epoc®

BLOOD ANALYSIS

Veterinary User Guide

CE

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The epoc System is a breakthrough blood analysis system providing state-of-the-art lab results within seconds: quick turnaround time with no refrigeration. This portable device consists of the blood analyzer, mobile computer, and disposable test cards and requires blood samples as small as 100 microliters.

This Veterinary User Guide describes the proper use and operation of the epoc Blood Analysis System as applied to veterinary purposes. An extensive epoc System Manual describing the system as applied to treating human patients is available for reference in English and many other languages. This manual also includes full epoc System specifications in Section 13.

Even though the epoc System is designed to be user friendly, all operators require training by authorized personnel prior to conducting patient testing.

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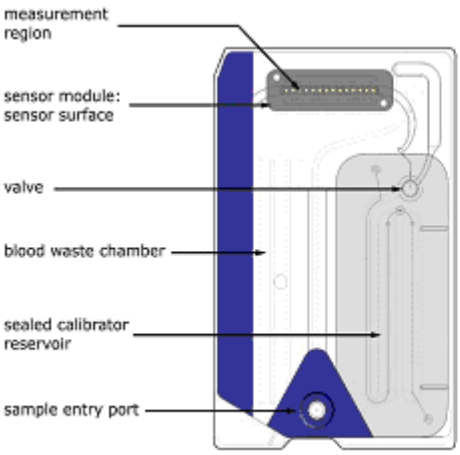
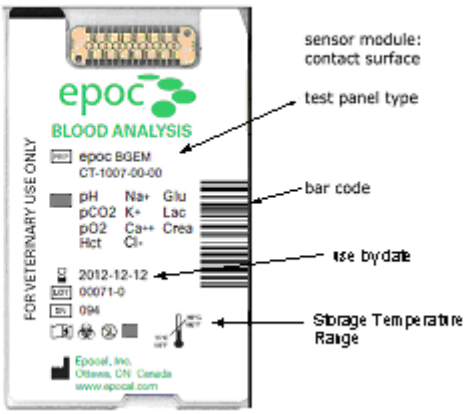
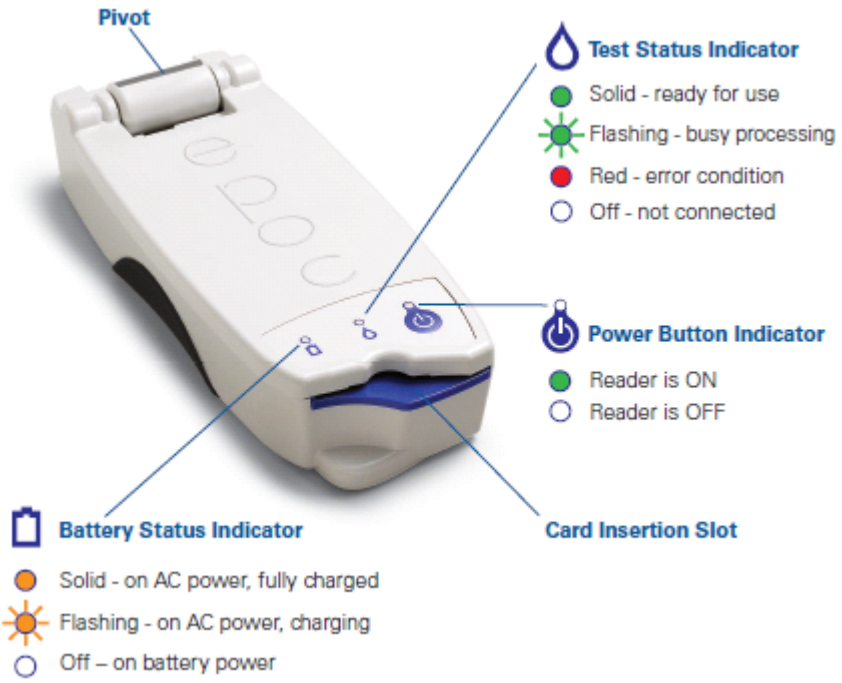
01 epoc System Components

Test Cards





Reader

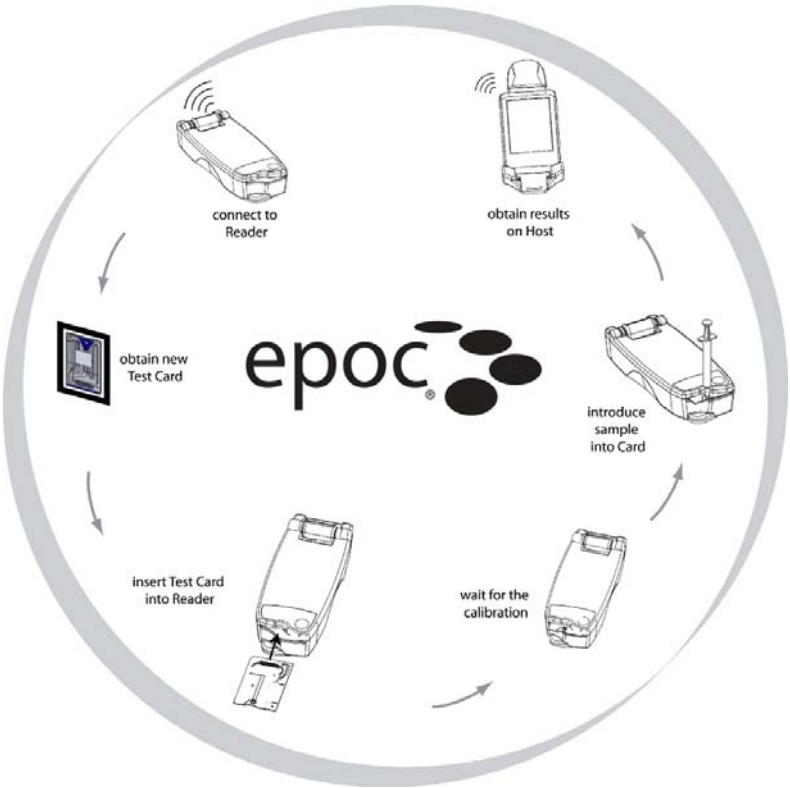


epoc Host

epoc System assembled

02 Test Process Overview

1. The initiation of a test starts with establishing a communications link between the Host and Reader;
2. A Test Card is removed from its Card Pouch;
3. The Test Card should be inserted immediately into the Reader;
4. During the 165 second calibration period, the User acquires a blood sample for the test;
5. After calibration is complete, the Reader Indicator and epoc Host inform User that the Test Card is ready to receive a blood sample. The sample can be introduced at any time thereafter within 7.5 minutes. After 450 seconds, the sample introduction period times-out, and the Test Card can no longer accept a sample;
6. Approximately 40 seconds after sample introduction, the Host displays analytical Test Results;
7. The Test card can be removed from Reader. It must be discarded as biohazard waste.



