epoc Blood Analysis System

epoc CLSI Procedure Manual with epoc Host²

51008148-EN Rev: 11

This is a template and does not replace the epoc® System Manual.

TABLE OF CONTENTS

Procedure #:

epoc Blood Analysis System Procedure Manual

Prepared By	Date Adopted	Supersedes Procedure #

Review Date	Revision Date	Signature

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This Procedure Manual is intended to provide a ready outline reference for performance of the assay. These abbreviated directions for use are not intended to replace the complete package insert. It is the obligation of every manufacturer of medical devices labeled FOR *IN VITRO* DIAGNOSTIC USE to provide a complete package insert in accordance with FDA labeling regulation (21 CFR 809.10). Prepared in accordance with the guidelines recommended by the Clinical and Laboratory Standards Institute, Wayne, PA 19087; CLSI Document GP02-A2.

Epocal Inc. provides epoc System Procedure Manuals for your use. The Procedure Manuals are required to include the same information as listed in the package insert. Any modifications to this document are the sole responsibility of the Laboratory.

epoc BGEM Test Card

CLIA Complexity: MODERATE

INTENDED USE

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

SYSTEM OVERVIEW

The epoc Blood Analysis System is a portable blood analyzer that consists of three components: epoc Reader, epoc Host mobile computer, and epoc Test Card. These components work together to provide blood test results in under a minute. Test results may be collected and managed by a data management system, such as the EDM or another data manager compatible with the epoc System.

The epoc Reader

- Is a battery powered portable device
- Has an internal barcode scanner
- Has card slot for accepting test card
- Reads epoc Test Cards during blood test
- Has status indicators to inform user of test progress
- Measures electrical signals from test card sensors
- Transmits test results wirelessly via Bluetooth® to the epoc Host

The epoc Host[2]

- Is a dedicated use mobile computer with epoc Host software application installed
- Communicates wirelessly via Bluetooth with epoc Reader
- Calculates analytical values from sensor data sent by epoc Reader
- Displays test results

The epoc Test Card

- Is a single-use device with port for blood sample introduction
- Contains array of sensors on a sensor module
- Contains calibration fluid within sealed reservoir
- Generates electrical signals proportional to analyte concentrations in sample
- Uses barcode to identify card type, “Use By” date, serial and lot number

The Data Manager

- Is a software program used with the epoc System to collect and manage Test Results and other information from epoc Hosts

SUPPLIES AND STORAGE REQUIREMENTS

epoc Test Cards

epoc Test Cards should be stored at room temperature (15°C – 30°C), but they may be transported by the distributors at lower temperatures (2°C – 30°C), provided transportation times do not exceed eight (8) days.

Never use Test Cards shipped outside the specified temperature limits (2°C – 30°C).

Never subject Test Cards to excessive shock (dropping, throwing, shaking) during shipping, handling, or storage.

Never use a Test Card if the card pouch seal has been compromised in any way.

Quality Control Fluids

Aqueous Blood Gas, Electrolyte, Metabolite, and/or Hematocrit Control Fluids are commercially available for verifying integrity of newly received test card lots.

Follow the Manufacturer's storage and handling instructions.

If ampoules are taken from cool storage, equilibrate the ampoules to Room Temperature (20°C – 25°C). Equilibration time for blood gas QC Fluids is four (4) hours minimum for a full box, and one (1) hour for single ampoules outside of the box.

epoc Reader

- The Reader can be operated between 15°C – 30°C. There is an internal ambient temperature monitor that will disable the Reader function if room temperature falls outside of this range. A Reader brought in from a warm or cool environment, such as during shipment, should be allowed to equilibrate before being used.
- The Reader can be operated at atmospheric pressures between 400 – 825 mmHg. There is an internal barometric pressure sensor that monitors this and will disable the Reader function if the atmospheric pressure is outside of this range.
- The Reader must be used in relative humidity of less than 85% at 30°C, non-condensing. The Reader's electronic QC checks leakage current within the Reader to detect compromised performance due to high humidity.
- The Reader is designed to be light and portable and easily transported to a testing location. However, the Reader must rest on a flat horizontal surface without movement for the duration of the test.
- Always keep the epoc Reader in a dry location. Immediately wipe away any liquids on the outside Reader surfaces (using appropriate Biohazard protection). Always follow the recommended cleaning procedure.
- Never sterilize or autoclave any part of the epoc System.

CLEANING

Please follow the cleaning procedures below when caring for the epoc System. Deviations from these instructions can lead to irreparable damage to the device.

Do not expose any Host cradle or Reader pivot electrical contacts to cleaning solutions. In the event that electrical contacts are exposed to liquids, ensure they are dry before cradling the Host with the Reader.

Never submerse the epoc Reader and epoc Host into any liquid. Never allow fluids to pool in Pivot or Membrane Switch areas.

Never apply liquid directly anywhere onto the internal or external areas of the epoc Host or Reader.

General Cleaning Methods

Do not allow any liquid to enter the epoc Reader or epoc Host and come in contact with the electrical components.

