Training Module Siemens Healthineers

epoc Blood Analysis System

HOOD5162003081572, 4/2020

epoc® System Overview

epoc Blood Gas Analysis System

epoc Host Mobile Computer

epoc BGEM Test Card

epoc Reader

epoc Blood Gas Analysis System

The epoc blood gas analysis system is a portable blood analyzer composed of THREE items:

Host:
- Communicates via Bluetooth with epoc reader
- It calculates analytical values sent from reader

Reader:
- Battery powered device with internal barcode scanner
- The readers accepts test cards, measures electrical signals from test card sensors, and transmits
- Test results via Bluetooth to epoc host

Test Card:
- Single use, credit card sized card with port for blood sample entry.
- It contains an array of sensors and calibration fluid in a sealed reservoir.

epoc Blood Gas Analysis System

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Each Host has a dedicated reader

Both devices need to be turned on to communicate

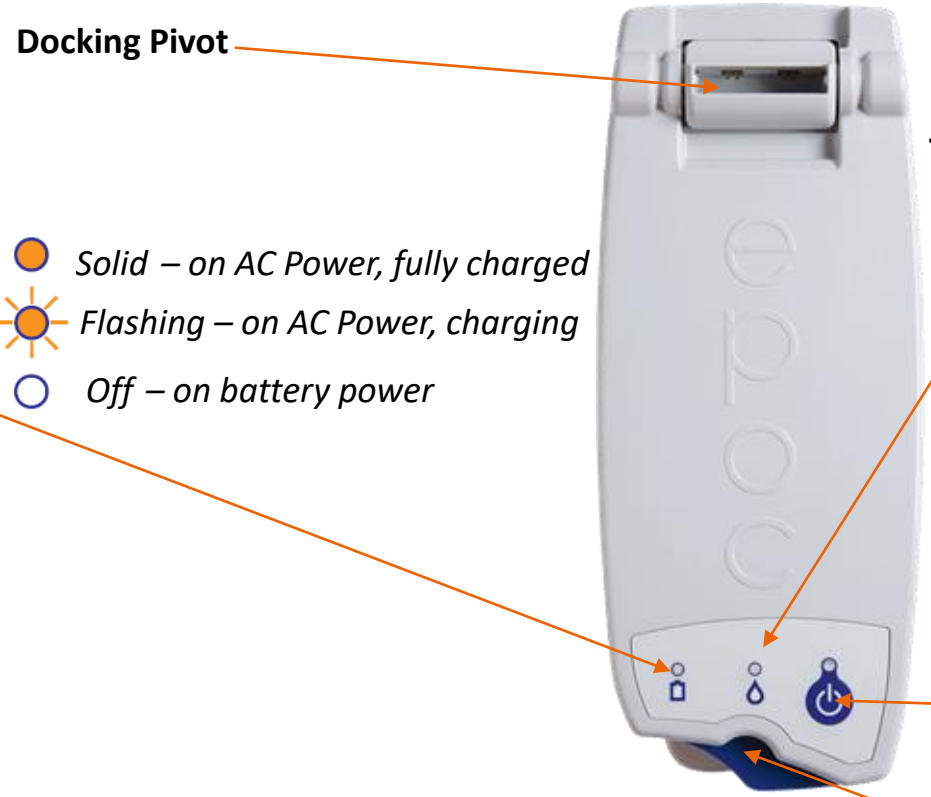
Each host and dedicated reader will connect by Bluetooth and can communicate up to 30 feet.

epoc Host Components

--Lithium ion rechargeable battery	--50 test cards per charge with typical use	--Time to recharge <5 hours

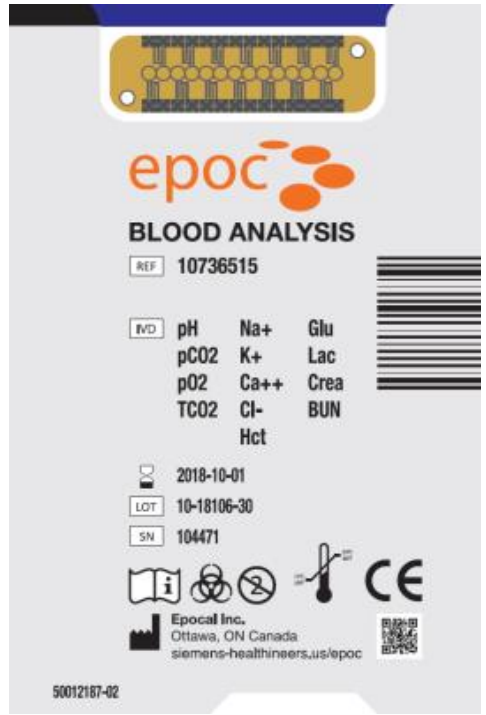
epoc Reader Components

Lithium ion rechargeable battery*	50 test cards per charge with typical use	Maintenance Free



epoc Test Card

- **Single-use, self-calibrating, 92uL whole blood sample**
- **Capillary – 90uL**
- **pH, pCO_2, pO_2, Na, K, Cl, iCa, Glu, Lactate, Crea, BUN, TCO2 and Hct (plus calculated values are available)**
- **<u>Room temperature storage 15-30 C</u>**
- **Bar-coded for patient safety – can't use expired cards**
- **<u>Insert test card into reader immediately after removing from pouch</u>**

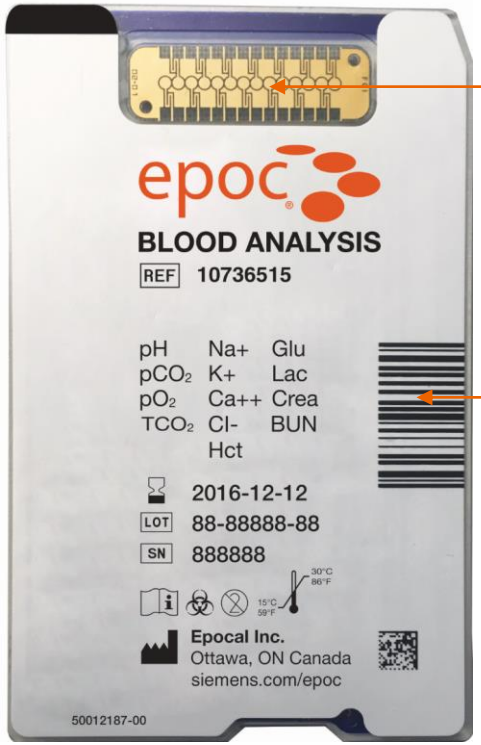


epoc Test Card Components

Sensor Module:
Sensor Surface-Do Not touch

Test Card – Top

Sample Entry
Port- Do not touch



Test Card – Bottom

Sensor Module:
Contact Surface-Do not touch

Barcode

Open package only when ready to use test card.

Test card should go directly from package into reader.

Test card is single use only.

Reader reads barcode on test card upon insertion.

Sample Requirements

Whole blood

Syringes or epoc capillary tubes

92 µL sample from syringe

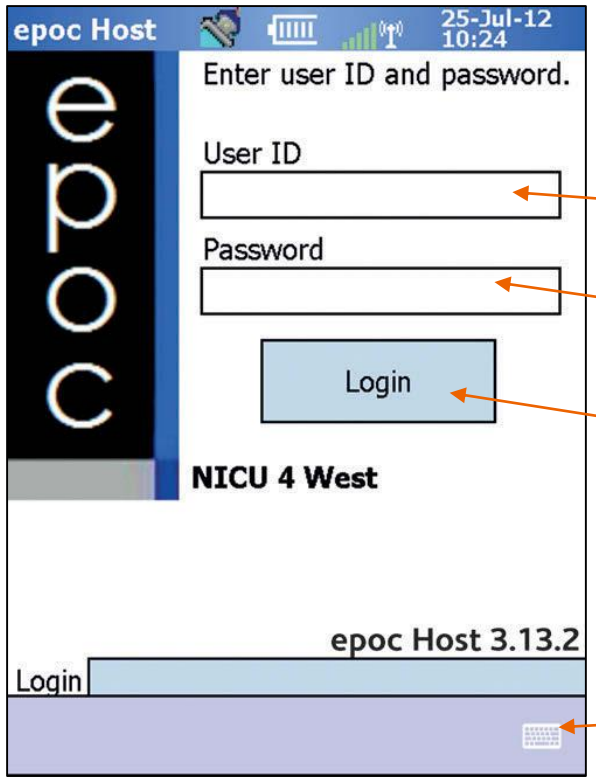
epoc Care-Fill capillary tubes (90 µL)

epoc System Operation

Testing Process

- Confirm patient identification
- Turn on both host and reader
- Log in
- Host and reader sync (happens automatically)
- Reader automatically performs a 15 second internal QC after log in
- Insert test card
- Two minute 45 second test card calibration will begin-while this is occurring you can perform the following:
  - Confirm patient identification
  - Enter patient information, test information, and test selection
  - Collect Sample
- Inject sample when prompted
- Sample Analysis (happens automatically after sample injected)
- Document Critical Values by using the Flashing Doctor Button(if applicable)
- Tap “X” after reviewing results to exit test screen to save and send data(if applicable)
- Log out
- Connect to charging AC Adaptor to charge

System Operation - User ID



Begin by scanning your badge

User ID
User ID barcode

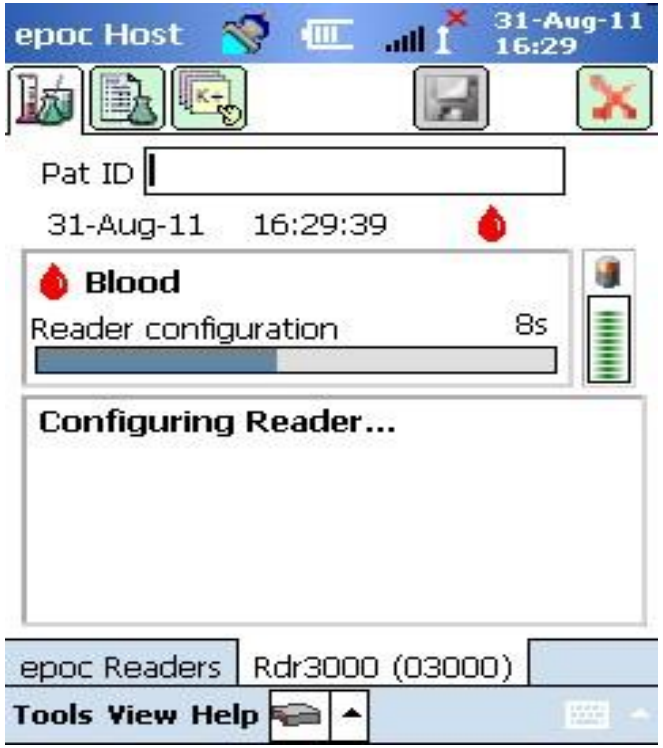
User ID = Employee number
Assigned number(if applicable)