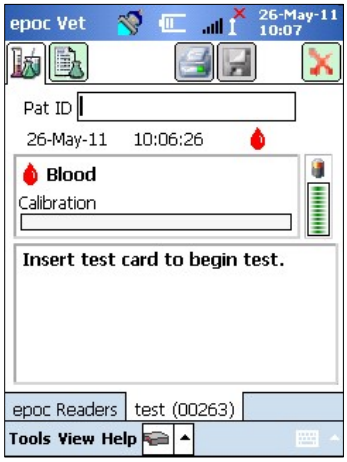
03 User Interface

The epoc Host Application has a simple, intuitive user interface.

The **Tabs** within the software allow the User to navigate to different parts of the application using the Stylus.

The **Buttons** perform actions and enable fields for text input.

An Example Screenshot shows the basic elements of the user interface.



The user interface is context dependent and changes depending on where and what a User is doing.

There is always a **Toolbar** 

at the bottom of the Screen that contains Menu Items and Toolbar Buttons. The Text Input Button is located in the bottom right corner of the screen.

Select different screens by tapping the **Screen Tabs** 

at the bottom of the Screen. Screens are available for each connected Reader and for each opened Test Record.

Navigate multiple pages within each Screen by tapping on the **Page Tabs**  across the upper left corner of the Screen.

Additional Buttons  are located in the upper right corner of the screen, which are unavailable for use when colored gray.

The interface varies depending on whether the User is using an Operator or Administrator Account.

04 Test Cards

Storage and Handling

	Always store Test Cards at room temperature (15°-30° C). Never fridge-store or allow Test Cards to freeze.
	The shipping boxes are not to be used for storage. It is the responsibility of the customer facility to constantly maintain the temperature above 15° and below 30° C. The temperature monitors are for shipping use only.
	Test card pouches provide a low humidity environment for card storage. The card pouch should be opened and the Test Card removed only when conducting blood or QA testing. Never store Test Cards outside of the card pouch or near intense light or heat sources.
	Never use a Test Card if the card pouch seal has been compromised in any way. The low humidity threshold within the pouch may have been exceeded.
	For a blood or QA test, a Test Card must be taken directly from the card pouch. Never place a Test Card on any surface prior to use.
	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.
	Strong mechanical shocks to the card container may induce bubbles in the Test Cards. Never drop or otherwise mechanically stress the Test Cards or pouches.

Shelf Life

	All epoc Test Cards have a limited shelf life. Test cards must be used before the end of the "Use By" date printed on each Test Card.
	The "Use By" date is encoded into the Barcode on each Test Card. The epoc Reader will reject any Test Card past the "Use By" date on the Test Card. The "Use By" date is based upon continuous storage of the Test Cards between 15° and 30°C.

epoc BGEM Test Card Specifications

Test Name	Acronym	Measured	Calculated	Units	Measurement Range
pH	pH	√		pH units	6.5–8.0
Carbon Dioxide Partial Pressure	pCO_2	√		mm Hg	5–250
				kPa	0.7-33.3
Oxygen Partial Pressure	pO_2	√		mm Hg	5–750
				kPa	0.7-100
Sodium	Na+	√		mmol/L	85–180
				mEq/L	
Potassium	K+	√		mmol/L	1.5–12.0
				mEq/L	
Ionized Calcium	Ca++	√		mmol/L	0.25–4.0
				mg/dL	1.0-16.0
				mEq/L	0.5-8.0
Chloride	Cl-	√		mmol/L	65 - 140
Glucose	Glu	√		mmol/L	1.1–38.5
				mg/dL	20-700
				g/L	0.20-7.00
Lactate	Lac	√		mmol/L	0.30 - 20.00
				mg/dL	2.7 – 180.2
				g/L	0.03 - 0.18
Creatinine	Crea	√		mg/dL	0.30 – 15.00
				µmol/L	26 - 1326
Hematocrit	Hct	√		% PCV	10–75
				L/L	0.10-0.75
Hemoglobin	cHgb		√	g/dL	3.3–25
				mmol/L	2.0-15.5
				g/L	33-250
Actual Bicarbonate	$cHCO_3$-		√	mmol/L	1–85
				mEq/L	1–85
Total Carbon Dioxide	$cTCO_2$		√	mmol/L	1–85
				mEq/L	1–85

Base Excess of Extra Cellular Fluid	**BE(ecf)**		√	mmol/L	-30-+30
Base Excess of Blood	**BE(b)**		√	mmol/L	-30-+30
Oxygen Saturation	**cSO_2**		√	%	0–100
Anion Gap, K+	**AGapK**		√	mmol/L	-10-+99

⚠	**Only veterinary test cards must be used in veterinary blood analyzers, and vice versa.**

05 Blood Collection

The epoc System is designed for point-of-care blood analysis. In general, it is recommended to test samples **immediately after drawing a sample** to obtain results that represent the Patient's status with the greatest accuracy**.**

Sample Type	• Fresh whole blood from arterial, venous, or capillary sources.
Sample Volume	• >92µL, non-volumetric quantity.
Sample Collection	• 23 gauge or larger needle. **See table below for details on sample tubes and syringes.**
Anticoagulant	• When needed, use Li or Na heparin only. **See table below for restrictions on Heparin use.** • Cat blood should be drawn into anticoagulant to prevent clotting.
IV or indwelling line	• Avoid using line if possible. If using, draw and discard 3-6 times the volume of the line to avoid contamination of sample.

	Always wear protective gloves when handling blood samples.