Wipe epoc Reader and epoc Host using a damp soft cloth or gauze pad with one of the following:

- Mild detergent or non-abrasive cleaner;
- Alcohol;
- Soap and water.

Note: If you are uncertain about the compatibility of a specific cleaning or decontamination agent, contact your service representative.

Cleaning Devices After They Come in Contact with Blood

The following procedure may be used to clean the epoc Reader or epoc Host when either of the devices may come in contact with blood or other contamination.

Method 1: With Bleach

Requirements:

- 10% household bleach solution
- Wipes or gauze pads
- Protective gloves

Wear appropriate gloves to perform the following procedure:

1. Prepare 10% household bleach solution (nine (9) parts tap water with one (1) part household bleach). It is recommended that the solution be prepared fresh daily.
2. Soak several gauze pads in the bleach solution. When removing a pad from solution, squeeze excess liquid, so that the pad does not drip.
3. Gently rub any areas of dried blood with one or more moist pads until they are soft enough to wipe clean.
4. After removing any stained areas, clean all surfaces twice with fresh pads soaked in the bleach solution. Ensure that the bleach solution is in contact with the surface for three (3) minutes before wiping it off and rinsing.
5. Rinse all surfaces using fresh pads soaked in warm tap water. Allow surfaces to dry before turning ”ON” any of the epoc System components.
6. Dispose of the used gauze pads in a biohazard disposal receptacle.

Method 2: With 70% Isopropyl Alcohol

Requirements:

- 70% isopropyl alcohol
- Wipes or gauze pads
- Protective gloves

Wear appropriate gloves to perform the following procedure:

1. Before use, remove excess solution from prepared wipes or gauze pads saturated in 70% isopropyl alcohol.
2. Gently rub any areas of dried blood or contamination with one or more moist pads until the stains are soft enough to wipe clean.
3. After removal of stained areas, clean all surfaces twice with fresh pads soaked in 70% isopropyl alcohol. Ensure the cleaned surface is wet with 70% isopropyl alcohol for at least five (5) seconds with each cleaning.
4. Discard pads after use in biohazard disposal containers according to the policies and procedures of your facility.

BLOOD SAMPLE COLLECTION

The epoc System is designed for point-of-care blood analysis. Test samples immediately after drawing a sample to obtain results that represent patient status with greatest accuracy. Always use ISO 80369-7 compliant syringe for sample introduction.

- The epoc System is intended to be used with fresh whole blood samples only. Do not use clotted samples.
- Always wear protective gloves when handling blood samples.
- The specimen used to fill a Test Card must be collected and handled properly to ensure that the results represent patient's current status.
- Blood samples must be collected according to the facility's policies and procedures.
- When anticoagulants are needed, use exclusively heparin for the anticoagulant.

Sample Type

Fresh whole blood from arterial, venous or capillary sources, introduced to the Test Card from a syringe or an epoc Care-Fill™ Capillary Tube. See “Sample Collection Details” below for the time periods when the blood is considered fresh and thus suitable for testing.

Sample Volume

At least 92µL.

Note: The epoc Care-Fill Capillary Tube capacity is 90 microliters plus the volume of air pushed behind the sample when the plunger is fully depressed, which brings it to over 92 microliters.

Tests and Sample Collection Methods

Test	Sample Collection Details		
	Syringes 1 or 3 mL plastic Without anticoagulant (must be run within 3-5 min) With Li or Na heparin With balanced heparin	Evacuated Tubes With Li or Na heparin Without anticoagulant must be run immediately. Note that clot activators may be present in some collection devices.	Capillary Tubes epoc Care-Fill Capillary Tubes only
pO_2	Non-iced syringes [1,9] Test in less than 30 min[1,9]	Not recommended[1]	Test in less than 5 min recommended
pH/pCO_2*	Test in less than 30 min[1,9]	Test in less than 30 min[1,9]	Test in less than 5 min recommended
TCO_2	Test in less than 30 min to avoid possible air contamination[31,32,33] and/or artifacts of metabolic activity[13,14]	Do not underfill*** Test in less than 30 min to avoid artifacts of metabolic activity [13,14]	Test in less than 5 min recommended
Ca++ ****	With Li or Na heparin only if <10 IU/mL[11] With balanced heparin only if <70 IU/mL[11] Test in less than 30 min to avoid artifacts of metabolic activity[1,9,11]	With Li or Na heparin only if <10 IU/mL[11] Tube should be filled to its nominal volume[11] Test in less than 30 min to avoid artifacts of metabolic activity[1,9,11]	Care-Fill capillary tubes contain 65 IU/mL of calcium balanced lithium heparin Test in less than 5 min recommended
Glu	Test in less than 30 min to avoid effects of glycolysis[13,14]	With Li or Na heparin only (do not use NaF) Test in less than 30 min to avoid effects of glycolysis[13,14]	Test in less than 5 min recommended
Lac	Test in less than 5 min to avoid effects of glycolysis[18]	With Li or Na heparin only (do not use NaF) Test in less than 5 min to avoid effects of glycolysis[18]	Test in less than 5 min recommended
Hct	Immediate testing is recommended in order to avoid RBC settling. *Note: Re-suspension of RBC requires an air bubble of significant volume*[22]	With Li or Na heparin only (do not use EDTA) Test in less than 1 h to avoid effects of glycolysis and electrolyte shifts[5]	Immediate testing is recommended in order to avoid RBC settling
All other tests	Test in less than 1 h to avoid effects of glycolysis and electrolyte shifts[5]	With Li or Na heparin** Test in less than 1 h to avoid effects of glycolysis and electrolyte shifts[5]	Test in less than 5 min recommended

* Non-iced samples recommended. Iced samples may cause increased pH internal quality control failures.

