaling oxygen-enriched air. Low levels of PO_2 are associated with congestive heart failure, acute pancreatitis, preeclampsia and other pulmonary disorders including pneumonia, asthma and emphysema.

High levels of Hct are associated with dehydration, impaired hemoglobin function, cardiovascular disorders and renal disorders. Low levels of Hct are associated with hemolytic anemias as from immunological causes, abnormalities of the RBC membrane or enzyme deficiencies, iron deficiency and deficiency of vitamin B12 or folate.

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.

Ionized calcium is the only physiologically active form of calcium. Increased or decreased levels of ionized calcium are directly related to hyperparathyroidism and hypoparathyroidism respectively. Calcium regulates muscle contraction, hormone secretion and membrane permeability. Acidosis (low pH) causes an increase in the amount of ionized calcium and alkalosis (high pH) causes a decrease in the amount of ionized calcium.

Chloride is the major extracellular anion and it has a direct effect on osmotic pressure, water distribution and anion-cation imbalance. Low chloride levels are caused by chronic pyelonephritis, Addisonian crisis, metabolic acidosis and prolonged vomiting. High chloride levels are observed in dehydration, congestive heart failure, hyperparathyroidism and extensive treatment with or intake of chloride.

Two standard solutions are used to calibrate the hematocrit sensor. The analyzer then measures the electrical impedance of the blood sample to obtain the hematocrit value. Next, the hematocrit value obtained is corrected for the concentration of the sodium ion.

REAGENTS

EasyStat Reagent Module (REF 7101)

Calibrant A Solution, 720mL
7.30–7.50 pH
30–40 mmHg CO_2
125–175 mmHg O_2
135–145 mmol/L Na^+
3.5–4.5 mmol/L K^+
1.1–1.5 mmol/L Ca^{++}
105–115 mmol/L Cl^-
Buffer
Preservative
Wetting Agent

Calibrant B Solution, 415mL
6.80–7.00 pH
66–76 mmHg CO_2
0 mmHg O_2
80–85 mmol/L Na^+
9.0–11.0 mmol/L K^+
Buffer
Preservative
Wetting Agent

Calibrant C Solution, 555mL
2.4–3.1 mmol/L Ca^{++}
32–38 mmol/L Cl^-
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.

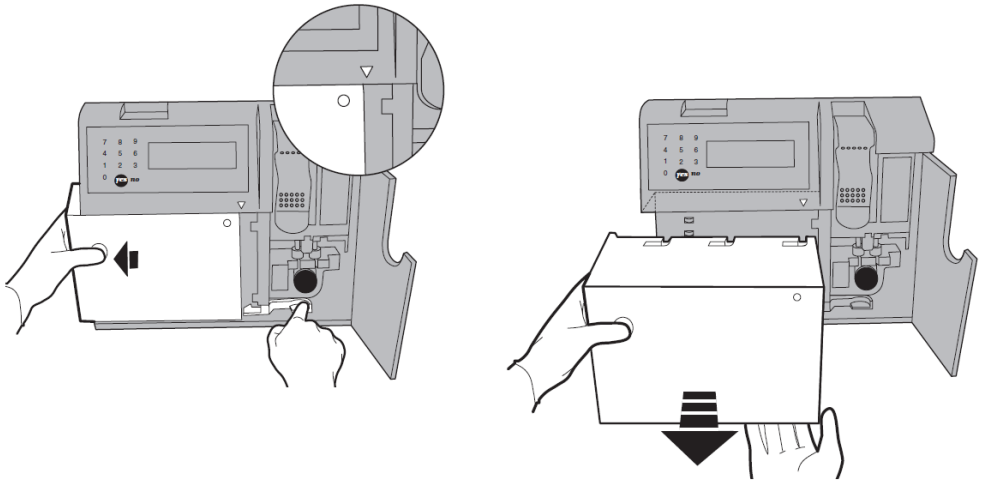
INSTRUCTIONS FOR REAGENT MODULE HANDLING, STORAGE AND STABILITY

The Reagent Module is ready to use as supplied. Unopened, the Reagent Module is stable until the install by date listed on the label if stored at 4–25°C. Once installed, the Reagent Module is stable on-board the EasyStat analyzer for 35 days. DO NOT FREEZE.

REMOVAL OF USED REAGENT MODULE

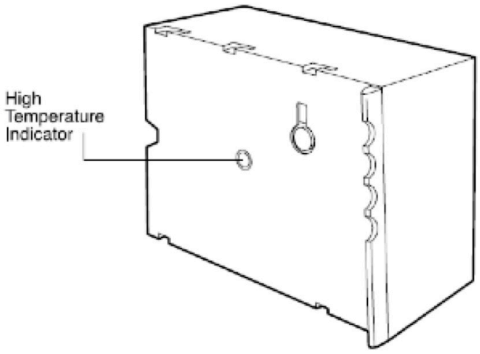
Follow standard laboratory precautions when removing a used Reagent Module.

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. The display prompts you to **REMOVE REAGENT MODULE**. 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 EasyStat analyzer. Dispose of the used Reagent Module according to local regulations.

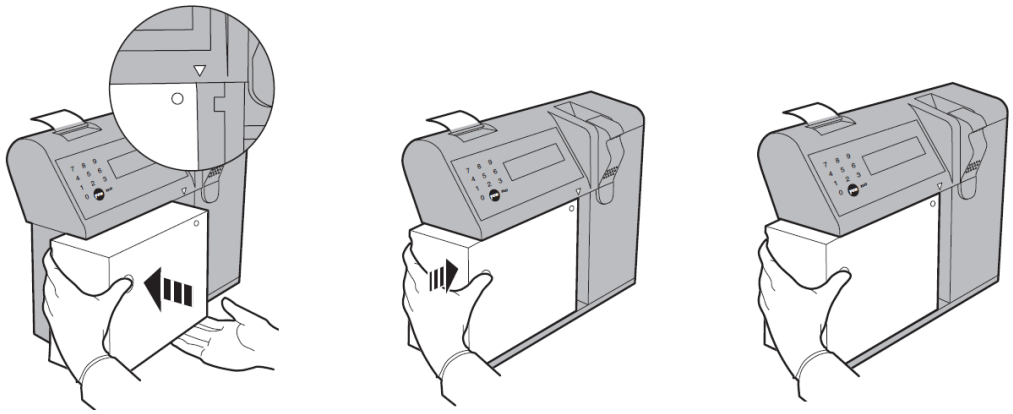


INSTALLATION OF NEW REAGENT MODULE

NOTE: Prior to installation of a new Reagent Module, it must be stored at room temperature for a minimum of four (4) hours. When the indicator on the back of the Reagent Module is blue, the module has been exposed to excessive temperature and must not be used.



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 pH, PCO_2, PO_2, Hct, Na^+, K^+, Ca^{++}, and Cl^- values, and install by date of the reagent module.

ADDITIONAL INFORMATION

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

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