	
	**Blood samples must be collected according to the facility's policies and procedures.** **Always follow the specific instructions provided by other medical manufacturers when considering information in this section.**

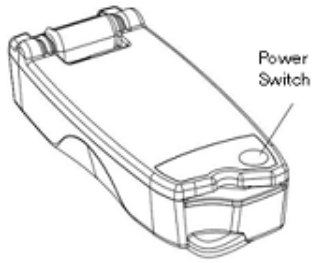
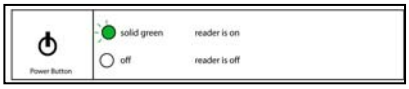
Sample Collection Method

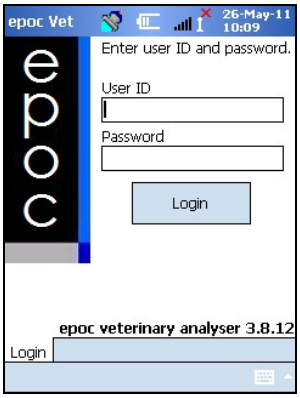
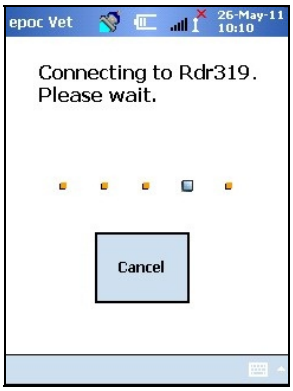
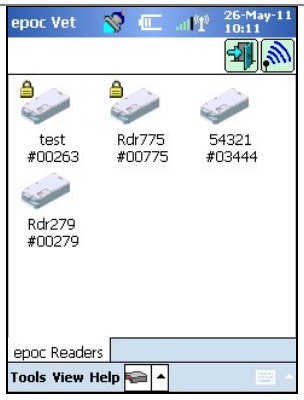
See table below for options for specific tests and sample collection methods:

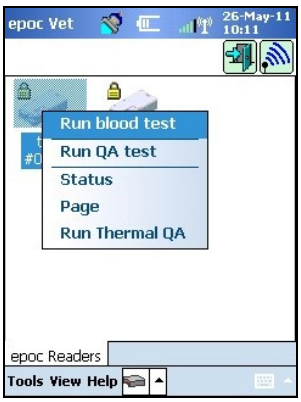
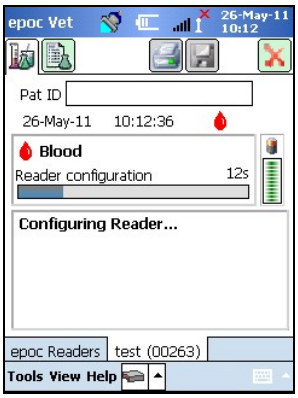
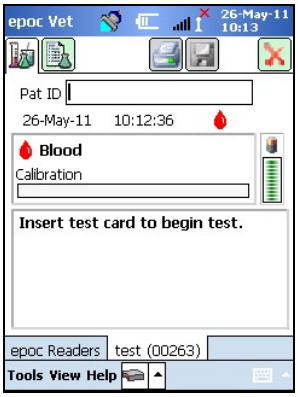
Test	Syringes	Evacuated Tubes
pO_2	• 1 or 3ml plastic, non-iced • Test in less than 30 min	• Not recommended
pH / pCO_2	• 1 or 3ml plastic • Test in less than 30 min	• Without anticoagulant • With Li or Na heparin
Ionized Calcium (Ca++)	• 1 or 3ml plastic • Without anticoagulant • With Li or Na heparin only if <10 IU/ml • With balanced heparin only if <70 IU/ml	• Without anticoagulant • With Li or Na heparin only if <10 IU/ml
Hematocrit (Hct)	• 1 or 3ml plastic • Immediate testing is recommended in order to avoid RBC settling. (Note: Re-suspension of RBC requires an air bubble of significant volume[4])	• Without anticoagulant • With Li or Na heparin only (do not use EDTA). *Cat blood should be drawn into anticoagulant to prevent clotting.*
All other tests	• 1 or 3ml plastic	

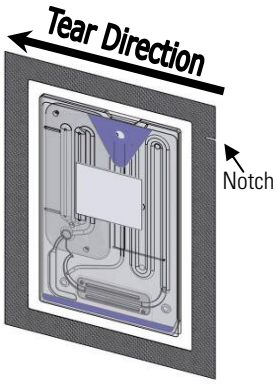
06 Running a Test

Power Up Host and Reader

Turn "ON" epoc Reader		Press the Power Button to turn "ON" the Reader.	
		The Power indicator will turn green indicating the epoc Reader is "ON" and ready for use. Press and hold the Power Button for several seconds to turn "OFF" the Reader when not in use to conserve battery power.	
			
		The Reader can be operated on battery power only or while the battery is being charged using the AC Adapter provided with the Reader.	
Turn "ON" epoc Host		Press the Power Button to wake up the epoc Host if the screen is blank.	

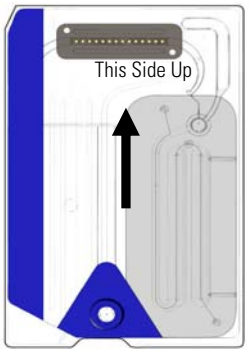
Login to epoc Host Software		Enter a valid User ID and Password and press the Login button. **If no User ID and Password have been assigned, users can login by inputting any character into each field.**	
Begin a Test			
Establish Connection Between Host and Reader		**When there is a single dedicated Reader:** The epoc Host will automatically connect to its dedicated epoc Reader. The Host—Reader connection can be cancelled by tapping the Cancel button. *Only* epoc *Readers that are turned ON will be located by the* epoc *Host.* *If the system administrator has configured the system to connect with a single* epoc *Reader, the* epoc *Host will automatically connect to that* epoc *Reader only.*	
		When there are multiple Readers: If the system administrator has configured the system for multiple epoc Readers, all epoc Readers available for connection are shown. The **Reader Icon**  displays the Reader Name above and the serial number below.	

		Once the desired Reader is displayed: 1. Press and hold the Reader Icon to select it for testing. A drop down menu is displayed. 2. For a blood test, select: "Run blood test." OR For a QA test (if authorized), select: "Run QA test." *Only* epoc *Readers that are turned ON will be located by the* epoc *Host.* *The* ***Discovery icon***  *can also be tapped to find ("discover") more readers. Tapping the discovery icon when inactive will initiate this discovery process. Tapping the discovery icon while discovering will end the discovery process.*	
Initialization of Test Cycle		• A two- level internal Electronic QC Test of Reader is run automatically; • Configuration data are sent by the Host to the Reader; • The motorized mechanism inside the Reader can be heard as it resets; • Reader information (name, serial number) is displayed on the bottom tab; • The Test Status Indicator of the Reader turns on and stays green. ***8 Hour Electronic QC Check:*** *The* epoc *Host checks that the Electronic QC Test of the Reader has been run within the past 8 hours.* *If the* epoc *Host has been connected to the Reader continuously for 8 hours or more, the Host will disconnect from the Reader and inform the User they must reconnect to the Host so that another Electronic QC Test could be performed.*	
Check Test Information		The Host Screen displays: • The Patient ID or Lot Number field; • Current Date and Time; • The type of test: Blood test or QA test; • The battery charge level of the Reader.	