** Use of evacuated collection tubes containing Na heparin may cause a positive error on the sodium results.[10] See the subsection on sodium below for additional details.

*** Underfilling blood collection tubes may cause decrease of TCO_2 results. Always follow manufacturer recommendations for sample collection devices.

**** When using evacuated tubes with heparin, the tubes should be filled to their nominal volume. This will keep binding of calcium ions by heparin at a minimum and consistent level.[11]

Note: The effect of heparin salts on calcium binding is such that each 5 IU/mL of heparin lowers ionized calcium concentrations by about 0.01 mmol/L.[11] Standard evacuated blood collection tubes have a heparin concentration of ≤17 IU/mL.

PRINCIPLES OF THE TEST PROCEDURE

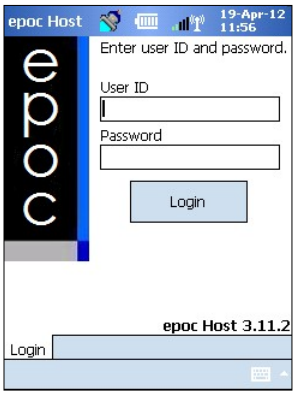
Starting a Blood Test

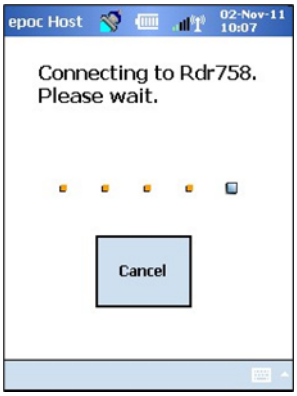
Cards brought from a warmer or colder storage environment (even within the same building) must be allowed to adjust to the same temperature as the testing room ambient temperature before use. The testing environment, epoc Reader, and epoc Test Cards must all be at the same temperature before conducting any testing. Only use the Test Cards that have been properly stored.

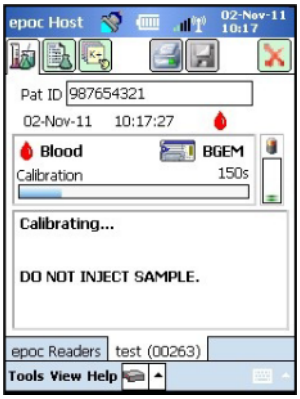
To complete a test, the following steps are required:

1. Turn "ON" the epoc Reader and epoc Host.
2. Start and log in to epoc Host software application.
3. Connect wirelessly to the epoc Reader from the epoc Host.
4. After Reader configuration is completed, remove a new Test Card from the pouch and immediately insert it into the epoc Reader. This will start the calibration period for the Test Card (the Reader will be flashing the green light, and the Host will display the message, "Calibrating… DO NOT INJECT SAMPLE").

Log in →Connect →Insert a card →Start calibration

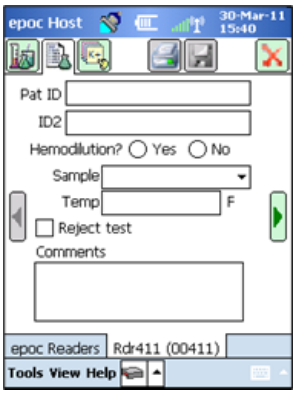


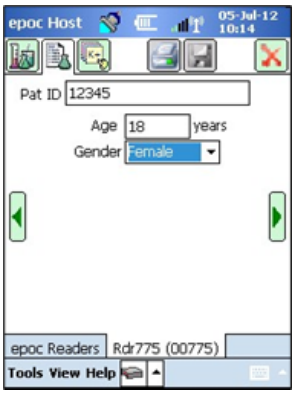


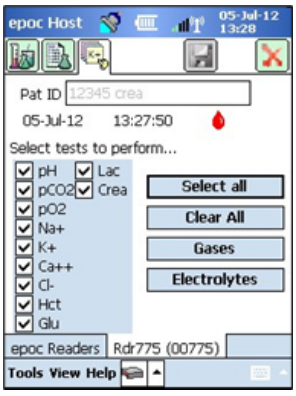


5. Use the 165-second calibration period to enter patient information, select tests and sample type (if applicable).
6. Collect a blood sample.
7. After calibration is complete, the green light on the Reader will turn steady and the Host will display "Inject Sample". Introduce the blood sample into the Test Card. Follow instructions below.