Password = no Password required
Password of choice(if applicable)

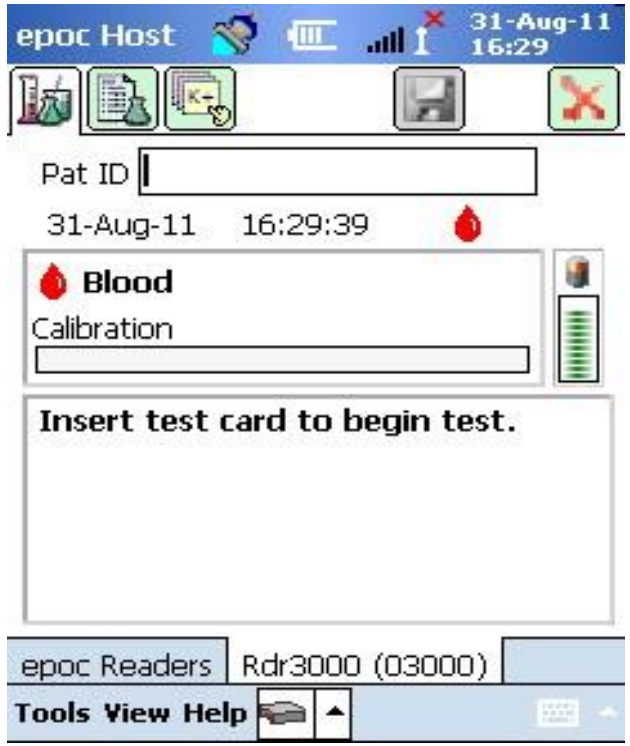
Login

Keyboard

System Operation Initial Screen



Initial Screen automatically runs quick epoc internal QC
(approx. 15 seconds)
Green light on reader will be “Blinking is thinking”



Once configuration is complete, it will prompt you to insert test card- Green light on reader will be “Steady is Ready”

System Operation Test Card Insertion

Open and insert test card immediately after opening.

Insert test card using a single, smooth, continuous motion with both thumbs positioned at the bottom of the card.

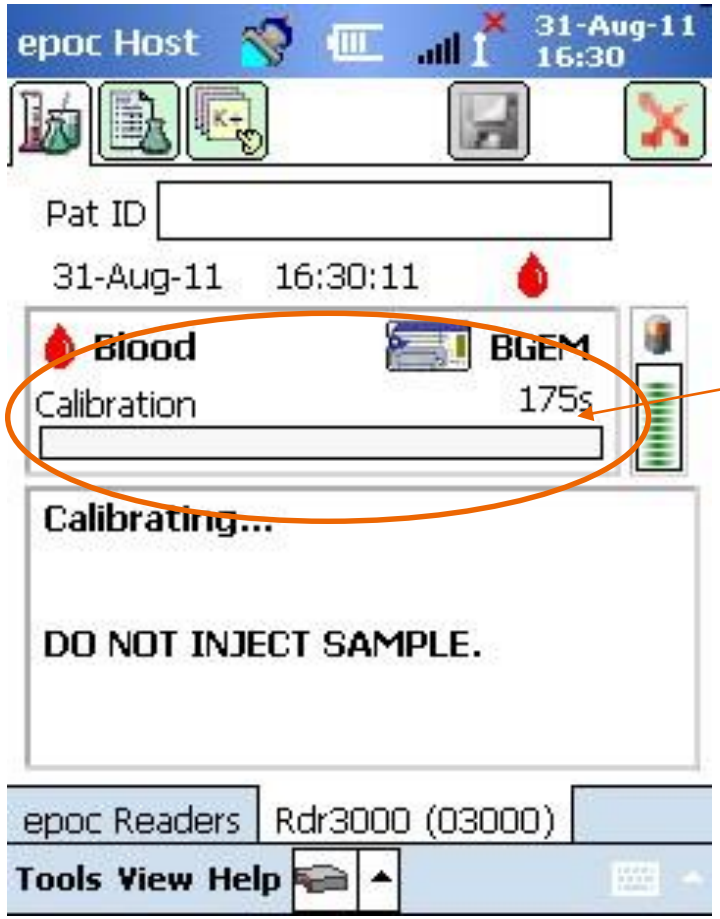
Insert the Test Card through the slight resistance that will be felt at the end of insertion.

You will be prompted to reinsert the test card if it is not in proper position or barcode is not read.
Note: Indicator Light will be “Red is Dead”

When card is inserted correctly, reader will initiate, indicator light will be “Blinking is thinking” and host will indicate calibration has begun.

Test card will be rejected
if card is expired.

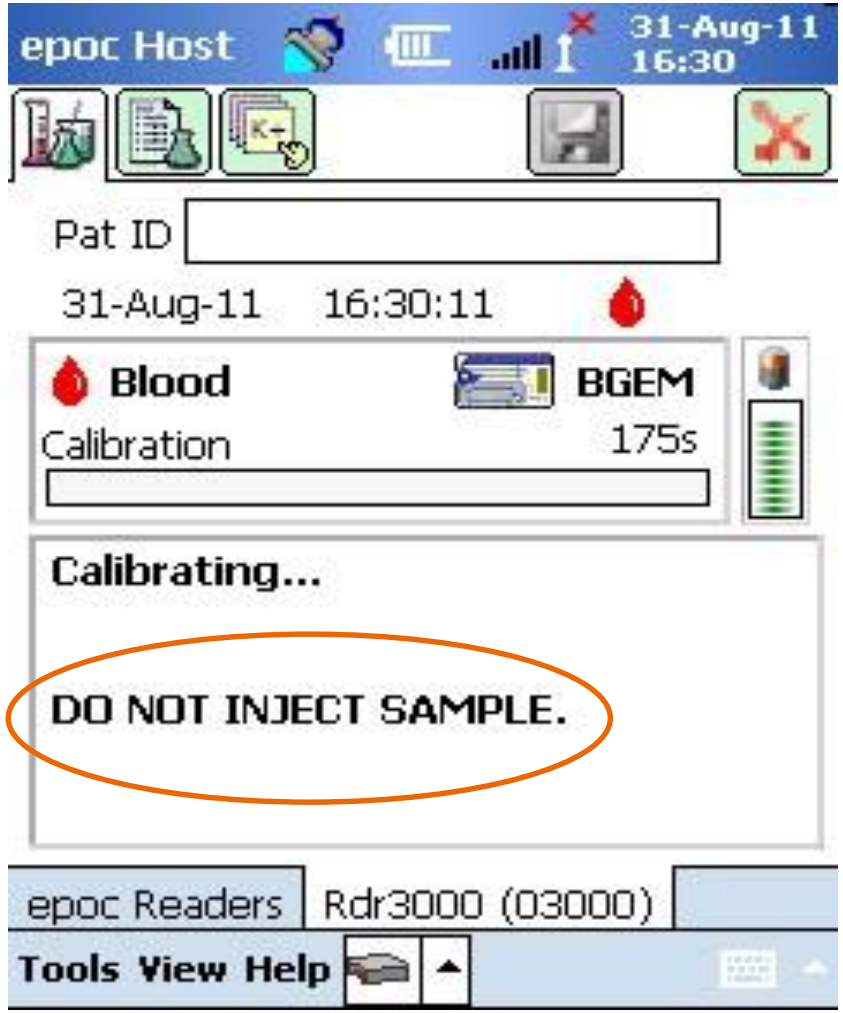
System Operation Test Card Calibration



A ~165 **second calibration** will begin once test card is properly inserted. Green indicator light on reader will be blinking.

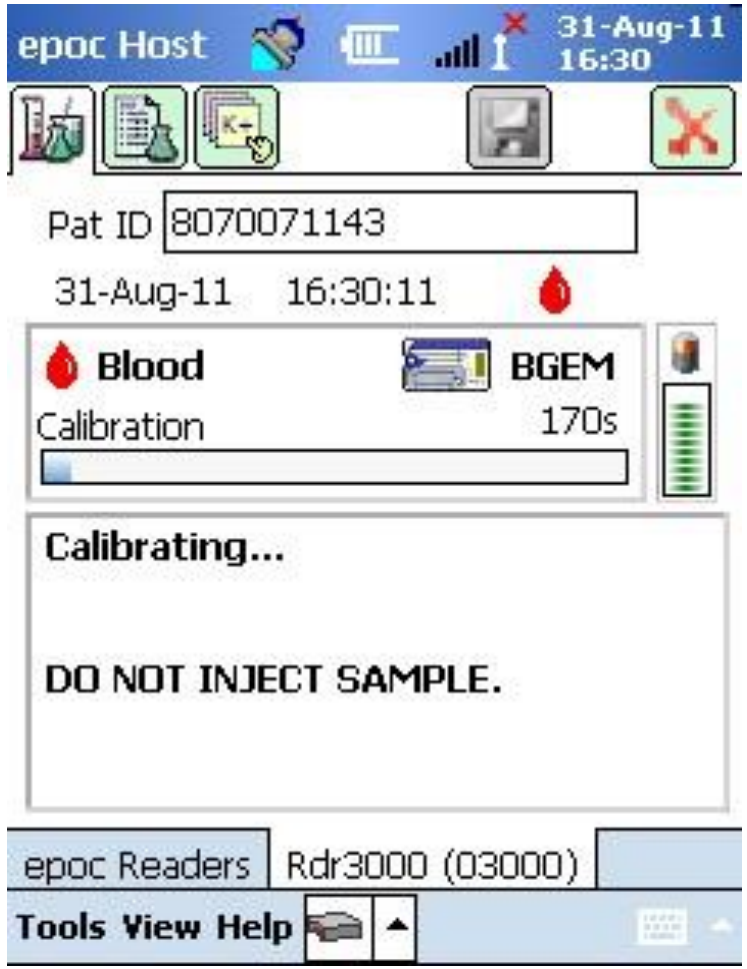
Calibration status Counts down in seconds.