		If running test cards on the "Use By" date, allow sufficient time to complete the test before midnight. Test results do not display after midnight of the "Use By" date. *Additional tabs*  *for accessing other test information entries that may be used to ensure a complete test record.* **Always verify that current date and time are correct before running a test.** **The date and time displayed become part of the test record.** **Contact the administrator prior to running a test if adjustment of the date and/or time is required.**	
Obtain Test Card			
Open Pouch		1. Select a properly stored veterinary Test Card; 2. Starting at the Notch, tear open the Card Pouch as shown. **The card pouch should be opened only when conducting blood or QA testing to assure a low humidity environment for the test card.**	

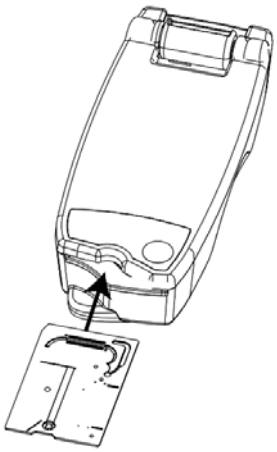
Remove Test Card from Pouch		1. Carefully (read cautions below) remove the Test Card from the card pouch. 2. Place the test card directly into the epoc Reader's Card Insertion Slot (details below). 3. Discard the empty pouch. **Always take the Test Card directly from the Pouch before inserting it into the Reader.** **Never touch the Sensor Module's contact surface or Blood Sample Entry Port.** **Never place the Test Card on any surface before running a test.**	

Insert Test Card into Reader

Orient Test Card		Position the Test Card with the Blue Label side facing upwards and the Sensor Module towards the Reader. *Test Cards are "keyed" using a Notch in the corner to ensure correct card orientation during insertion.* **The epoc Reader must be placed on a stable horizontal surface, such as a tabletop, prior to inserting the Test Card.** **Never insert anything except a Test Card into the Reader's Card Insertion Slot.**	

Insert Test Card

1. Push the Test Card into the Reader's Card Insertion Slot at the front of the Reader with a smooth single motion. Continue inserting the Test Card until the slight resistance is felt;
2. Push the Test Card past this point to "lock" it into place. This is the final Test Card position;
3. The Reader beeps once, and the Test Status Indicator turns solid green to notify the User that the Test Card has been successfully inserted.



Insertion of a Test Card causes the Barcode Reader in the Reader to turn "ON." Avoid abrupt stops or unevenness in speed during Test Card insertion in order for the Barcode to be successfully read.

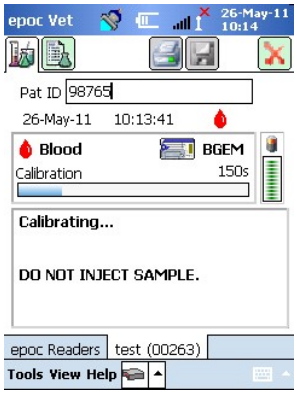
Any problem reading the Barcode (or any other error) causes the Test Status Indicator to turn solid red. Check the Host for an error message and completely remove the Test Card from the Reader.

Upon correct Test Card insertion, the Reader is configured for the card type indicated by the Test Card Barcode. The Reader performs a series of card integrity checks.

Test Sequence

Test Card Calibration

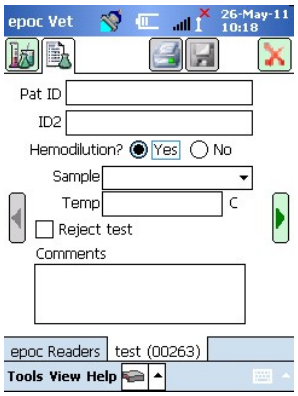
1. The motorized mechanism in the Reader can be heard as calibration fluid is released over the sensors within the Test Card;
2. The Test Status Indicator on the Reader flashes green to indicate the start of the test calibration sequence;
3. The Host confirms the start of the test by entering the calibration mode and displays the calibration progress.

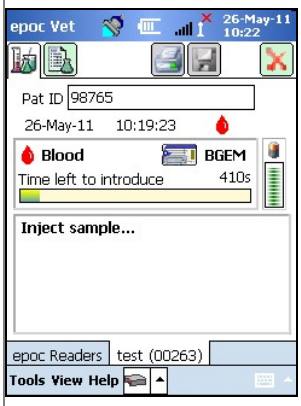


The calibration process takes approximately 165 seconds to complete.

During the calibration sequence, the User can prepare the patient and obtain the blood sample.

⚠	**The Reader must rest on a flat horizontal surface without movement for the duration of the test.**

		Read information on Sample Collection in BGEM Test Card Specifications Section of this Guide to ensure that blood samples are properly collected and handled for testing.	
Enter Test Information		Test information can be entered at any time during the test. The Patient ID may be entered using the stylus and text input display accessible from the bottom of the screen, or using the barcode scanner (see below). For a **Blood Test**: 1. Select the Test Information Tab on the Reader Screen to enter the Patient ID, Species type, and related information; 2. The system administrator may require the Hemodilution settings; 3. Using the arrow, additional settings related to respiratory therapy may be entered. For a **QA Test** (not shown): 1. Select the Test Information Tab on the Reader Screen to enter the QA fluid Lot Number to identify the test results for the card under test; 2. The Test Information Page for QA tests contains only the Comments field (not shown). *If the Patient ID is not entered prior to completion of the test, the User is prompted to enter the Patient ID when the test results are displayed.* *Patient information entered **prior to completion** of the test is saved automatically with the test results when the test is complete. Patient information entered **after** the test is complete, but before the next test starts, must be saved by tapping the **Save** button.* **Exercise care when entering the patient IDs and other information.** **Ensure the correct Reader is selected by verifying that the Reader name corresponds with the Reader used to conduct the test.**	