→Enter sample… →and patient info → Select tests → Inject sample







8. Observe and possibly print the Test Results.
9. Remove the Test Card and discard it as biohazard waste. Follow your facility's policy and procedure for the disposal of biohazardous materials.

Introducing the sample too soon or too late will cause an error and abort the test. A new Test Card must be inserted and the test procedure started again.

Once logged in and connected to an epoc Reader, steps 4 through 9 above are required to perform another test.

Sample Introduction

1. Hold the syringe barrel vertically between fingertips and thumb (Figure 1).

   Keep Syringe vertical and perpendicular to the Test Card to avoid sample spillage.

   Complete steps 2 and 3 below in one continuous motion to ensure best performance of sample introduction.

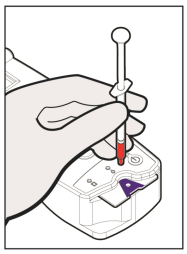


Figure 1

2. Using slight downward pressure, secure the syringe's luer tip into the center recess of the blood sample entry port of the Test Card. Rotate the syringe up to ¼-turn to ensure a good seal (Figure 2).

   You should feel the syringe tip engage with the rubber seal of Test Card entry port. Press the syringe with enough downward force to engage the syringe tip with the blue rubber seal.

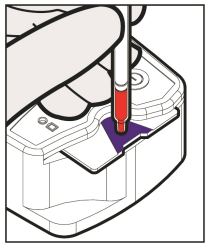


Figure 2

3. While maintaining downward pressure, use index finger of the other hand to steadily depress the syringe plunger with a single, smooth, continuous motion until prompted to stop (Figure 3).

   The Reader provides an audible beep and the Test Status Indicator flashes green indicating enough sample for analysis was received. The Host also displays sample acceptance.

   After the Reader has beeped, disengage the syringe from the Card by tilting it as opposed to pulling it straight up.

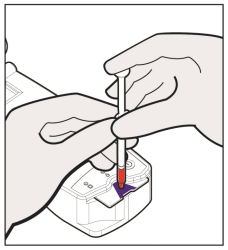


Figure 3

Learn to use the audio and visual feedback to perform this step easily and reliably. A normal dispense operation takes about one (1) second or less.

Sample introduction should never exceed two (2) seconds. Failure to head the audio or visual prompts may cause the sample to flow out of the card and possibly into the epoc Reader.

Avoid rapid sample introduction because it can cause fluid segmentation. This condition is detected by the system. The test is aborted and the Host displays an error message.

How to Inject Using a Capillary Tube:

<u>Note:</u> Where epoc Care-Fill Capillary Tubes are used, refer to Appendix C of the epoc System Manual with Host² or the Care-Fill Capillary Tube Package Insert for additional information.

1. Hold the capillary tube vertically by the large end of the adapter, insert it into the test card sample port, and rotate the adapter ¼-turn to ensure a good seal.
2. Maintain hold of the adapter and use the fingers of your other hand to forcefully push the plunger completely down in a single motion.
3. Continue to hold the plunger completely down while waiting for the Reader to beep.

After the Reader has beeped, disengage the capillary tube from the card by tilting it as opposed to pulling it straight up.

The sample may be introduced at any time during 450-second (or 7.5-minute) period after calibration. A screen bar indicates the remaining time. If the card's calibration times out, the card is no longer available to accept a sample.

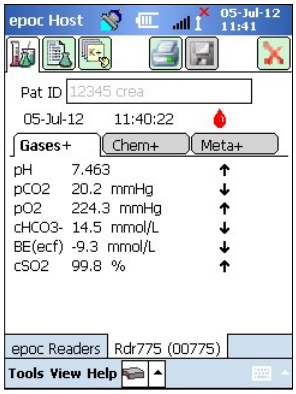
The Reader automatically analyzes the test sample. The analysis process takes approximately 45 seconds after sample introduction. The progress bar displays the progress of the test.

When a test is complete, three (3) Tabs 

show test results. Click on tabs to display each set of results data. Results displayed depend upon the Test Card type (see the bottom side of the Test Card) and tests selected.

Interpretation of Results

Test results are displayed grouped as gases, electrolytes, and metabolites. Temperature-corrected results are displayed in the first tab (Gases+) if the patient's temperature had been entered before the test was complete.



Test results for Gases+ include:	Test results for Chem+ include:	Test results for Meta+ include:
pH	Na+	Glu
pCO_2	K+	Lac
pO_2	Ca++	BUN, Urea
pH(T)	Cl-	Crea
pCO_2(T)	TCO_2, $cTCO_2$	GFRmdr, GFRmdr-a
pO_2(T)	AGap, AGapK	GFRckd, GFRckd-a,
$cHCO_3$-	Hct	GFRckd21
BE (ecf)	cHgb	GFRswz
cSO_2	BE (b)	BUN/Crea, Urea/Crea
A		
A-a		
a/A		
A (T)		
A-a (T)		
a/A (T)		

For each type of test result, messages appear if data cannot be determined or displayed:

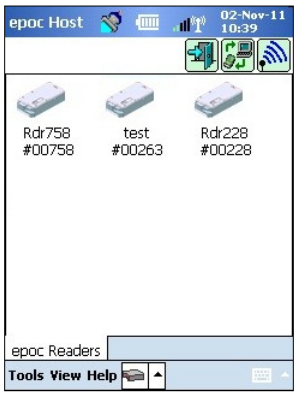
Message	Interpretation
cnc	Could not calculate. Component required for calculation was not available.
Failed iQC	Failed Internal Quality Control
expired	Card was expired. Results are not displayed.