System Operation Test Card Calibration



DO NOT inject sample during test card calibration or when the reader indicator light is blinking. If this occurs , reader indicator light well turn red. Card is no longer usable and will have to be replaced with a new card along with repeating patient information in all fields.

System Operation Test Card Calibration



While calibrating you can:

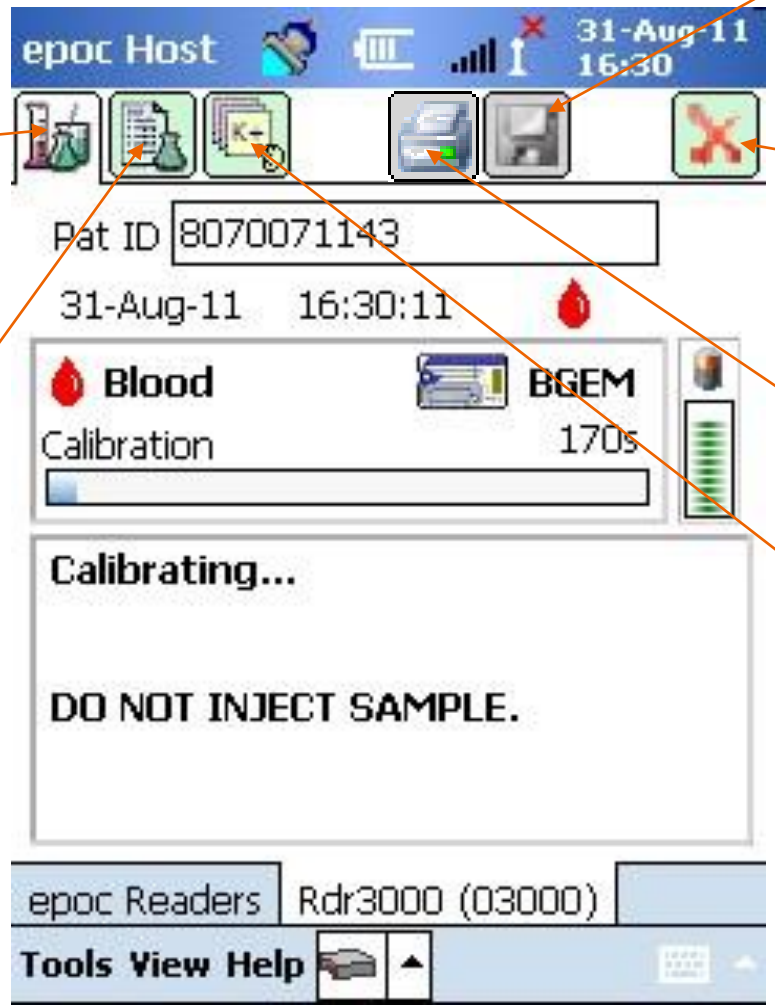
Complete required data fields
or
Collect Sample

Pre Analysis Data Entry and Required Fields

Pre Analysis Data Entry

Test Results Icon- Beakers

Test Information Icon- Notepad with Beaker



Save Icon

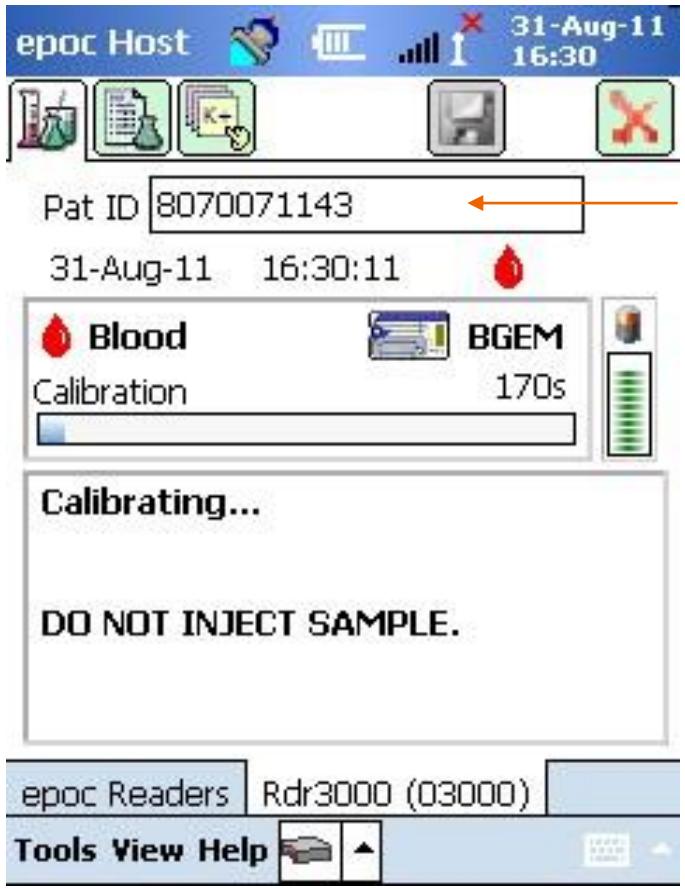
Red X Icon

Printer Icon

Test Selection Icon- K+

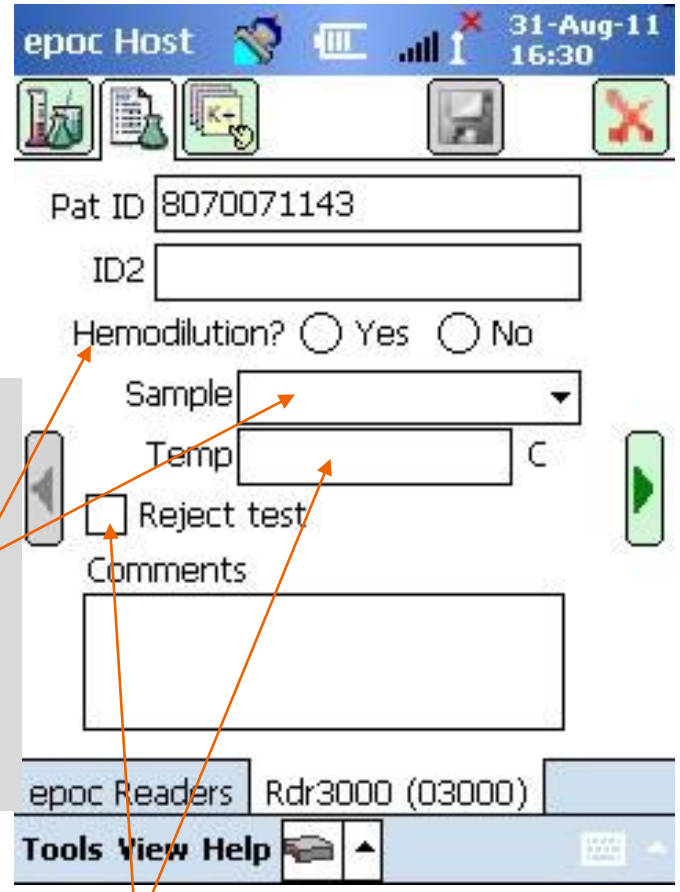
Pre Analysis Data Entry

1.



On the Test Result Icon-(Beakers) Compete required fields:
Patient ID by entering patient ID or by barcoding patient armband(if applicable).

2.



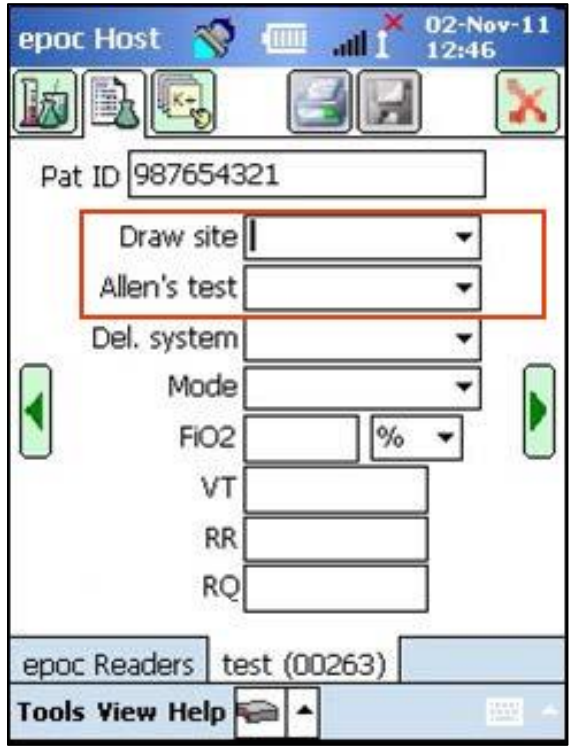
On the Test Information-(Notepad and Beaker)

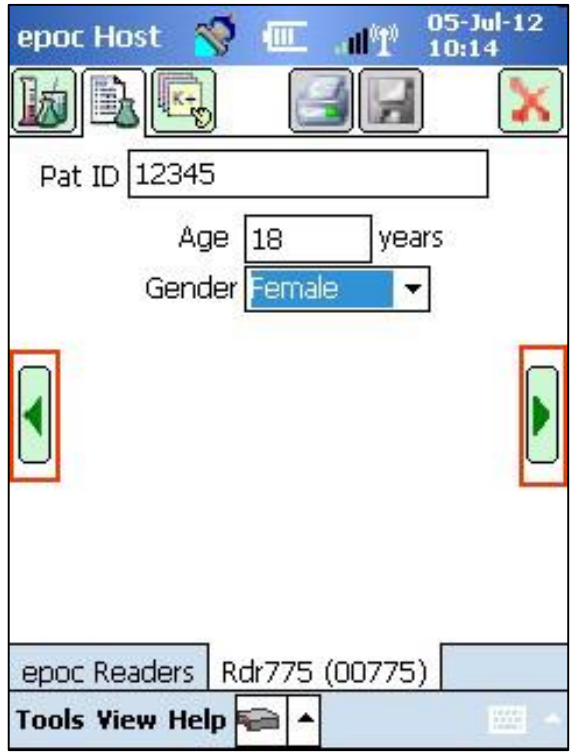
Complete required fields:
Hemodilution(if applicable) and Sample type-use the drop down arrow for available sources(if applicable).

Not required but available: Temperature(If you enter temperature, the temp correct results will have a (T) behind the test name in the results field), Reject test and Comments.