Using Barcode Scanner		1. Press the stylus in the Patient ID field. A cursor will appear. 2. Activate the Barcode Scanner by pressing the Read Barcode Button at the left or right side of the epoc Host. The Barcode Icon at the top of the screen indicates when the barcode scanner is ready to scan.	
Sample Introduction Window		The epoc Host displays the message, "Inject sample…." The screen has a bar indicating the time remaining to introduce a sample. The blood sample must be introduced into the card during this 7.5 min (450s) period. ⚠ **Introducing the sample too soon or too late will cause an error and abort the test. In this case, a new Test Card must be inserted and the test procedure started again.**	

Sample Introduction Method

1. Hold the syringe barrel vertically between finger tips and thumb (**Figure 1**).

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

Figure 1

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

2. Using slight downward pressure, secure the syringe luer's tip into the center recess of the blood sample entry port of the Test Card. Rotate the syringe up to 1/4 turn to ensure a good seal (**Figure 2**).

   The User should feel the Syringe Tip engage with the Rubber Seal of the Test Card Entry Port. Press the Syringe with enough downward force to engage Syringe Tip with Blue Rubber Seal.

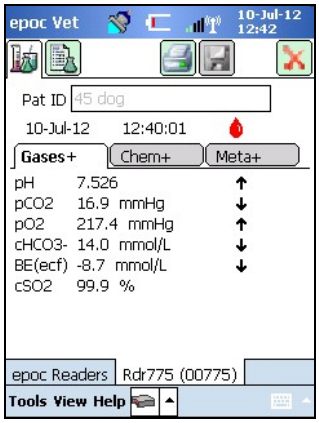
Figure 2

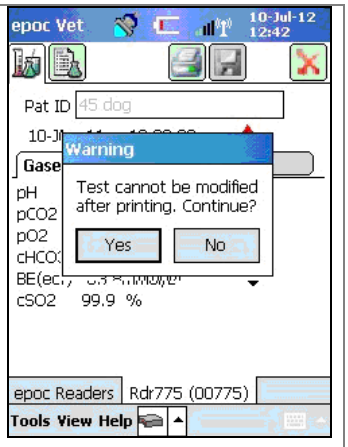
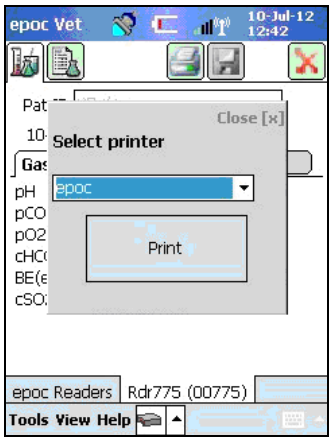
3. While maintaining downward pressure, use the index finger of your other hand to steadily depress the Syringe Plunger with a single, smooth, continuous motion until prompted to stop (**Figure 3**).

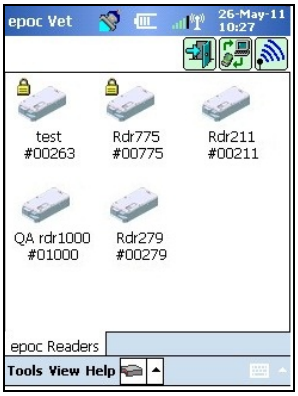
Figure 3

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.

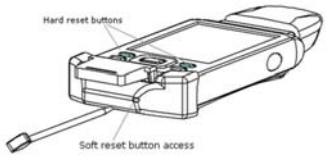
Learn to use the audio and visual feedback to perform this step easily and reliably. A normal dispense operation takes about 1 second or less.

		<table><tr><td>⚠</td><td>**Sample introduction should never exceed 2 seconds. Failure to heed the audio or visual prompts may cause the sample to flow from the vent hole at the end of the Test Card waste chamber and possibly into the epoc Reader.**</td></tr><tr><td>⚠</td><td>**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.**</td></tr><tr><td>⚠</td><td>**Never attempt to clean inside the Reader**</td></tr></table>	
Sample Analysis		The Reader automatically analyzes the test sample. The analysis process takes about 40 seconds.	
Test Completion		Once the analysis is complete: 1. The epoc Host displays the Test Results from the Reader Screen (tab on left). Test results can be viewed in three (3) sub-tabs "Gases+," "Chem+," and "Meta+"; 2. The Test Status Indicator on epoc Reader will flash green, indicating the Test Card can be removed. Motorized mechanism is heard briefly as the Calibration Fluid Plungers are disengaged; 3. Remove the Test Card from the Reader and dispose of it using appropriate biohazard precautions. *The Patient ID must be entered before the test results are displayed. Once saved, the Patient ID textbox and Save button are disabled again.* <table><tr><td>⚠</td><td>**Always wear protective gloves when removing a Test Card from the Reader.**</td></tr></table>	

Print Results (optional)		To print a Test Result: 1. Ensure all desired data fields have been completed; 2. Tap the Print Button  ; 3. Follow the on-screen instructions.	
		Select a printer from the drop-down list, and tap on the Print Button. Results will be printed along with the appropriate reference ranges for the species selected.	
Running Another Test		After a used Test Card is removed, the Reader's Test Status Indicator will turn solid green, indicating that the Reader is ready to perform another test.. Repeat same procedure to complete another test. **Never reuse a Test Card. Test Cards are designed for single use only.** **Starting a new test permanently saves the previous test record. Changes to that test are no longer possible.**	

Close Test and Disconnect Reader		When all testing with a Reader is complete and all data entries are made, the test is closed by tapping on the Close Button  in the top right to close the Reader Screen for that Reader. Disconnecting a Reader does not affect the connection or test status of other Readers already discovered or connected. **Closing the test and disconnecting the Reader permanently saves the test, and changes to that test are no longer possible.**	
EDM Synchronization		**For epoc Data Manager (EDM) users only**: 1. Disconnect all readers from running the tests; 2. Press the EDM Synchronization Button  on the Host. Synchronizing with the EDM may also be accessed from the Tools menu, lower left corner. The epoc Host also retrieves configuration information such as operator lists by using this feature. *The System Administrator may configure the epoc Host to synchronize upon closing a test. In this configuration, the EDM synchronization procedure occurs immediately after the Reader Screen is closed at the end of a test.*	
Log Out and Turn Power "OFF"		Log out of the epoc Host Application when finished testing and viewing test results. 1. Select "Tools," then "Logout" on the menu at the bottom left corner of the screen, or press the Logout button  . 2. Use the Power Button on the Host to turn the device "OFF." *The Reader automatically powers "OFF" after 20 minutes of idle time to conserve battery power, but only if:* *a) The Reader is NOT plugged in, and* *b) The Reader is NOT connected to a Host.*	