If the patient test results seem inconsistent with the clinical assessment, a fresh patient sample should be collected and tested on another Test Card.

Certain substances, such as drugs, may affect the test results. See the lists of interferences for each analyte below.

If the Host has been configured to allow additional information to be recorded with the results, then the Clipboard button will be displayed next to the results. If one or more of the test results fall outside of its critical range and the Host has been configured to flag critical results, the result will appear in bold red with out-of-critical-range indicator and the Doctor button displayed. Tap the Clipboard button or the Doctor button (whichever is applicable) to access a new window with the Action dropdown containing selections for Notify physician, Notify RN, Repeated test, Sent to lab, Expected values, and Other.

Synchronization with a Data Manager



When using a compatible data manager, users can synchronize with the data manager as follows.

After disconnecting all Readers from running tests, test results can be sent to a data manager by pressing the data manager synchronization button on the Host. The epoc Host also retrieves configuration information such as operator lists by using this feature. Synchronizing with the data manager may also be accessed from the Tools menu, lower left corner.

The Administrator may configure the epoc Host to synchronize upon closing a test. In this configuration, synchronization with the data manager occurs immediately after the Reader Screen is closed at the end of a test.

Printing Test Results

Tap the Print button in the top right corner of the Test Results screen to send test results to a mobile printer connected to the Host. The Print button appears only if there are printers configured and is not enabled during a test.

Measurement Ranges (some values may be rounded)

Note: The tables below provide the data for reference ranges as published in literature (see references for details). Institutions should confirm their own reference range values.

Measured Parameters			
Test	Units of Measure	Measurement Range	Reference Range[8-10,22]
pH	pH units	6.5 – 8.0	7.35 – 7.45 arterial
			7.32 – 7.43 venous
pCO_2	mmHg	5 – 250	35 – 48 arterial
			41 – 51 venous
	kPa	0.7 – 33.3	4.7 – 6.4 arterial
			5.4 – 6.8 venous
pO_2	mmHg	5 – 750	83 – 108 arterial**
	kPa	0.7 – 100	11.1 – 14.4 arterial**
Na+	mmol/L	85 – 180	138 – 146
	mEq/L		
K+	mmol/L	1.5 – 12.0	3.5 – 4.5
	mEq/L		
Ca++	mmol/L	0.25 – 4.00	1.15 – 1.33
	mg/dL	1.0 – 16.0	4.6 – 5.3
	mEq/L	0.5 – 8.0	2.3 – 2.7
Cl-	mmol/L	65 – 140	98 – 107
	mEq/L		
TCO_2	mmol/L	5 – 50	22 – 29 arterial
			23 – 30 venous
	mEq/L	5 – 50	22 – 29 arterial
			23 – 30 venous
Glu	mmol/L	1.1 – 38.5	4.1 – 5.5
	mg/dL	20 – 700	74 – 100
	g/L	0.20 – 7.00	0.74 – 1.00
Lac	mmol/L	0.30 – 20.00	0.36 – 0.75 arterial
			0.56 – 1.39 venous
	mg/dL	2.7 – 180.2	3.2 – 6.8 arterial
			5.0 – 12.5 venous
	g/L	0.03 – 1.80	0.03 – 0.07 arterial
			0.05 – 0.12 venous
BUN	mg/dL	3 – 120	8 – 26
Urea	mmol/L	1.1 – 42.8	2.9 – 9.3
	mg/dL	7 – 257	17 – 56
	g/L	0.07 – 2.57	0.17 – 0.56
Crea	mg/dL	0.30 – 15.00	0.51 – 1.19
	µmol/L	27 – 1326	45 – 105
Hct	% PCV	10 – 75	38 – 51
	L/L	0.10 – 0.75	0.38 – 0.51

* Some units for Glucose may not be available in all regions.

** As per CLSI C46-A2[1], arterial blood samples are preferred for blood gas analysis. Therefore, reference ranges for arterial blood gases may not be directly applied to venous and capillary blood gases. Note that there are conflicting reports[23-27,30] regarding the validity of pO_2 analysis performed on arterialized capillary blood samples, compared to arterial pO_2. Variability in both capillary collection process and in capillary blood itself may affect test results for pH, pO_2, pCO_2, and calculated sO_2 of capillary samples.