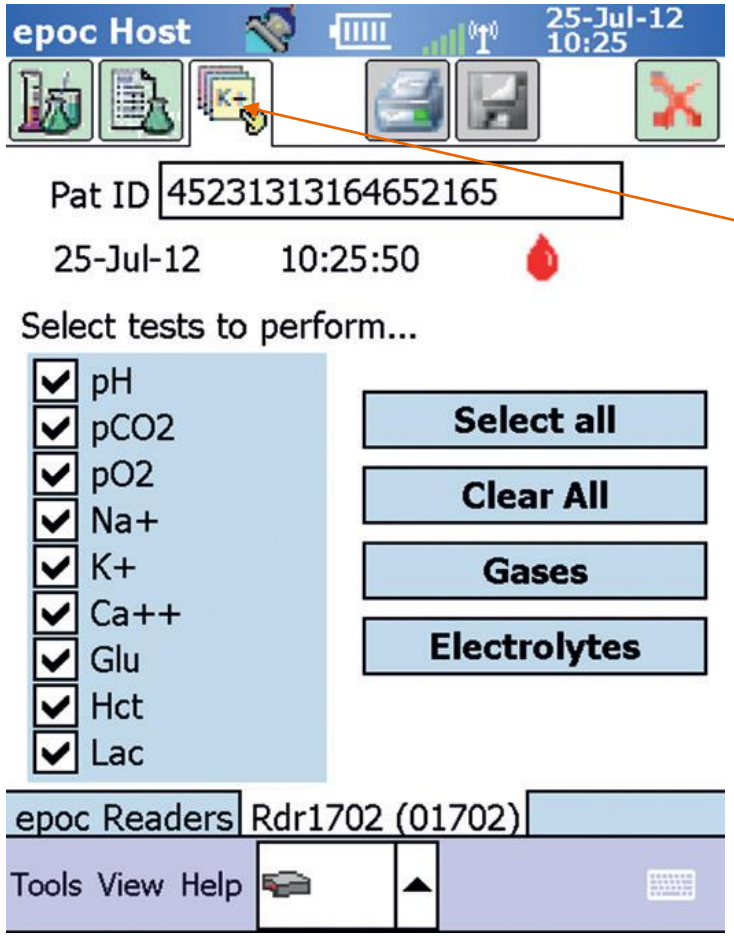
Pre Analysis Data Entry

Below are examples of Additional options under the Test Information Icon(Notepad and Beaker) Pre-Analysis Data is available by clicking on the green arrows at the side.





Pre Analysis Data Entry

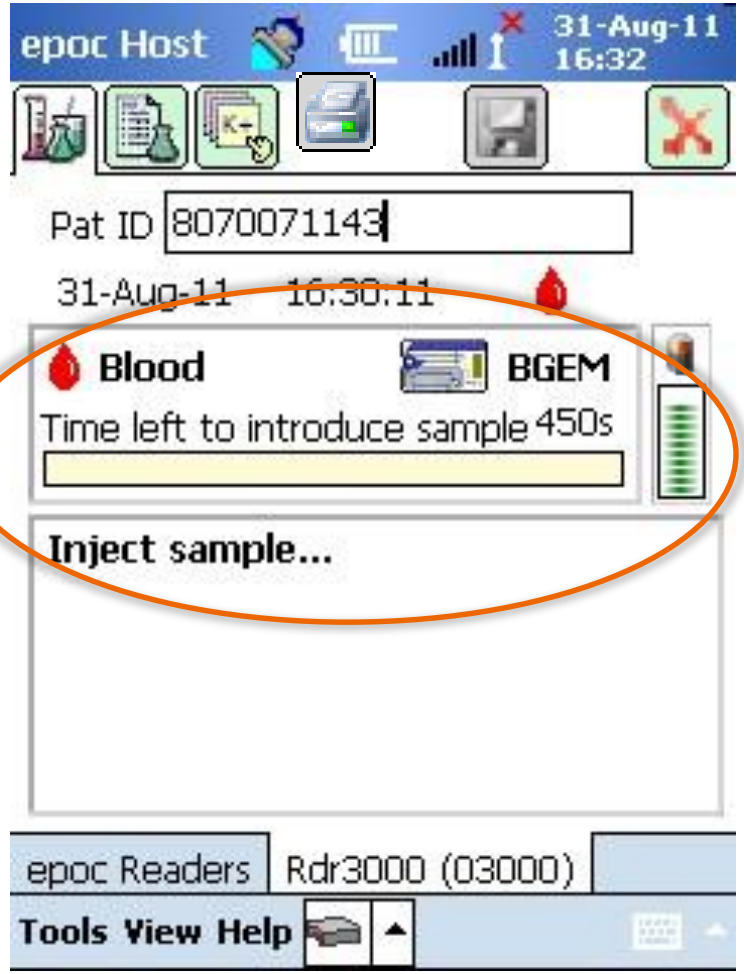


Tap on Test Menu icon-K+ and select the ordered tests

Quick tabs automatically select noted tests

Sample Analysis

Sample Analysis



Once calibration is complete the device will prompt you to Inject the sample and the Test Status Indicator light on the reader will be “Steady and Ready”.

Note: You have **7.5 minutes** to inject sample.
If the sample is not injected within 7.5 minutes, you must dispose of test card and start process over with a new test card.

Note: For capillary sample collection,
use epoc Care-Fill Capillary Tubes(information for capillary process is available later in this section).

Sample Analysis - Sample Application Syringe


Figure 1


Figure 3

To inject sample:

- Expel 1-2 drops if size allows
- Using slight downward pressure, secure the syringe's tip into the blood sample entry port.
- Rotate the syringe up to ¼ turn to ensure a good seal.
- While maintaining downward pressure, use the index finger to steadily depress the syringe plunger with a single, smooth, continuous motion until prompted to stop.
- The Reader provides an audible beep and the Test Status Indicator flashes green indicating enough sample for analysis was received. The Host also displays- Analyzing Sample.

Note: Introducing the sample too soon or too late will cause an error(Test Status Indicator light will be Red) and abort the test. A new Test Card must be inserted and the test procedure started again.

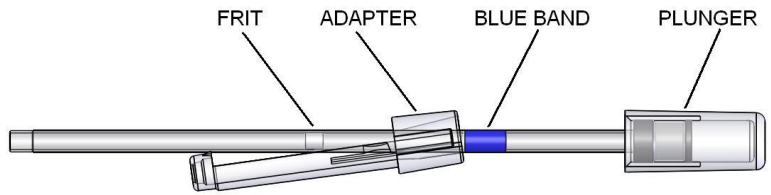
Note: If sample is not analyzed immediately after collection, mix by gentle inversion.

Sample Analysis - Sample Application Care-Capillary

epoc® *Care-Fill™* Capillary Tube Instructions For Use

When removing capillary tube from box

- Do not remove, re-position or depress plunger
- Do not remove adapter

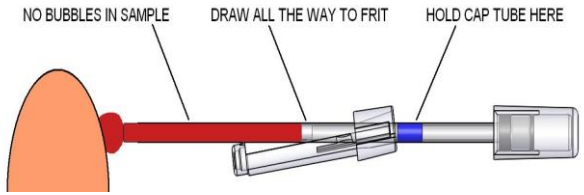


When holding the capillary tube

- Hold by the blue band
- Do not hold or handle by the plunger

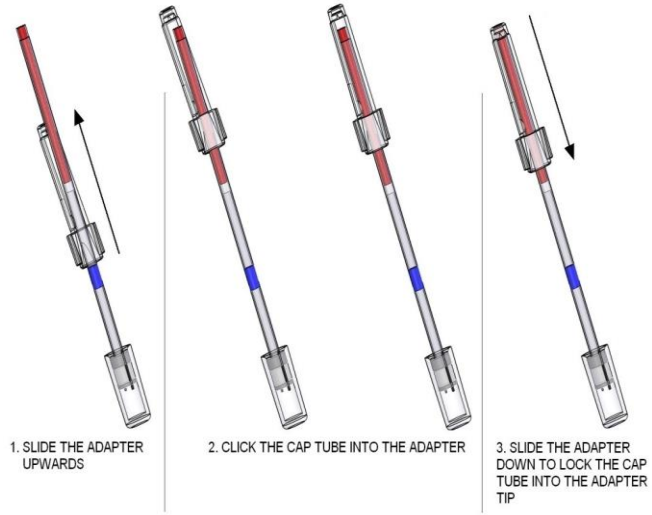
1. Draw Patient Sample

- Hold cap tube by blue band
- Hold tube horizontally, pointing toward puncture site and contact blood drop
- Continue filling tube until blood sample contacts white Plug



2. Prepare for Sample Introduction

- Hold cap tube by blue band and point end of cap tube upwards:
  - Side adapter towards end of cap tube and insert tube into Adapter
  - Gently push cap tube into Adapter end until it clicks and locks in place

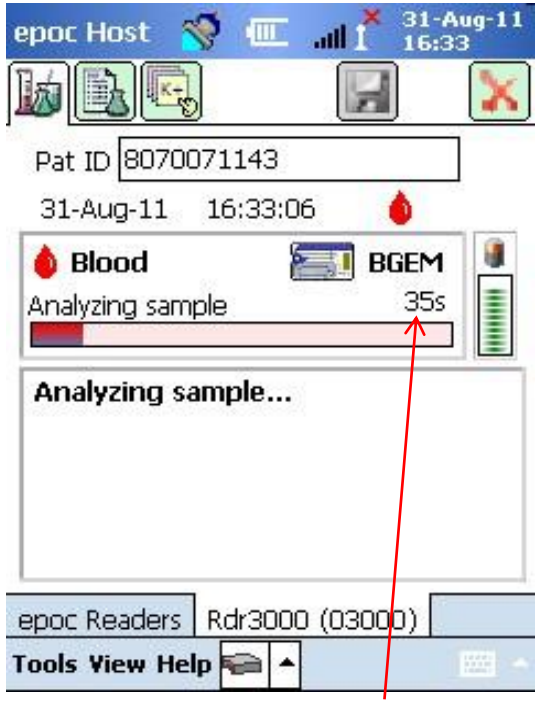


3. Introduce Patient Sample

- Hold cap tube by large end of adapter and insert into test card sample port, rotating up to ¼ turn to ensure good fit
- Using fingers of other hand, push plunger down completely in one motion until reader beeps
- Leave capillary tube on test card until test is completed

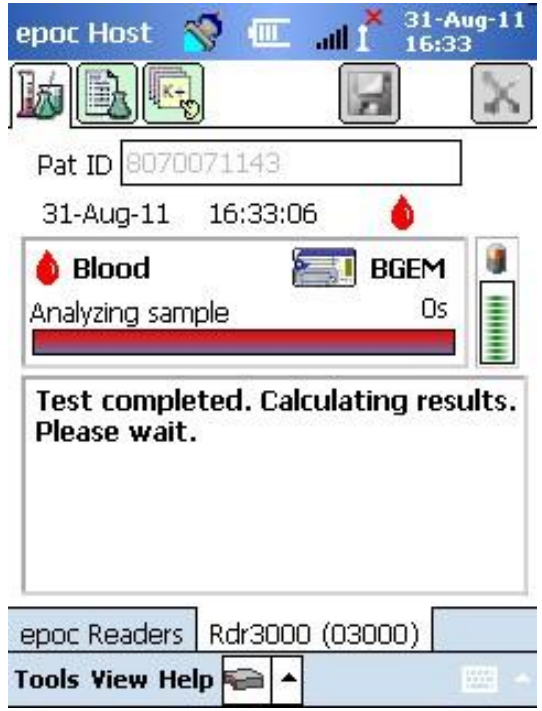
Sample Analysis

1.