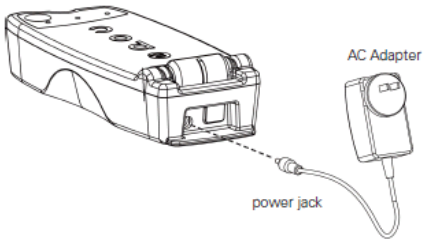
07 Routine Procedures

Soft Reset	A **Soft Reset** is like rebooting a computer. It is useful if the epoc Host is non-responsive. **Data will not be lost after a Soft Reset.** Using the tip of the stylus, lightly press and release the Soft Reset button located inside the hole on the bottom of the epoc Host 
Hard Reset	Performing a **Hard Reset** is also like rebooting a computer. It is useful if the epoc Host is non-responsive and a Soft Reset proves ineffective. The data will not be lost after a Hard Reset, but the date and time may need to be reset. 1. Using your index and middle finger, **press** and **hold** the two **Hard Reset buttons** located below the LCD screen (see diagram above). 2. While continuing to hold these two buttons, use the tip of the stylus to lightly press and release the Soft Reset button located inside the hole on the bottom of the epoc Host. 3. Continue pressing the two buttons while the Socket splash screen appears and then disappears. 4. Release the two buttons when the **GREEN Windows Mobile startup screen** appears.

Charge Reader Battery with AC Adaptor

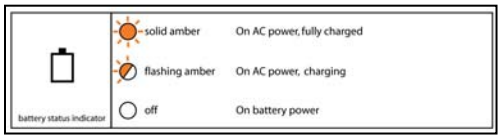
The epoc Reader contains a Lithium Ion Rechargeable Battery. The battery compartment is not available to the User.

1. The AC Adaptor recharges the Reader when the Reader is either "ON" or "OFF";
2. The AC Adapter plugs into the Power Jack located at the rear of the Reader.



⚠	**Exercise caution if using an Extension Cord or Power Bar with the Reader AC Adaptor. These devices may void the product safety certification if not appropriately certified or approved for medical use.**
⚠	**The Reader Battery must be replaced by authorized Epocal service personnel only.**
⚠	**Use only the AC Adapter, as specified by the label on the bottom of the Reader.**

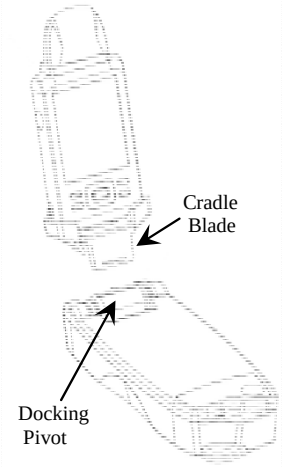
1. When the Reader is charging, the **amber** Battery Status Indicator will flash. When charging is complete, this indicator will stay solid **amber**;



2. When the indicator is off, it indicates that the AC Adaptor is not connected and the Reader is operating on battery power;
3. It takes approximately four hours to recharge a fully discharged Reader Battery.

Charge Host Battery using Reader

1. The epoc Host contains a Lithium Ion Rechargeable Battery;
2. To re-charge the battery, insert the epoc Host Cradle Blade into the epoc Reader Docking Pivot. Connect the Reader AC Adaptor to the Power Jack at the rear of the Reader and also into the wall receptacle;
3. Up to four (4) hours may be required to fully recharge the battery. The Host can be operated normally while it is being charged;
4. The **red** Charging Indicator turns "ON" indicating that the Host battery is charging. The indicator turns solid **green** when charging is complete.



Charge Host Battery using Host AC Adaptor

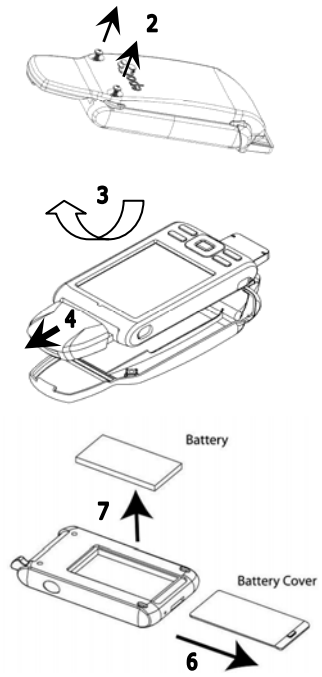
A separate AC Adaptor is available for use with the epoc Host as an accessory. The adaptor allows the User to separately recharge the battery in the epoc Host when outside the Patient's vicinity.

Replace Host Battery

Replacing the Battery

To remove the cradle for epoc Host Version B (Plastic Back, one piece):

1. Turn off epoc Host;
2. Undo two (2) Screws using a correct screwdriver, so that they remain captive in plastic housing;
3. Unclip the Cradle from the Barcode Scanner and lift the Host up and out to remove from the Cradle;
4. The SD slot is beneath the Barcode Scanner. If needed, carefully pull the Barcode Scanner from its slot to gain access;
5. Use the Stylus to release the Battery Cover;
6. Remove the Battery Cover from the back of the Host;
7. Remove the Battery;
8. Replace the Battery in accordance with replacement battery information found in Section 13 of the epoc System Manual;
9. Replace the Battery Cover and fasten securely;
10. Insert the Barcode Scanner in the Host. Re-assemble the Host into the Cradle. Carefully align Host with the Cradle Connector. Fasten two (2) attachment Screws.



Only replace with a Battery designated for use.

Always dispose of batteries in accordance with local regulations. Never place a Battery in municipal waste.

08 QA Testing

Aqueous Blood Gas, Electrolyte, and Metabolite Control Fluids are commercially available for verifying integrity of newly received Test Card Lots. Recommended products are described in the table below.

Control Fluids do not contain animal serum or serum products, but do contain buffers and preservatives.

QA Test feature of the epoc System provides following characteristics:

- Ranges are increased, so the User can test analyte levels at, or just outside of, the Measurement Range;
- QA Test Results are stored separately from Blood Test Results in the epoc Data Manager.