Calculated Parameters			
Acronym	Units of Measure	Measurement Range	Reference Range[8-10,22]
$cHCO_3$-	mmol/L	1 – 85	21 – 28 arterial
			22 – 29 venous
	mEq/L	1 – 85	21 – 28 arterial
			22 – 29 venous
$cTCO_2$	mmol/L	5 – 50	22 – 29 arterial
			23 – 30 venous
	mEq/L	5 – 50	22 – 29 arterial
			23 – 30 venous
BE(ecf)	mmol/L	-30 – +30	-2 – +3
	mEq/L		
BE(b)	mmol/L	-30 – +30	-2 – +3
	mEq/L		
cSO_2	%	0 – 100	94 – 98 arterial
A	mmHg	5 – 800	†
	kPa	0.67 – 106.64	†
A–a	mmHg	1 – 800	†
	kPa	0.13 – 106.64	†
a/A	%	0 – 100	†
	fraction	0 – 1	†
AGap	mmol/L	-14 – +95	7 – 16
	mEq/L		
AGapK	mmol/L	-10 – +99	10 – 20
	mEq/L		
GFRmdr, GFRmdr-a	mL/min/1.73m^2	2 – 60 or >60*	†
GFRckd, GFRckd-a, GFRckd21	mL/min/1.73m^2	1 – 225	†
GFRswz	mL/min/1.73m^2	1 – 275	†
BUN/Crea	mg/mg	0.2 – 400.0	12.0 – 20.0
Urea/Crea	mmol/mmol	0.8 – 1615.4	48.5 – 80.8
	mg/mg	0.4 – 856.8	25.7 – 42.9
cHgb	g/dL	3.3 – 25	12 – 17
	mmol/L	2.0 – 15.5	7.4 – 10.6
	g/L	33 – 250	120 – 170

* Numeric values will be reported for values between 2-60 mL/min/1.73 m2. Values >60 will be reported as > 60 mL/min/1.73 m2. This range is based on the specific National Kidney Disease Education Program (NKDEP) recommendation for reporting eGFR values. Please refer to the following web link: http://nkdep.nih.gov/lab-evaluation/gfr/reporting.shtml. eGFR > 60 does not exclude the possibility of mild renal disease. Further laboratory testing may be necessary to distinguish normal renal function from mild renal disease.

† Widely accepted reference ranges are not well established. Institutions should establish and set their own reference range values.

Calibration Verification

Commercially available five (5) Level Calibration Verification Sets can be used for verification of calibration of epoc Test Cards within reportable ranges.

Note: Level 6 Calibration Verification Fluids, for TCO_2 only, are available separately.

Calibration verification solutions are prepared using pure salts in a physiologically buffered aqueous solution. They do not contain human serum or serum products.

Manufacturer	Description	Level	REF No.	Usage
Eurotrol Inc., Ede, The Netherlands	Eurotrol Hematocrit Verification Fluids	1-5	190.000.005	Hematocrit Calibration Verification
	Eurotrol Calibration Verification Fluids	1-5	267.000.005	All but Hematocrit Calibration Verification
		6	266.006.010	TCO_2 only* Calibration Verification

*Level 6 fluids complement calibration verification for the upper end of the TCO_2 range.

Some Calibration Verification Fluids may not be approved for sale in all countries.

QUALITY CONTROL

Verification of Newly Received Test Cards

Note: epoc Test Cards are shipped using validated shipping containers and delivery methods. Only approved shipping and handling procedures must be followed.

- In certain countries, Test Card shipping cartons include two (2) Temperature Monitors. If they are included, verify Test Card shipping temperatures are satisfactory using Temperature Monitors in the shipping carton. If temperature monitors indicate they were stored outside of the specified temperature range, place the card shipment on "Hold" and isolate from possible use. Contact Siemens Healthineers Remote Services Center or your local Siemens technical support representative.
- From each lot in each shipment of cards, analyze at least two (2) levels of fluid controls using any verified Reader.

Starting a QA Test

When performing quality control functions, be sure to follow the control fluid manufacturer's instructions. If ampoules are taken from cool storage, equilibrate the ampoules to room temperature (20°C – 25°C) for four (4) hours minimum for a full box, and for one (1) hour for single ampoules outside of the box.

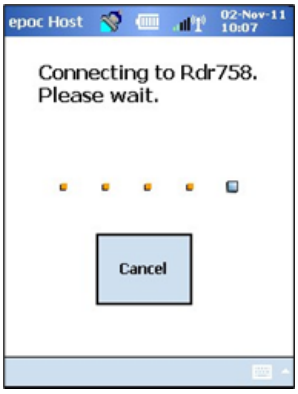
All aqueous control fluids, including proficiency test samples, must be run as a QA test when using the epoc System. QA test feature provides the following characteristics:

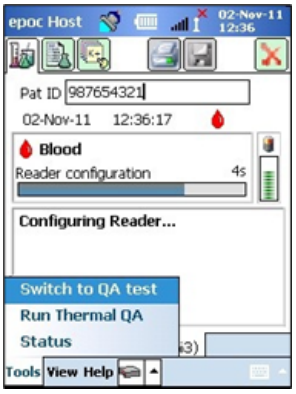
- The reportable range symbols ">" and "<" are not used to mark the test results outside of their reportable range, so the User can test levels at, or just outside of, reportable ranges
- The hematocrit reading is reported as "uncorrected", i.e. it does not take into account the sodium concentration of the sample. This is done so the hematocrit sensor can be evaluated independently from the sodium sensor (note that sodium sensor performance is verified separately)
- Adjustments to calculations for fluid matrix
- QA test results are stored separately from Blood test results in the data manager or within the epoc Host

