MEDICA

IVD CE

EASYBLOODGAS REAGENT MODULE
REF 6101

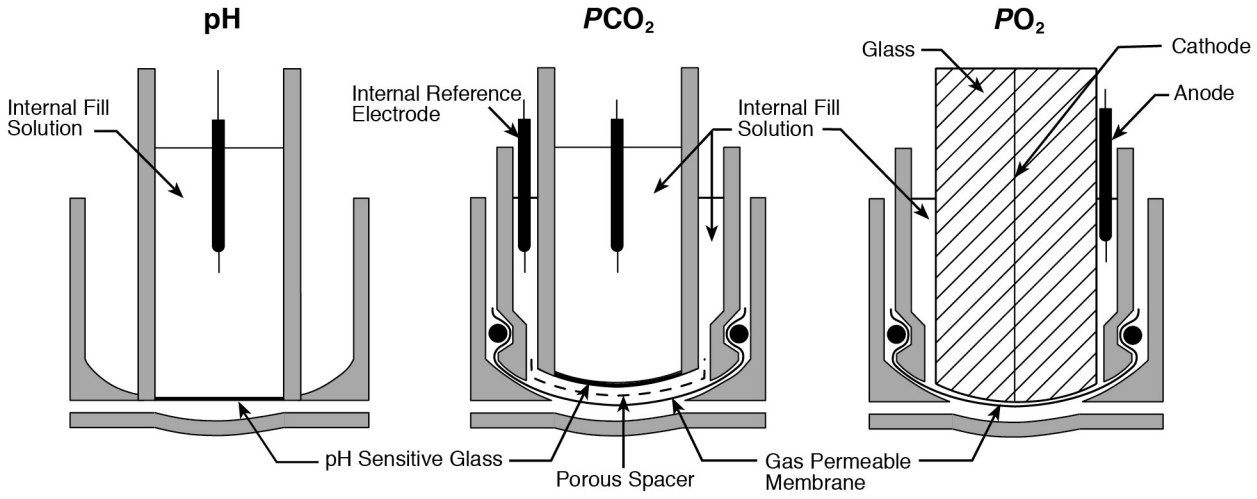
INTENDED USE

The EasyBloodGas 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) on whole blood samples using the MEDICA EasyBloodGas™ Analyzer.

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

SUMMARY AND EXPLANATION

The PO_2 electrode is electrically independent from the other electrodes during measurements. The PCO_2 electrode has an internal reference electrode that is used during measurements, and is also independent from the other electrodes. The pH electrode makes all measurements relative to the reference electrode.



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 and other disorders 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.

REAGENTS

EasyBloodGas Reagent Module (REF 6101)

Calibrant A Solution, 550mL
7.30–7.50 pH
30–40 mmHg CO_2
125–175 mmHg O_2
Buffer
Preservative
Wetting Agent

Calibrant B Solution, 300mL
6.80–7.00 pH
66–76 mmHg CO_2
0 mmHg O_2
Buffer
Preservative
Wetting Agent

Rinse Solution, 700mL
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.

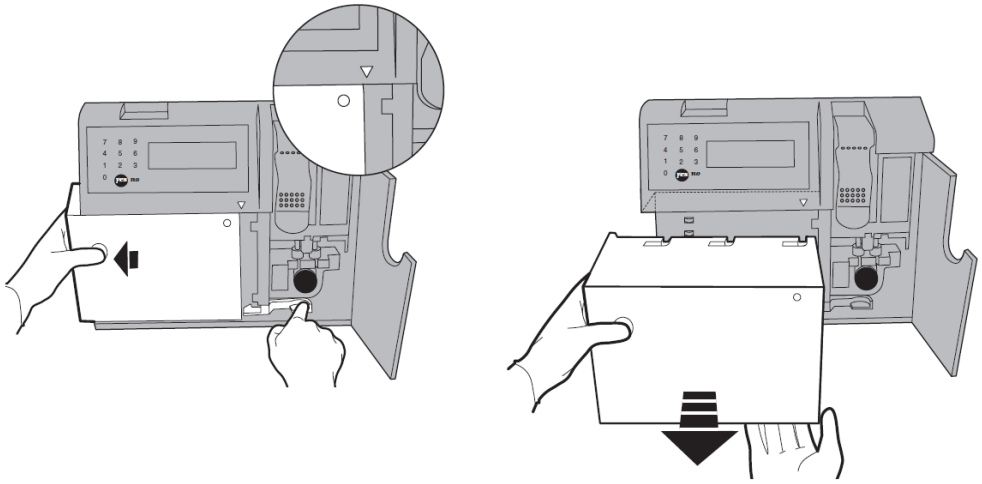
INSTRUCTIONS FOR REAGENT MODULE HANDLING, STORAGE AND STABILITY

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 EasyBloodGas analyzer for 45 days. DO NOT FREEZE.

REMOVAL OF USED REAGENT MODULE

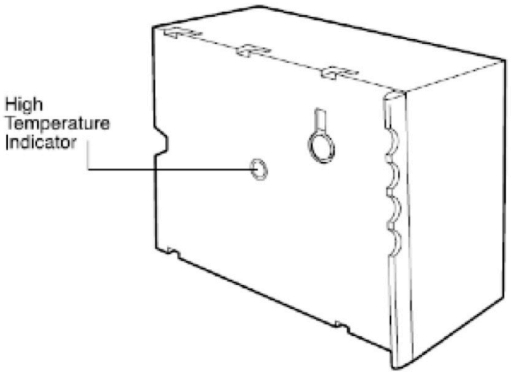
Follow standard laboratory precautions when removing a used Reagent Module.

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 EasyBloodGas analyzer. Dispose of the used Reagent Module according to local regulations.

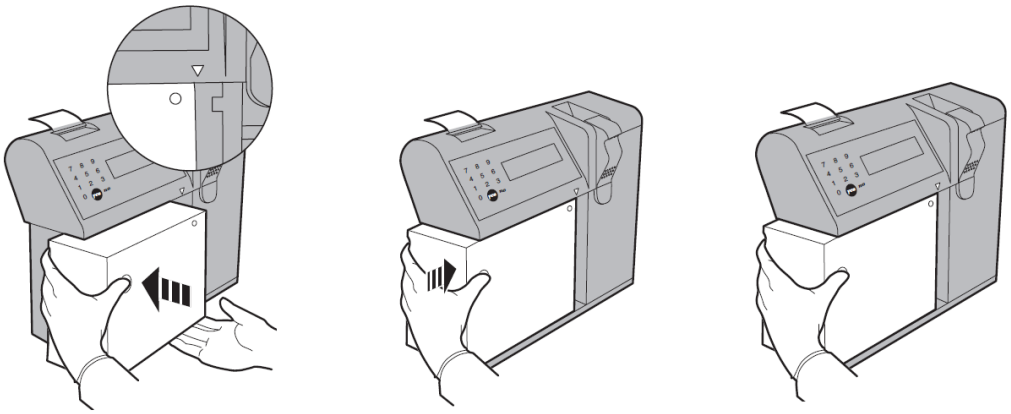


INSTALLATION OF NEW REAGENT MODULE

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 and PO_2 values and the install-by date of the reagent module.

ADDITIONAL INFORMATION

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

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