QC Fluids Recommended for Verification of epoc Test Cards

Manufacturer	Description	REF No.	Usage	Level	Quantity	Volume	Epocal Order No.
Eurotrol Inc., Ede, The Netherlands	Eurotrol GAS-ISE-Metabolite QC	179-1-B913	BGEM	1	12 Ampoules	2.5 ml	CC-0007-00-00
Eurotrol Inc., Ede, The Netherlands	Eurotrol GAS-ISE-Metabolite QC	179-2-B913	BGEM	2	12 Ampoules	2.5 ml	CC-0008-00-00
Eurotrol Inc., Ede, The Netherlands	Eurotrol GAS-ISE-Metabolite QC	179-3-B913	BGEM	3	12 Ampoules	2.5 ml	CC-0009-00-00

	**Always follow Manufacturer's Storage Instructions.**
	**All Aqueous Control Fluids must be run as QA Test when using epoc System.**

Quality Control Fluids with Blood Gases

Quality Control Fluids contain dissolved gases, so they become very unstable over time after opening the Ampoule.

	**Always use a fresh Ampoule for each Test Card tested when testing multiple Test Cards using a single epoc Reader. Multiple Test Cards can be tested using one Ampoule only if tested at same time on multiple Readers.**
	**Once opened, Fluid should be analyzed immediately.**
	**Never use the last 0.5 mL of Control Fluid in Syringe.**
	**Gas Levels in Fluids vary with temperature. Deviation from room temperature affects gas levels in Fluid. Always handle Fluid carefully to avoid any heating or cooling.**

Procedure

1. If ampoules are taken from a cool storage, equilibrate the Ampoule to room temperature (20-25°C). Equilibration time for blood gas QC Fluids is four (4) hours minimum;
2. Immediately before use, shake the Ampoule vigorously for 5 to 10 seconds to equilibrate liquid and gas phases;
3. Always hold the Ampoule at the tip and bottom with your forefinger and thumb to minimize the increase in Fluid temperature. If necessary, tap the Ampoule tip to return Fluid into the bottom section of the Ampoule. Protect your fingers with gauze, tissue, or glove, or use an ampoule breaker to snap off the Ampoule tip at neck;
4. Immediately transfer Fluid from the Ampoule into a plain sterile 1 mL or 3 mL syringe with a 16-20 gauge blunt needle. When loading the syringe, **slowly** draw about 1mL of Fluid from the bottom of the Ampoule. Never invert the Syringe to expel the air trapped between the leading edge of Fluid and Syringe plunger (this will not affect the solution near the Syringe tip);
5. If air bubbles are continually drawn into the Syringe, or if a bubble is trapped near the Syringe tip, discard the Ampoule and the Syringe. Begin the process again with a fresh Ampoule and Syringe;
6. Before injecting Fluid in the Test Card, expel one (1) or two (2) drops from the Syringe;
7. Transfer Fluid immediately into the Test Card: remove the blunt needle and apply the Syringe luer in the Test Card's Sample Introduction Port as during a normal Blood Test procedure.

Temperature Correction for Blood Gas QC Fluids

It is well established that pCO_2 and pO_2 results are inversely affected by temperature.
Targets and ranges in Value Assignment Sheets can be adjusted to account for ambient temperature effects using the following table:

Temperature Correction for pCO_2 and pO_2 Targets for Aqueous Control Fluids

Parameter	Level	15-17°C	18-20°C	21-23°C	24-26°C	27-28°C	29-30°C
pCO_2	~70 mmHg	1.6	0.8	0.0	-0.8	-1.5	-2.0
pO_2	~55 mmHg	4.0	2.0	0.0	-2.0	-3.6	-5.0
pO_2	~95 mmHg	6.9	3.5	0.0	-3.5	-6.3	-8.6
pO_2	~145 mmHg	9.5	4.8	0.0	-4.8	-8.7	11.9

Parameter	Level	15-17°C	18-20°C	21-23°C	24-26°C	27-28°C	29-30°C
pCO_2	~9.33 kPa	0.22	0.11	0.00	-0.11	-0.20	-0.27
pO_2	~7.33 kPa	0.53	0.26	0.00	-0.26	-0.48	-0.66
pO_2	~12.66 kPa	0.92	0.46	0.00	-0.46	-0.84	-1.15
pO_2	~19.33 kPa	1.27	0.63	0.00	-0.63	-1.16	-1.59

For example, if ambient temperature in the laboratory is 15-17°C and pO_2 range is 135 to 155 mmHg, the Range can be adjusted by adding 9.5 mmHg to upper and lower limits to obtain the Adjusted Range: (135+9.5) to (155+9.5) = 144.5 to 164.5 mmHg.

Value Assignment Datasheets

The 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 Datasheets at http://www.epocal.com/ or contact your epoc Distributor.

Each Value Assignment Datasheet (VAD) is identified by Fluid Name, Level, Lot Number and epoc System Sensor Configuration Version. Assure all information is correct when using VAD to determine acceptability of results. The epoc System Sensor Configuration version is located in the epoc Host **Help, About** Menu.

Ranges displayed represent the maximum deviation expected when Fluids and Test Cards are performing properly. If the results are outside the specified ranges, refer to the Troubleshooting Section of this Guide or of the epoc System Manual.

	**Never use Target Values or Ranges from the package insert included with control fluids.**

09 Reference Ranges

RECOMMENDED REFERENCE RANGES				
Chemistry/Hematology:				
PARAMETERS	**Units**	**CANINE**	**FELINE**	**EQUINE**
Sodium	mmol/L	139 – 150	147 – 162	128 - 142
Potassium	mmol/L	3.4 - 4.9	2.9 - 4.2	1.9 - 4.1
Ionized Calcium	mmol/L	1.12 - 1.40	1.20 - 1.32	1.25 - 1.75
Chloride	mmol/L	106-127	112-129	100-111
Glucose	mmol/L	3.33 - 6.38	3.33 - 7.22	3.44 - 7.44
	mg/dL	60-115	60-130	62-134
Lactate	mmol/L	0.60 - 2.90	0.50 - 2.70	0.30 - 1.50
Creatinine	mg/dL	0.5-1.3	1.0-2.2	0.4-2.2
	µmol/L	44-115	88.4-195	35-195