To complete a QA test, the following steps are required:

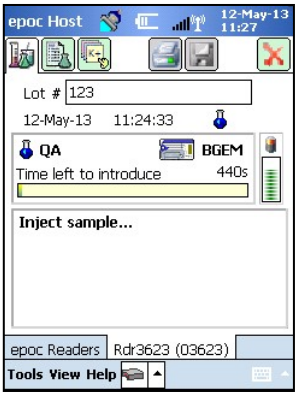
1. Turn "ON" the epoc Reader and epoc Host.
2. Start and log in to epoc Host software application.
3. Connect wirelessly to the epoc Reader from the epoc Host.
4. Select Tools and select Switch to QA test from drop down menu.
5. After Reader configuration is completed, remove a new Test Card from the pouch and immediately insert it into the epoc Reader. This will start the calibration period for the Test Card (the Reader will be flashing the green light, and the Host will display the message, "Calibrating… DO NOT INJECT SAMPLE")

Log in and connect →Switch to QA test →Insert a card →Start calibration





6. Use the 150-175 second (approximate) calibration period to enter the QC Lot number and select tests (if applicable).
7. After calibration is complete, the green light on the Reader will turn steady and the Host will display "Inject Sample". Introduce the blood sample into the Test Card. Follow instructions below.



Sample Introduction

1. Immediately before use, shake the ampoule vigorously for at least fifteen seconds to re-equilibrate gases with the solution. When shaken, the ampoule should be held between the thumb and forefinger to avoid warming the solution. Swirl the ampoule gently to return the solution to the bottom of the ampoule.
2. Allow bubbles to rise between shaking and before opening the ampoule. Protect the fingers with gauze, tissue, or gloves.
3. In order to preserve gases in the control fluid, immediately transfer the fluid from the ampoule into a plain syringe by slowly aspirating it through a large-bore needle.
4. Without delay, deliver the fluid into the Test Card.
    a. Hold the syringe barrel vertically between fingertips and thumb.
    b. Using slight downward pressure, secure the syringe's luer tip into the center recess of the sample entry port of the Test Card, rotating up to ¼-turn to ensure a good seal.
    c. While maintaining downward pressure, use the index finger of the other hand to steadily depress the syringe plunger in a single, smooth, continuous motion until prompted to stop (audible beep and the reader indicator green light will start flashing)
5. Once the analysis is complete, approximately 45 seconds after sample introduction, the epoc Host displays the Test Results from the Reader Screen.
6. Remove the Test Card and discard it as biohazard waste. Follow your facility's policy and procedure for the disposal of biohazardous materials.

Transfer with Syringe

To transfer control fluids from an ampoule to the Test Card, Epocal recommends plain 1-mL or 3-mL syringes and 14-20-gauge blunt tip needles. Carefully draw over 1 mL of fluid from the bottom of the ampoule.

During the draw, air may remain entrapped between the syringe plunger and the fluid. Never attempt to expel it. This air is far enough as to not affect the solution near the tip of the syringe. However, an air bubble traveling though the sample would contaminate it throughout its entire volume.

Whenever a stream of air bubbles is drawn into the syringe, or an air bubble gets nested near the syringe tip, discard both the syringe and the ampoule. Begin again with a new syringe and ampoule.

Before injecting Fluid in the Test Card, expel a few drops from the syringe.

Remove the needle and apply the syringe luer in the Test Card's sample entry port as during a normal blood test procedure.

Value Assignment Datasheets

Value Assignments are lot and software (sensor configuration) specific, and appropriate Value Assignment Datasheets (VADs) must be used.

Value Assignment Datasheets contain target values and acceptable ranges for Aqueous Control and Calibration Verification Fluids specific to the epoc System.

Printable Value Assignment Datasheets (VADs) and electronic Value Assignment Datasheets (eVAD) for the epoc System are available at Siemens Healthineers Document Library.

Never use Target Values or Ranges from the package insert included with Control Fluids.

Target Values and Ranges are established for measured values for the epoc System. QC for calculated values is accomplished by performing QC on the measured values which are used to compute the calculated values.

Ensure that high resolution printers are used when printing out VADs to facilitate scanning of QC fluid lot barcodes (Code 128B).

Each Value Assignment Datasheet is identified by the Fluid Name, Level, Lot Number, and epoc System Sensor Configuration Version. VADs change with sensor configuration changes and changes to control fluid lot numbers. Assure all information is correct when using a VAD to determine acceptability of your results. The epoc System Sensor Configuration version is located in the epoc Host's Help, About menu.

Optional Quality Control: Calibration Verification

Follow the calibration verification procedure to verify accuracy of test results over an extended measurement range of a test. Performance of this procedure at defined intervals may be required by regulatory or accreditation bodies. While commercial calibration verification sets contain five (5) levels, verification of the measurement range can be accomplished using lowest, highest, and mid-levels.