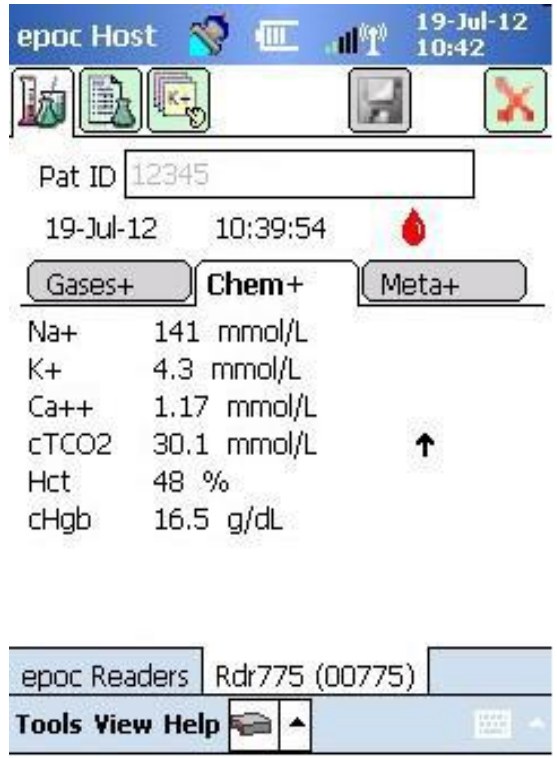
Once the sample is injected the time remaining is displayed to show how many seconds remain before sample analysis complete.

2.



Once analysis is complete, results will calculate. Time from sample injection to results is approximately 35 seconds.

3.



Results will display.

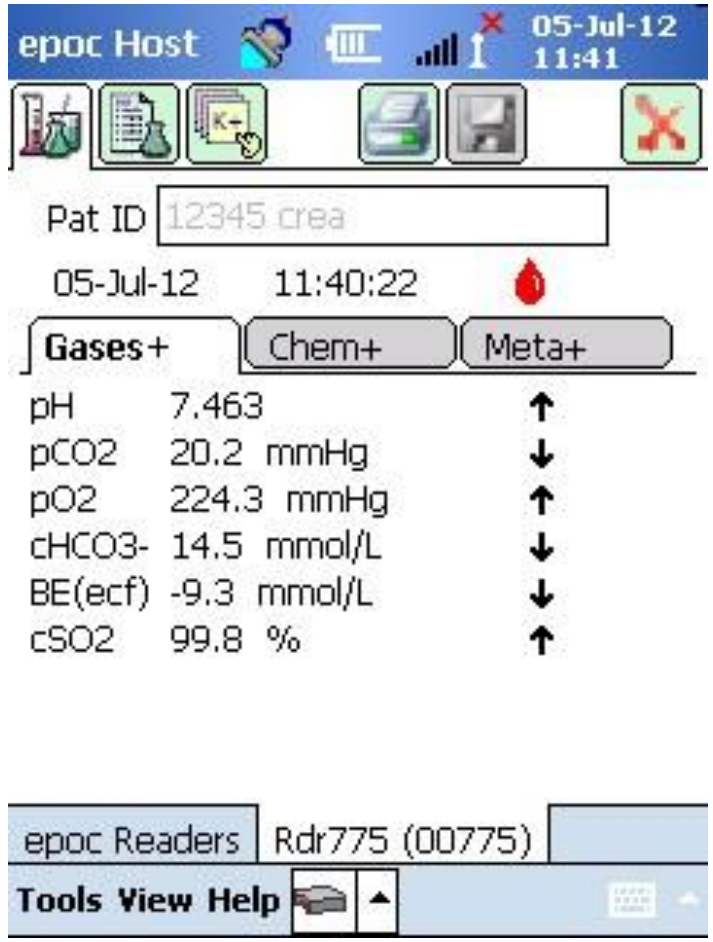
Sample Analysis

Note: All results do not report on one tab

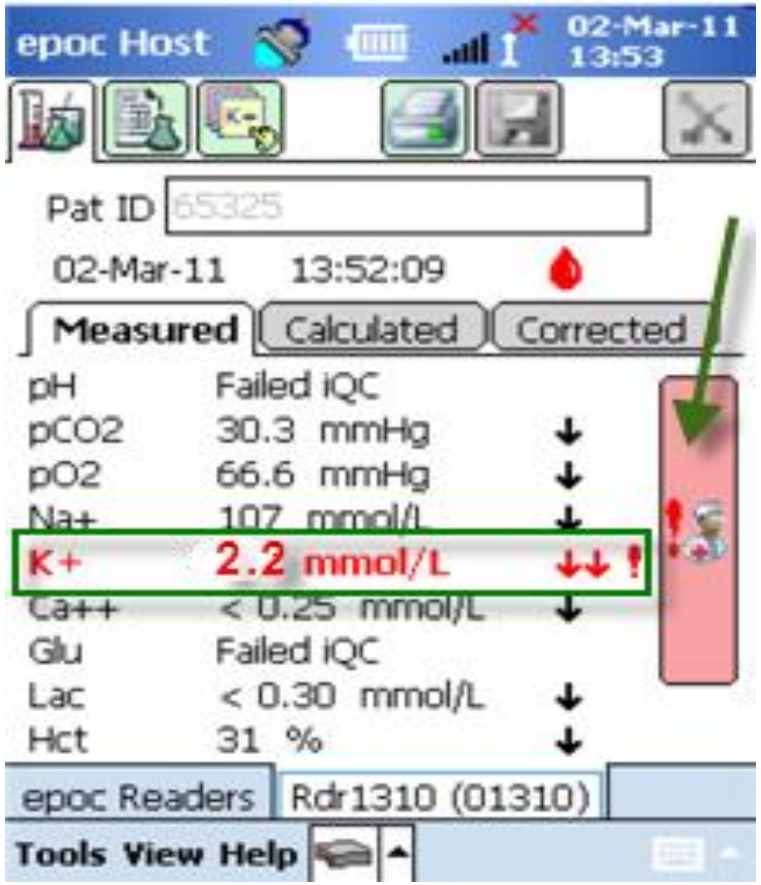
Results are shown under Gases, Chemistry or Metabolites

Tap on each tab to see results

If a result is in the Critical range, it will be reported in RED



Critical Value Documentation

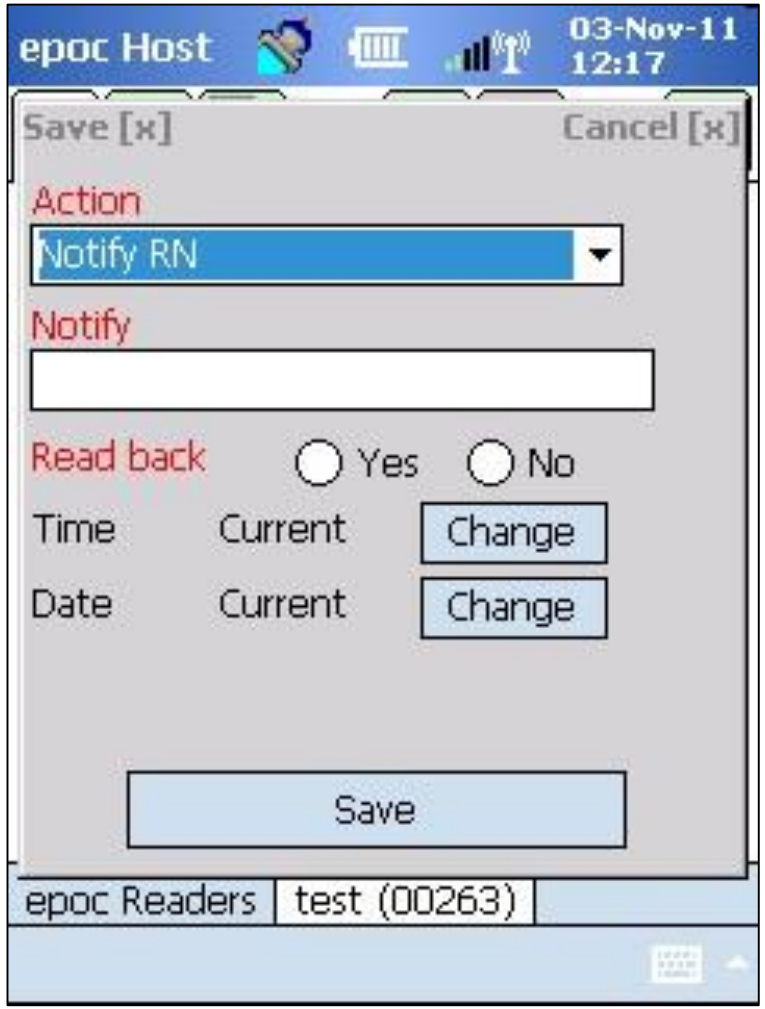


Click on the flashing Doctor Icon to open the Critical Actions Window to document required critical information.

