

03-July-2019

To whom it may concern

The **epoc Blood Analysis System** is intended for use by trained medical professionals as an in vitro diagnostic device for the quantitative testing of samples of heparinized or un-anticoagulated arterial, venous, or capillary whole blood in the laboratory or at the point of care.

The **Blood Gas Electrolyte and Metabolite (BGEM) Test Card** panel configuration includes sensors that quantitate pH, pCO<sub>2</sub>, pO<sub>2</sub>, Sodium, Potassium, Ionized Calcium, Chloride, Total Carbon Dioxide, Glucose, Lactate, Blood Urea Nitrogen, Creatinine, and Hematocrit.

In response to your question Siemens Healthineers is providing the following response.

The epoc System requires the epoc BGEM Test Card to operate. Siemens Healthineers is the only manufacturer of this product and only authorized representatives may sell this product.

Each BGEM Test Card is barcoded with lot specific information and test card type. The system runs proprietary software and internally scans each test card. The system is a closed system and does not accept any third party test card(s).

Thank You,



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