Commercially available five (5) Level Calibration Verification Sets can be used for verification of calibration of epoc Test Cards within reportable ranges.

Note: Level 6 Calibration Verification Fluids, for TCO_2 only, are available separately.

Calibration verification solutions are prepared using pure salts in a physiologically buffered aqueous solution. They do not contain human serum or serum products.

Manufacturer	Description	Level	REF No.	Usage
Eurotrol Inc., Ede, The Netherlands	Eurotrol Hematocrit Verification Fluids	1-5	190.000.005	Hematocrit Calibration Verification
	Eurotrol Calibration Verification Fluids	1-5	267.000.005	All but Hematocrit Calibration Verification
		6	266.006.010	TCO_2 only* Calibration Verification

*Level 6 fluids complement calibration verification for the upper end of the TCO_2 range.

Some Calibration Verification Fluids may not be approved for sale in all countries.

Optional Quality Control: Proficiency Testing

Follow Proficiency Testing (External Quality Control) procedure to verify the accuracy and precision of epoc System test results over multiple laboratories and/or sites. -Laboratories can choose to register with various proficiency testing organizations.

Organization	Contact Information
CAP	800-323-4040
WSLH	800-462-5261
API	800-333-0958 ext 3023

Proficiency testing samples are run as a QA Test when using epoc System (same as Control and Calibration Verification Fluids).

Please note that in all proficiency testing, until an appropriate peer group is established for the test system, some tests may fail due to matrix effects.

Optional Quality Control: Whole Blood Tests

When whole blood is used for epoc System quality control tests, as it is in the case of whole blood precision tests, these samples should be run in the Blood Test mode. Always select the Blood Test (not QA Test) mode when testing blood samples.

Verification of Reader Performance

The epoc Reader comes equipped with automated internal quality control procedures which are performed electronically during the initialization of the epoc Reader when connecting with an epoc Host and immediately before testing process each time a test is run. Electronic QC is automated, so no User procedures are required. Date and time of "Last EQC" is recorded with test results.

The epoc Reader contains a Thermal Control Subsystem consisting of two (2) Heater Blocks each with an embedded factory calibrated precision chip-based Temperature Sensor. There is one (1) calibrated Thermistor located elsewhere within the Reader. When measurements are performed at a controlled temperature, a Heater Block contacts Test Card's sensor region and maintains temperature of the sensors and fluids that come into contact with the sensors at the required temperature: $37^{o}C \pm 0.15^{o}C$.

A real-time Thermal QC verification occurs each time a blood test or a QA test is performed on the epoc System. The real-time Thermal QC is a set of checks that monitors the temperatures inside the Reader and compares these against expected behaviors at different points during a blood test or a QA test. When an anomaly is detected by Thermal QC, a test is aborted indicating a message for the Thermal QC error, "iQC Failure: Thermal Check (E38)". Refer to the Troubleshooting and Error Messages section of the system manual if you receive this error message.

CLINICAL SIGNIFICANCE

The Blood Gas Electrolyte and Metabolite (BGEM) Test Card panel configuration includes sensors that quantitate pH, pCO_2, pO_2, Sodium, Potassium, Ionized Calcium, Chloride, Total Carbon Dioxide, Glucose, Lactate, Blood Urea Nitrogen, Creatinine, and Hematocrit.

pH, pCO2, pO2 (blood gases) measurements from the epoc Blood Analysis System are used in the diagnosis and treatment of life-threatening acid-base disturbances.

Sodium and Potassium measurements from the epoc Blood Analysis System are used in diagnosis and treatment of diseases involving electrolyte imbalance.

Ionized Calcium measurements from the epoc Blood Analysis System are used in diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany.

Chloride measurements from the epoc Blood Analysis System are used in the diagnosis and treatment of electrolyte and metabolic disorders.

Total Carbon Dioxide measurements from the epoc Blood Analysis System are used in the diagnosis and treatment of disorders associated with changes in body acid-base balance.

Glucose measurements from the epoc Blood Analysis System are used in the diagnosis and treatment of carbohydrate metabolism disorders, including diabetes mellitus and idiopathic hypoglycemia, and of pancreatic islet cell tumors.

Lactate measurements from the epoc Blood Analysis System are used to evaluate the acid-base status and are used in the diagnosis and treatment of lactic acidosis (abnormally high acidity of the blood).

Blood Urea Nitrogen measurements from the epoc Blood Analysis System are used in the diagnosis and treatment of certain renal and metabolic diseases.

Creatinine measurements from the epoc Blood Analysis System are used in the diagnosis and treatment of certain renal diseases and in monitoring renal dialysis.

Hematocrit measurements from the epoc Blood Analysis System are used to distinguish normal from abnormal states of blood volume, such as anemia and erythrocytosis.

THEORY OF OPERATION

For information regarding the Theory of Operation, refer to the epoc System Manual with epoc Host[2].

LIMITATIONS AND INTERFERENCES

For information regarding Limitations and Interferences, refer to the epoc System Manual with epoc Host[2].

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