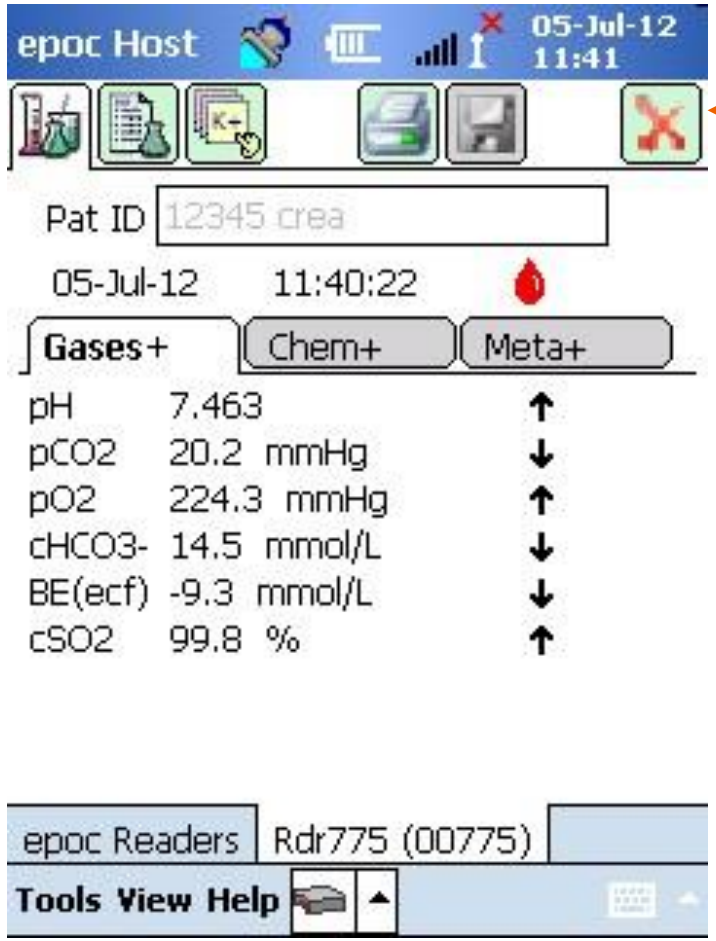
Critical Value Documentation

Critical Actions Window

- Mandatory fields appear in red in the Critical Actions Window. Action dropdown contains selections for Notify physician, Notify RN, Repeated test, Sent to lab, Expected values and Other
- Select Notify to enter text information such as the name of Physician who was notified. Open keyboard in the bottom right to open and click on it again to close
- Select Yes or No to record action of reading back test results
- The time and date of the action is automatically recorded using current time and date
- Click on the ‘Save” button to save
- Once you document and save, the flashing Doctor will now be steady and no longer flashing



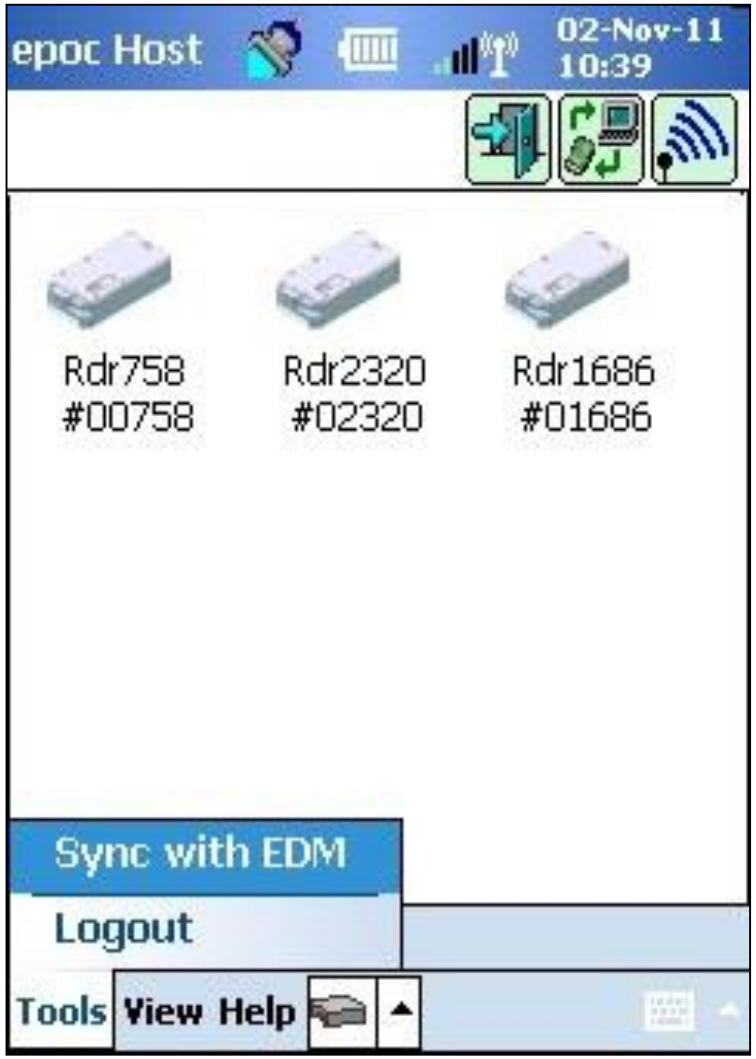
Test Conclusion-Exiting Patient Sample



Click on the **Red X**
if no further testing needed **OR**
1. remove old test card
2. insert new test card to start a new test

Note: You cannot edit any information after clicking on the Red X or starting a new test

Logging Out



Final step is logging out by clicking on the green door.

When data manager is present, the Synchronization Icon is used to exchange information between the epoc Host and on site computer system.

Tap the Logout Icon to logout and display the Login screen again.

Locate Readers by pressing the Discovery button. During discovery mode, the Host searched for Readers in the vicinity.

Conclusion

epoc System Screenshot User Guide

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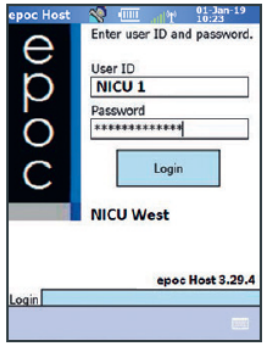
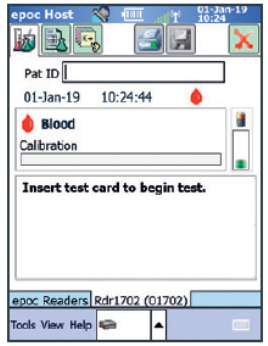
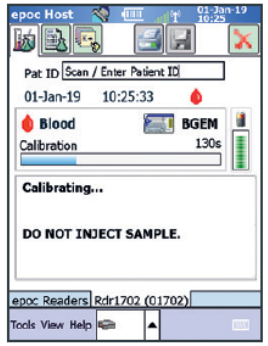


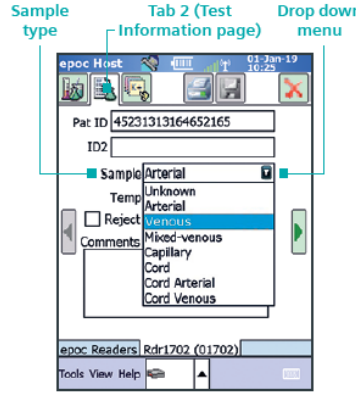
1 Scan or enter user ID



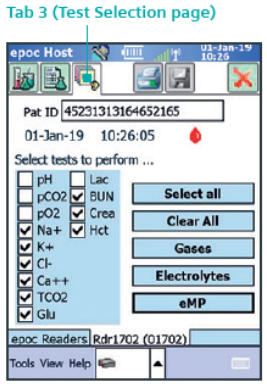
2 Insert test card when prompted



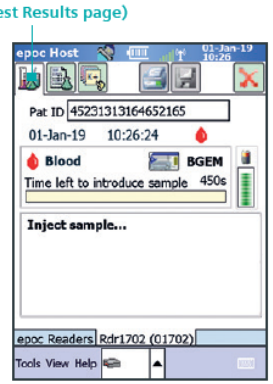
3 Scan or enter patient ID



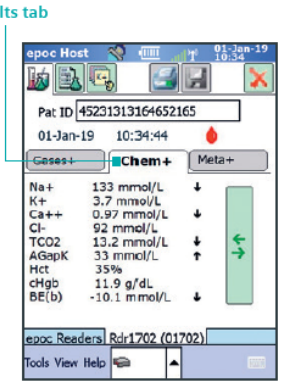
4 Enter sample type and other required information on Tab 2