Chemistry/Hematology:				
PARAMETERS	**Units**	**CANINE**	**FELINE**	**EQUINE**
Hematocrit	%	35 – 50	24 – 40	30 - 45
Hemoglobin	g/dL	12.0 – 17.0	8.0 – 13.0	10.0 – 15.0
$cTCO_2$	mmol/L	17 – 25	16 – 25	24 - 32
Anion Gap K+	mmol/L	8-25	10-27	5-15
Blood Gases - Arterial:				
PARAMETERS	Units	CANINE	FELINE	EQUINE
pH		7.350 - 7.450	7.250 - 7.400	7.320 - 7.440
pCO_2	mmHg	34.0 - 40.0	28.0 - 34.0	36.0 - 46.0
pO_2	mmHg	85 – 100	90 – 110	90 - 100
$cHCO_3$-	mmol/L	20.0 - 24.0	16.0 - 20.0	24.0 - 30.0
Base Excess	mmol/L	(-5) - (0)	(-5) - (+2)	(-5) - (+5)
sO_2	%	>90	>90	>90
Blood Gases - Venous:				
PARAMETERS	Units	CANINE	FELINE	EQUINE
pH		7.350 - 7.450	7.250 - 7.400	7.350 - 7.450
pCO_2	mmHg	35.0 - 38.0	33.0 - 51.0	36.0 - 46.0
$cHCO_3$-	mmol/L	15.0 - 23.0	13.0 – 25.0	25.0 – 30.0

Note: These reference ranges have been provided by Woodley Equipment Company Ltd.

10 Troubleshooting

The epoc System has no User serviceable parts or adjustments. Do not attempt to open the Reader or Host, or tamper with epoc Test Cards.

Selected epoc Host Application Messages are listed in the table below. To resolve errors encountered while using the epoc Host Application, first attempt solutions in the Response section in the order recommended. If the problem persists, contact your Technical Support representative.

Error message	Action
Unable to connect to Reader	1. Verify that the Reader is turned "ON"; 2. Verify that the Reader is not connected to another epoc Host. If used by another Host, wait until test is complete; 3. Verify that that the Reader is within range; 4. Repeat discovery by tapping the Reader Discovery Icon at top right of the screen. If the Reader is not discovered, turn the Reader "OFF" and "ON," and then try to connect to the Reader again; 5. If still unable to connect, reset the Host and log into epoc Host application again.
Connection Failure: Connection to Reader lost	1. Verify the Reader is always in range, and always turned "ON"; 2. Reconnect to the Reader: by pressing the reconnection Button that appears on the Reader Screen (when connection is lost) to the right of the Patient ID/Lot Number Entry Box. OR by closing the Reader Screen using the red "X" in the top right corner, pressing on the Reader Icon, and selecting "Run blood test" (or "Run QA test").
Reader Failure: General error	1. Remove the Test Card; 2. Close the Reader Tab, then turn the Reader "OFF" and "ON" again; Reconnect and insert another Test Card to begin a new test.
Unable to read barcode	Remove the Test Card and insert it again with a swift, smooth motion. If unsuccessful after multiple attempts, use another Test Card.
Invalid barcode	1. Remove the Test Card; check that the Barcode is not damaged. If the Barcode is damaged, use another Test Card; If the Barcode appears to be undamaged, insert the Test Card again with a swift, smooth motion. If unsuccessful after multiple attempts, use another Test Card.

Ambient temperature too low to use Reader OR Ambient temperature too high to use Reader	1. Move the Reader to a location where the ambient temperature is within acceptable limits described in this User Guide; 2. Allow the Reader enough time to adjust to the new temperature; If the actual ambient temperature is within specified limits, contact your Technical Support representative.
Ambient pressure too low to use Reader OR Ambient pressure too high to use Reader	1. Move the Reader to a location where the atmospheric pressure is within acceptable limits; 2. Allow Reader enough time to adjust to the new environment; If the actual atmospheric pressure is within specified limits, contact your Technical Support representative.
Ambient pressure sensor failed QC	Close the Reader Tab, turn the Reader "OFF" and "ON," and then try again.
Failed Reader Electronic QC	If a Reader fails electronic QC, then first confirm failure. 1. Close the Reader Screen; 2. Turn the Reader "OFF" and "ON," and then try to connect to the Reader again; 3. If the Reader connects successfully (and therefore passes the electronic QC) it is acceptable for use.
Failed iQC: Calibration fluid not detected Fluidics check Humidity check Early injection Resistance check Sensor check	Remove the old Test Card and insert a new Test Card to begin another test If this message persists, try using a different Reader or contact your Technical Support representative.
Failed iQC: Thermal check	Use a different Reader. If the Reader is well equilibrated within environmental limits, but this message persists on Reader, contact your Technical Support representative.
Failed iQC: Fast sample injection	Remove the Test Card. Insert a new card and repeat the test. Inject the test sample a little slower.
Failed iQC: Insufficient sample detected	Remove the Test Card. Insert a new card and repeat the test. Ensure that the sample is fully injected within 3.4 seconds from the start of sample injection.
Failed iQC: Sample Delivery	Remove the Test Card. Insert a new card and repeat test. Ensure a smooth, steady injection. Avoid injecting air into the Test Card.
Fluid detected in test card	1. Remove and discard the old Test Card; 2. Insert a new Test Card into Reader.
Out-Of Range Results on the Test Card for Liquid Quality Control	From the epoc Host, disconnect from the Reader and then reconnect. If the wireless connection is successful and the electronic QC passes, verify the following: 1. Is the Control Value Assignment Datasheet correct? 2. Has the Use by Date of Controls been exceeded? 3. Have the Controls been handled correctly? 4. Have Test cards and Controls been stored correctly? Repeat the test. 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.

Failed iQC on Result Display	Remove the Test Card. Insert a new card and repeat the test.  Sometimes, Failed iQC is reported next to certain results (sample bubbles, contaminated sensor, etc.), whereas other parameters on the same test report OK. The reason for this could be non-conformities in individual sensors of the Test Card. Because each sensor is checked individually after sample injection, the User is still able to see valid test results obtained on remaining good sensors.
cnc on Result Display	Remove the Test Card. Insert a new card and repeat the test.  This message means "**C**ould **n**ot **c**alculate. Component required for calculation was not available." It should be noted that if the response of a failed sensor is needed to compute the result of a good sensor, the iQC failure may trigger cnc. This would happen even when the User had not selected the sensor which eventually failed the iQC.