epoc® Blood Analysis System – Implementation/Installation Checklist (United States Only)

(for US customers performing installations of 10 or less instruments or other installations not performed by Siemens Healthineers Implementation group)

Account:	SN:
Address:	Software Ver:
	LIS:
Contract:	

PRE-IMPLEMENTATION	Date COMPLETED
- Register for Document Library (www.siemens.com/document-library) as per Product Update 51016458 to access instrument documentation such as Customer Bulletins, Manuals, Safety Datasheets, Value Assignment Datasheets, and software upgrade files.	
- Register for PEPconnect (https://pep.siemens-info.com/en-us/epoc-system) It is recommended to complete the available training videos especially: - System Overview - Sample Processing - Quality Control	
- Register for LifeNet (https://lifenet.siemens-healthineers.com/welcome). LifeNet allows you to manage the performance and maintenance of your Siemens Healthineers equipment, 24/7, from any device.	
- Identify the primary operator(s) and system administrator for training.	
- Identify which analytes, units of measure, reference, and critical ranges will be reported.	
- Determine what verification requirements need to be performed per Regulatory/Facility requirements. For instance, For ABGs only, CAP requires a minimum of two levels of BGEM QC (I and III) and TJC requires three levels (I, II, and III) of control. All other analytes will require at least two levels (I and III) of BGEM QC. - Number of samples: Number of QC Levels and/or Calibration Verification Fluid, Test Cards (*epoc System Manual* (51012382): sections 9.2.3 and 9.3.1). - Syringes (see *epoc System Manual* (51012382): section 9.4.7 for QC; section 12.2.6 for blood). - Collection of samples: - Obtain samples that span reportable range. - Identify how specimens will be handled and run.	

INSTRUMENT INSTALLATION	Date COMPLETED
- Charge epoc Reader following *Quick Start Guide* (51000848).	
- Charge epoc Host and connect to Wi-Fi (if required for connecting to a data manager) following the *Quick Start Guide* (51005527).	
- Update the epoc Host Software following the options in *How to Update epoc Host Software and eVAD file* (51015397).	
- Install eDM Lite (if applicable) and connect Host following *eDM Lite User Guide* (51009017)	

HOST CONFIGURATION	Date COMPLETED
Host configuration options are found in sections 6 and 7 of epoc System Manual (51012382)	
- Set current date and time (section 6.7).	
- Create user accounts for Administrators/Operators/Operators authorized for QC testing and SW upgrades (section 6.9).	
- Set Administrator Options (section 7.7).	
- Set Barcode Options (section 7.8).	
- Sample Type Selection (section 7.10.10).	
- Enable analytes to be reported, set reportable ranges, and units of measure (sections 7.10.2 and 7.10.3).	
- Set Reference Ranges (section 7.10.4).	
- Set Critical Ranges (section 7.10.5).	
- For hematocrit results, apply Hemodilution Correction Factor (HCF) setting (as applicable) as per section 7.11. **Warning: Follow the healthcare institution requirements for configuring the HCF setting on the epoc Blood Analysis System. For patients that are hemodiluted, failure to apply the correct HCF setting may result in discrepant low hematocrit values.** Further details on HCF can be found in Product Bulletin 51017034.	
- If desired, install the electronic Value Assignment Datasheets (eVAD) using any approved Data Manager or Live Update Service. Refer to *epoc System Manual (51012382), Appendix E "User Guide: Enhanced QA Features for the epoc System"* and *How to Update epoc Host Software and eVAD file* (51015397) for more details on obtaining and using eVADs	
- Additional configuration options, such as Enforce Critical Handling, use of expired cards for training purposes, and saving raw data can be found in section 7 of *epoc System Manual (51012382).*	
QUALITY CONTROL	Date COMPLETED
- Perform Quality Control according to your facility's internal quality control procedures and regulatory requirements.	
- Review *Technical Bulletin: Control Fluid Use and Handling* (51015946).	
- Review *epoc CLSI Procedure Manual* (51008148).	
- Review the *IQCP Risk Assessment and Quality Control Plan* template for the epoc System (51010379).	
- Perform verification of epoc Reader performance - Thermal QA (*epoc System Manual* (51012382), *section 9.2.2*).	
- Calibration Verification & Accuracy Study – To verify the accuracy of the epoc System the calibration verification levels listed below should be analyzed once on each epoc reader: 1. epoc Eurotrol Calibration Verification fluids: All Levels (1-5) 2. epoc Hematocrit Calibration Verification fluids: All Levels (1-5) Value Assignment Data Sheets (VAD) for <u>single</u> Calibration Verification values can be found on Document Library or are available electronically (eVAD) when configured. *Note:* The account may require duplicate or triplicate Calibration Verification testing in which case the averages can be taken and recorded; please contact the Remote Service Center to obtain the appropriate Value Assignment Datasheets (VAD). Additionally, the following Calibration Verification fluids may be used:	

1. epoc Eurotrol Calibration Verification Level 6 for TCO_2 verification. 2. Eurotrol Hypoxic QC and Hyperbaric QC to verify the low and high end of the pO2 reportable range. *Note:* Fluids to be ordered directly from Eurotrol.	
- Precision - Precision studies consist of a minimum 20 tests with each of two levels (Level 1 and Level 3) of epoc Eurotrol GAS-ISE Metabolite QC fluids and two levels of epoc Eurotrol Hematocrit Controls (Level A and Level B). This study (40 total for ISE only & 80 total if Hct is included) can be performed over multiple analyzers for efficiency. Test Level 1 and Level 3 of the epoc Eurotrol GAS-ISE Metabolite QC fluids and levels A & B of the epoc Eurotrol Hematocrit Controls fluids on each additional epoc reader not included in the precision study above. The results shall be evaluated against the limits published in the appropriate Value Assignment Datasheets (VAD). Acceptable CVs for precision are determined by the facility as per requirements. *Note:* Total imprecision may want to be compared to the typical performance data for various analyte concentrations. Imprecision data should be statistically equivalent to typical imprecision performance data presented in the *epoc System Manual (51012382), section 12 "BGEM Test Card Specifications".*	
- Method Comparison, as needed - The objective is to estimate the average differences and the distribution of differences between results from the epoc System and results from the comparative method(s) using fresh, whole blood patient samples. The customer account will dictate the actual required number of comparison samples needed for each analyte. However, it is recommended to run a minimum of 20, but preferably 40, patient samples on epoc (preferably on two side by side systems) as well as current reference method(s). The goal, where possible, is to try to span the reportable range for each analyte. Refer to *CLSI EP09-A3 guidelines* and *Performance Verification Study for epoc System* (51009392).	
- Set Enhanced QA options (Appendix E of epoc System Manual 51012382).	
TRAINING	Date COMPLETED
- Complete recommended training in PEPconnect, including competency checklist and knowledge assessment.	
- Confirm registration of Document Library.	
- Review sample collection and handling videos for both syringes and capillaries (PEPconnect).	
- Review *Technical Bulletin: Control Fluid Use and Handling* (51015946).	
- Review *Product Update – Decontamination Procedure for epoc System* (51015147) and the *epoc System Manual (51012382), section 10 "Care and Maintenance of epoc System".*	
- Review the *epoc System Manual (51012382)* available in Document Library.	
- Confirm that primary operator has read and understood the provided materials.	

Questions

If you have any questions, please contact Siemens Healthineers Remote Services Center at 877-229-3711 Option 12 and then Option 5.