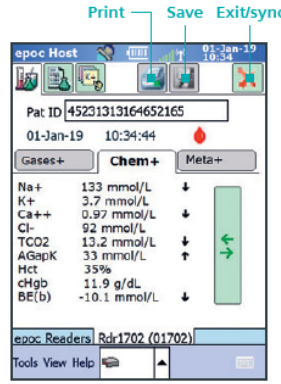
5 Select or deselect test analytes



6 Inject sample when prompted on Tab 1



7 View test results by tapping tabs

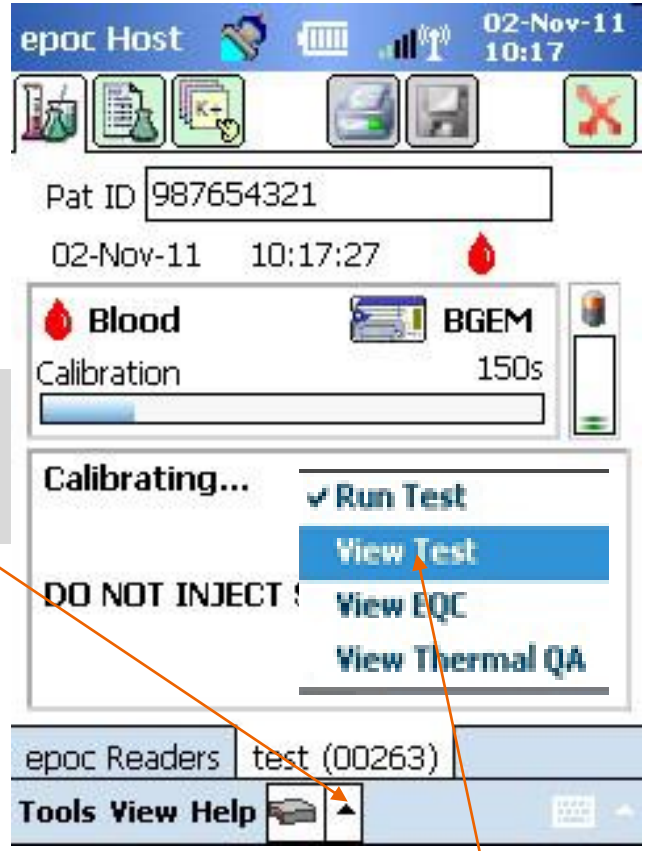


8 To print tap Printer icon
To save tap Save icon
To exit and sync tap red X

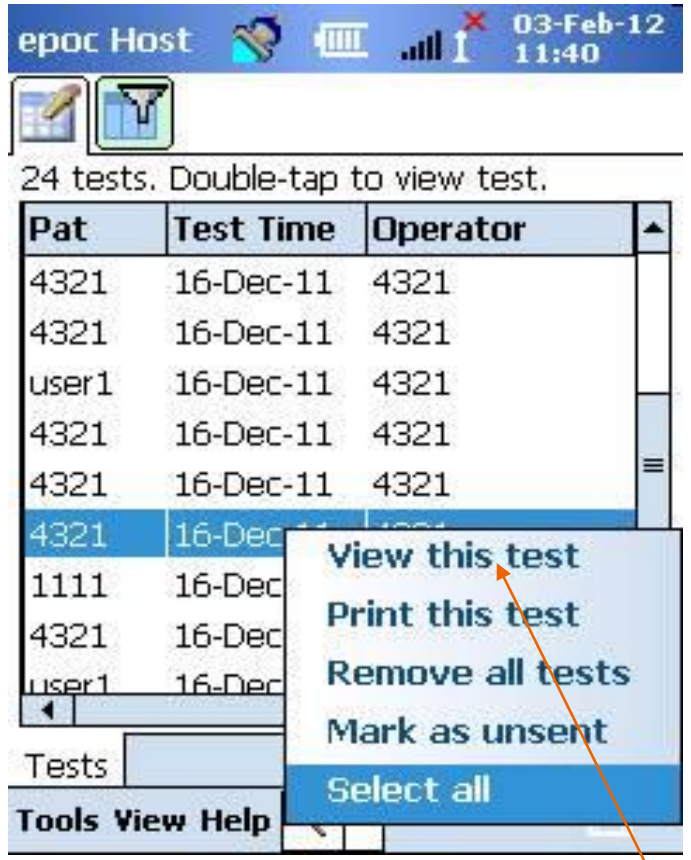
Result Review

Reviewing Previous Results

Press the black triangle-bottom/middle



Use the stylus to press "View Test"



Use the stylus to select patient
Tap and hold until "view this test"
Click "view this test"
Results will display in 15 seconds
Tap the "X" to exit

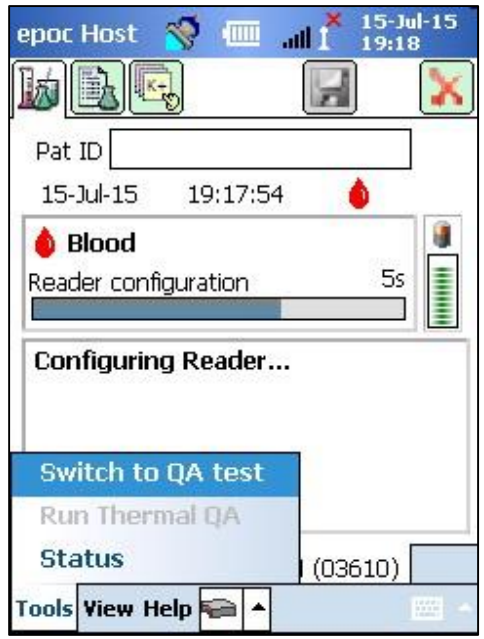
QC Analysis

epoc Quality Control

How To Run A QA Test Using An eVAD File

Option 1:

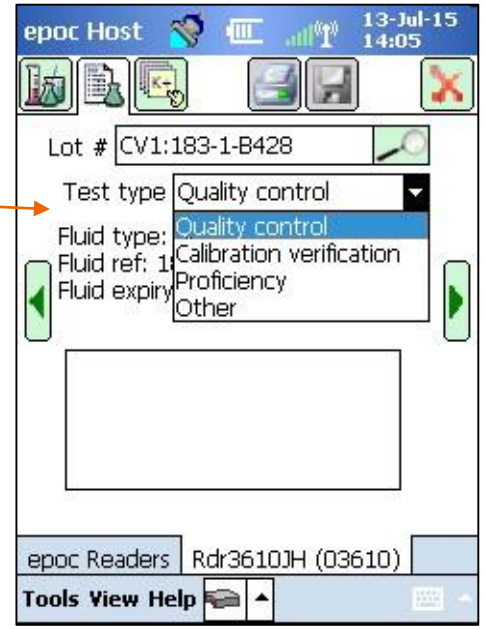
Log in as you would to run a patient. Click on Tools once logged in. Then click on Switch to QA test to convert to QA mode. Pat ID will switch to Lot # and Blood will switch to QA.



Option 2:

Select Test Information Icon(notepad with beaker)

- Select a test from the Test type drop down menu
- Choose Quality Control



Once Option 1 or 2 is chosen proceed with the following:

- Place curser in Lot # field
- Scan QA Lot number from the following
- QC box or vial
- Cal Ver will need the eVAD sheet from Document Library to barcode

epoc Quality Control

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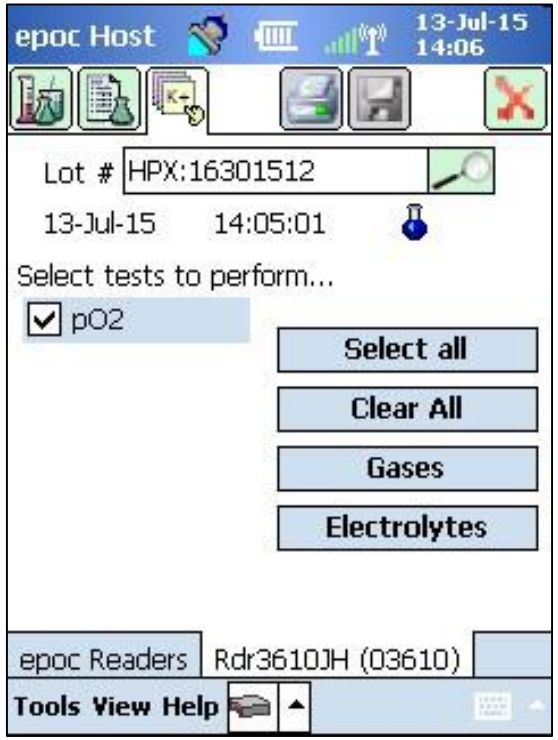
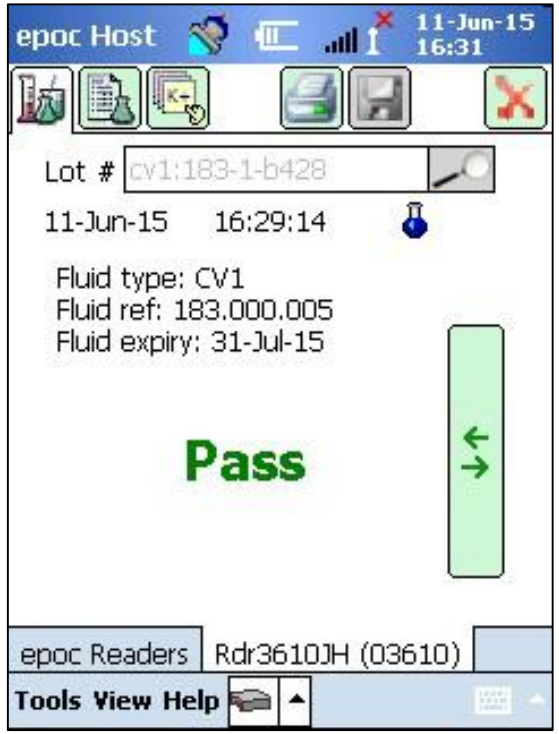
Once in QC mode

- Depending on the fluid type, all applicable analytes will be selected automatically as soon as the barcode is scanned. You may also adjust the list by unchecking the boxes for the analytes you do not wish to report.
- View the test results. When the QA test is completed, the screen will display **Pass** or **Fail**. Tap on the green bar to see the complete results.
- If incorrect version of the eVAD is present you will see results as apposed to Pass or Fail. Newest version of eVAD will need to be uploaded.

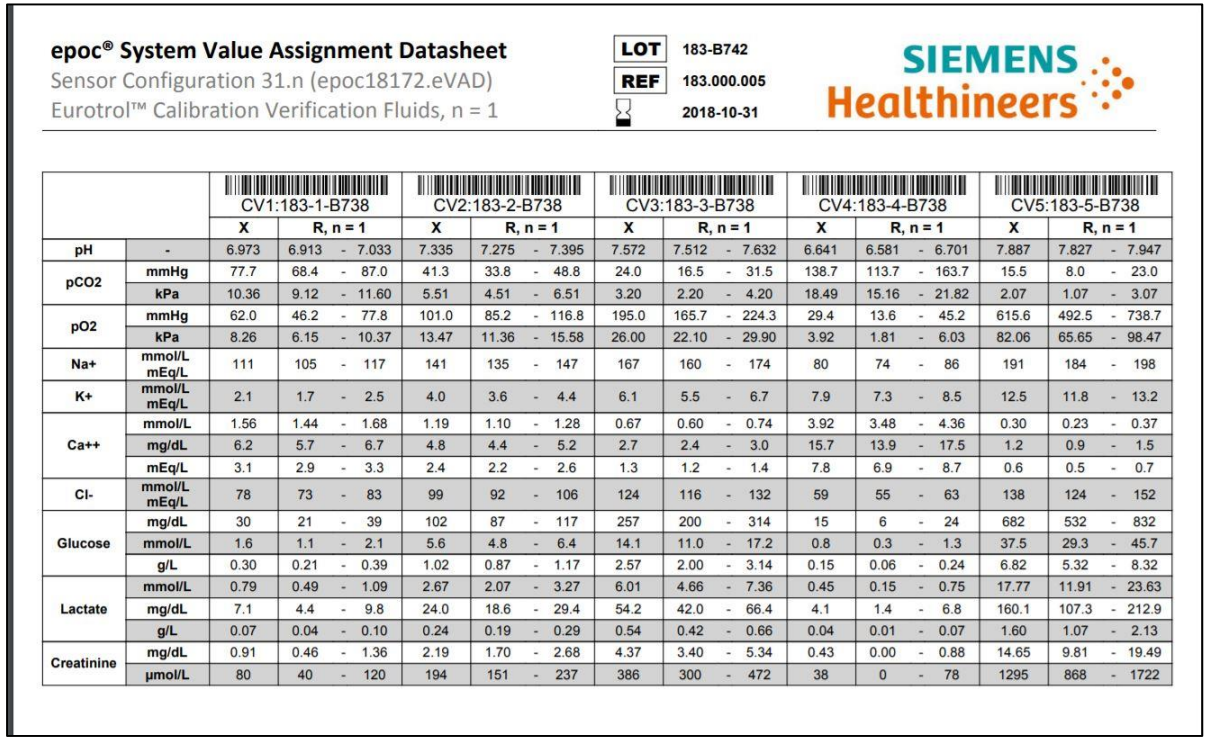




epoc Quality Control

How To Run A QA Test Using An eVAD File

- 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.
- Download the current Value Assignment on Document Library- Siemens-Healthineers at **https://doclib.siemens-healthineers.com/home.**
- Never use Target Values or Ranges from the package insert included with Control Fluids



epoc® System Value Assignment Datasheet
Sensor Configuration 31.n (epoc18172.eVAD)
Eurotrol™ Calibration Verification Fluids, n = 1

LOT 183-B742
REF 183.000.005
2018-10-31

SIEMENS Healthineers

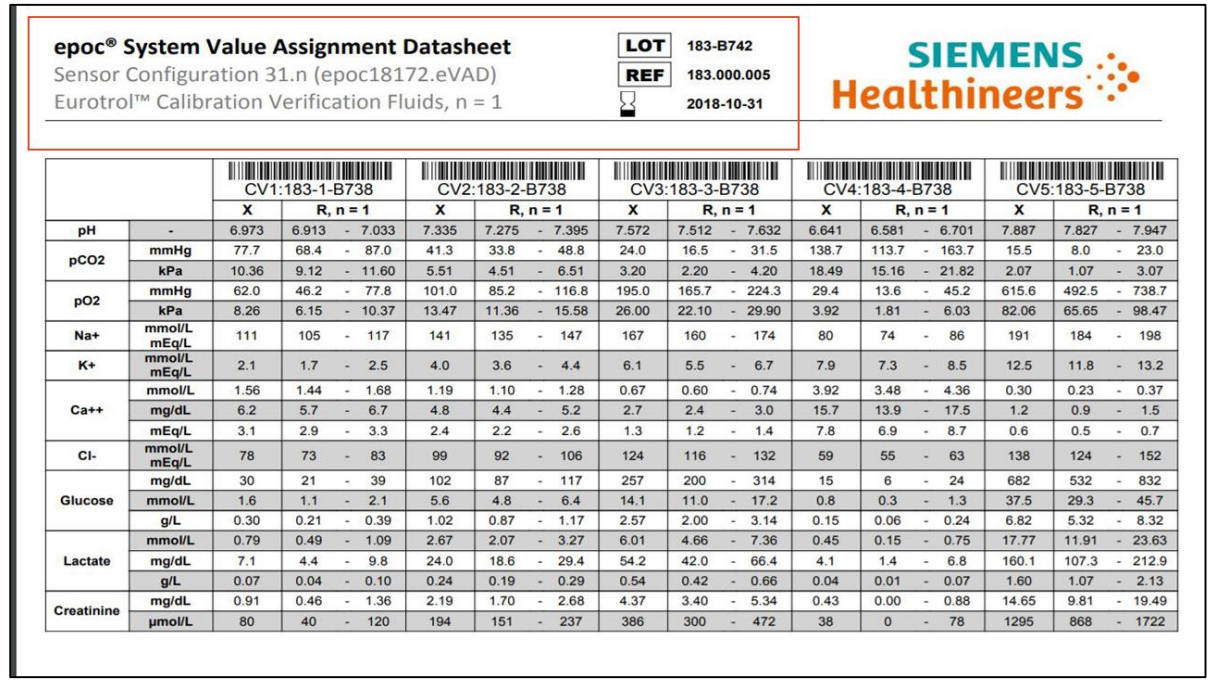
		CV1:183-1-B738		CV2:183-2-B738		CV3:183-3-B738		CV4:183-4-B738		CV5:183-5-B738	
		X	R, n = 1	X	R, n = 1	X	R, n = 1	X	R, n = 1	X	R, n = 1
pH	-	6.973	6.913 - 7.033	7.335	7.275 - 7.395	7.572	7.512 - 7.632	6.641	6.581 - 6.701	7.887	7.827 - 7.947
pCO2	mmHg	77.7	68.4 - 87.0	41.3	33.8 - 48.8	24.0	16.5 - 31.5	138.7	113.7 - 163.7	15.5	8.0 - 23.0
	kPa	10.36	9.12 - 11.60	5.51	4.51 - 6.51	3.20	2.20 - 4.20	18.49	15.16 - 21.82	2.07	1.07 - 3.07
pO2	mmHg	62.0	46.2 - 77.8	101.0	85.2 - 116.8	195.0	165.7 - 224.3	29.4	13.6 - 45.2	615.6	492.5 - 738.7
	kPa	8.26	6.15 - 10.37	13.47	11.36 - 15.58	26.00	22.10 - 29.90	3.92	1.81 - 6.03	82.06	65.65 - 98.47
Na+	mmol/L mEq/L	111	105 - 117	141	135 - 147	167	160 - 174	80	74 - 86	191	184 - 198
K+	mmol/L mEq/L	2.1	1.7 - 2.5	4.0	3.6 - 4.4	6.1	5.5 - 6.7	7.9	7.3 - 8.5	12.5	11.8 - 13.2
Ca++	mmol/L	1.56	1.44 - 1.68	1.19	1.10 - 1.28	0.67	0.60 - 0.74	3.92	3.48 - 4.36	0.30	0.23 - 0.37
	mg/dL	6.2	5.7 - 6.7	4.8	4.4 - 5.2	2.7	2.4 - 3.0	15.7	13.9 - 17.5	1.2	0.9 - 1.5
	mEq/L	3.1	2.9 - 3.3	2.4	2.2 - 2.6	1.3	1.2 - 1.4	7.8	6.9 - 8.7	0.6	0.5 - 0.7
Cl-	mmol/L mEq/L	78	73 - 83	99	92 - 106	124	116 - 132	59	55 - 63	138	124 - 152
Glucose	mg/dL	30	21 - 39	102	87 - 117	257	200 - 314	15	6 - 24	682	532 - 832
	mmol/L	1.6	1.1 - 2.1	5.6	4.8 - 6.4	14.1	11.0 - 17.2	0.8	0.3 - 1.3	37.5	29.3 - 45.7
	g/L	0.30	0.21 - 0.39	1.02	0.87 - 1.17	2.57	2.00 - 3.14	0.15	0.06 - 0.24	6.82	5.32 - 8.32
Lactate	mmol/L	0.79	0.49 - 1.09	2.67	2.07 - 3.27	6.01	4.66 - 7.36	0.45	0.15 - 0.75	17.77	11.91 - 23.63
	mg/dL	7.1	4.4 - 9.8	24.0	18.6 - 29.4	54.2	42.0 - 66.4	4.1	1.4 - 6.8	160.1	107.3 - 212.9
	g/L	0.07	0.04 - 0.10	0.24	0.19 - 0.29	0.54	0.42 - 0.66	0.04	0.01 - 0.07	1.60	1.07 - 2.13
Creatinine	mg/dL	0.91	0.46 - 1.36	2.19	1.70 - 2.68	4.37	3.40 - 5.34	0.43	0.00 - 0.88	14.65	9.81 - 19.49
	µmol/L	80	40 - 120	194	151 - 237	386	300 - 472	38	0 - 78	1295	868 - 1722

epoc Quality Control

How To Run A QA Test Using An eVAD File

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.



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epoc Maintenance and Troubleshooting

epoc Maintenance

Care of the epoc System

The epoc Blood Analysis System requires a minimum of care and maintenance. The following general practices are recommended:

Turn off the epoc Reader and Host when not in use in order to conserve the battery.

Store the epoc Reader and Host in a secure, dry location when not in use.

Periodically check the condition of the wires and cables of the AC adapter to check for wear and ensure integrity of electrical connections

Cleaning the epoc System

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

- Alcohol

Result Error Messages

Message	Interpretation
cnc	Could not calculate. Component required for calculation was not available
Failed iQC	Failed internal quality control
expired	Card was expired. Test results not displayed

epoc Troubleshooting

- Make sure host is seated properly in reader to verify proper charging
- Barcode Reader not working or frozen screen-soft reboot
- Soft reboot-hold power button down for 5 sec or if needed
- Hard reboot- hold 9, 1 and the power button down
- iQC error-use new card
- Electronic QC Failure- Turn reader and host on and off
- Red Indicator Light-remove card completely and re-insert
- Removing card will in process or Indicator light is “blinking and thinking”, could possibly damage the reader.
- Barcode works but does scan- Verify barcode area is clean, wipe bar code area
- Always carry system as a closed unit to prevent dropping
- Never submerse the epoc Reader and epoc Host into any liquid. Never allow fluids to pool in Pivot or Membrane Switch areas
- Refer to the System Manual for further information(Section 14)
- Call Siemens Technical Support-1-877-229-3711 Option # 5

epoc Troubleshooting

Out-of-range results on the Test Card for QA and Calibration

From the epoc Host, disconnect from the Reader, then reconnect. If the wireless connection is successful and Electronic QC passes, verify the following and then repeat the test:

- Use of correct control or Calibration Verification Value Assignment Datasheet
- Use by Date of Controls has not been exceeded
- The Controls have been handled correctly: see Instructions for Use
- Test Cards and Controls have been stored correctly
- If the repeat results are in range, the cards are acceptable for use. If the results are still out of range despite meeting the above criteria, repeat the test using a new box of control solutions and/or Test Cards. Contact Technical Services if Controls or Test Cards continue to fall outside of specified ranges

epoc Troubleshooting

Failed Reader Electronic QC

- If a Reader fails electronic QC, first confirm the failure.
- Close the Reader Screen, turn the Reader OFF and ON, and then try to connect to the Reader again.
- If Reader connects successfully, and therefore passes electronic QC, it is acceptable for use. If the problem is not resolved, contact Technical Services

Congratulations!!

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You have completed the epoc Training Module