Veterinary User Guide

with epoc NXS Host (Woodley)

Epocal Inc.
2060 Walkley Road
Ottawa, ON K1G 3P5 Canada
siemens-healthineers.com/epoc

Rev.: 00
siemens-healthineers.com/eIFU

2023-04

51020381-EN-00

Contents

1.0 Introduction

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 with epoc NXS Host as applied to veterinary purposes. An extensive epoc System Manual with epoc NXS Host describing the system as applied to treating human patients is available for reference in English and many other languages. The Manual also includes full specifications for epoc System hardware, as well as epoc Test Cards.

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

2.0 epoc System Components

The epoc Blood Analysis System is a portable blood analyzer comprised of three (3) components:

Figure 1

2.1. epoc Test Card

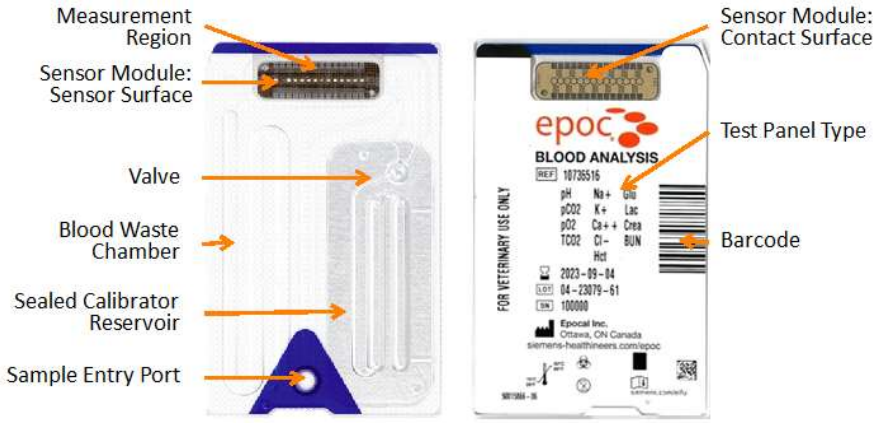

Figure 2

2.2. epoc Reader

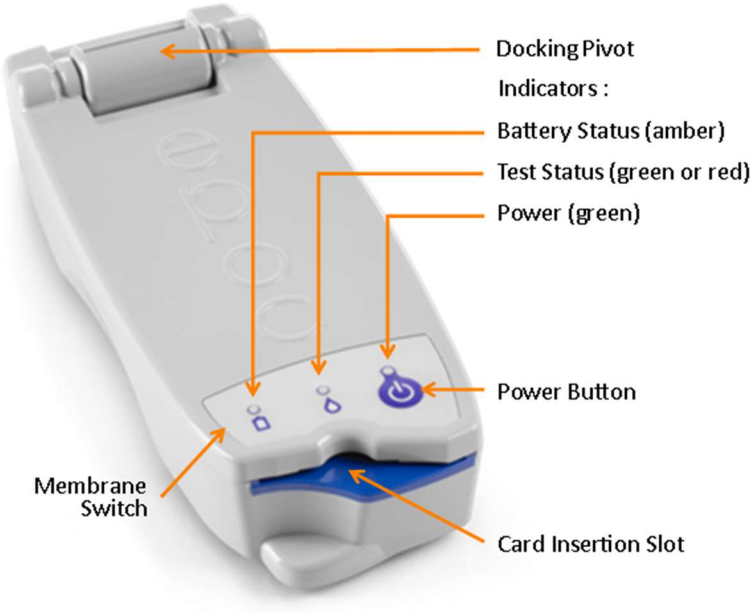

Figure 3

2.3. epoc NXS Host

Figure 4

3.0 Test Process Overview

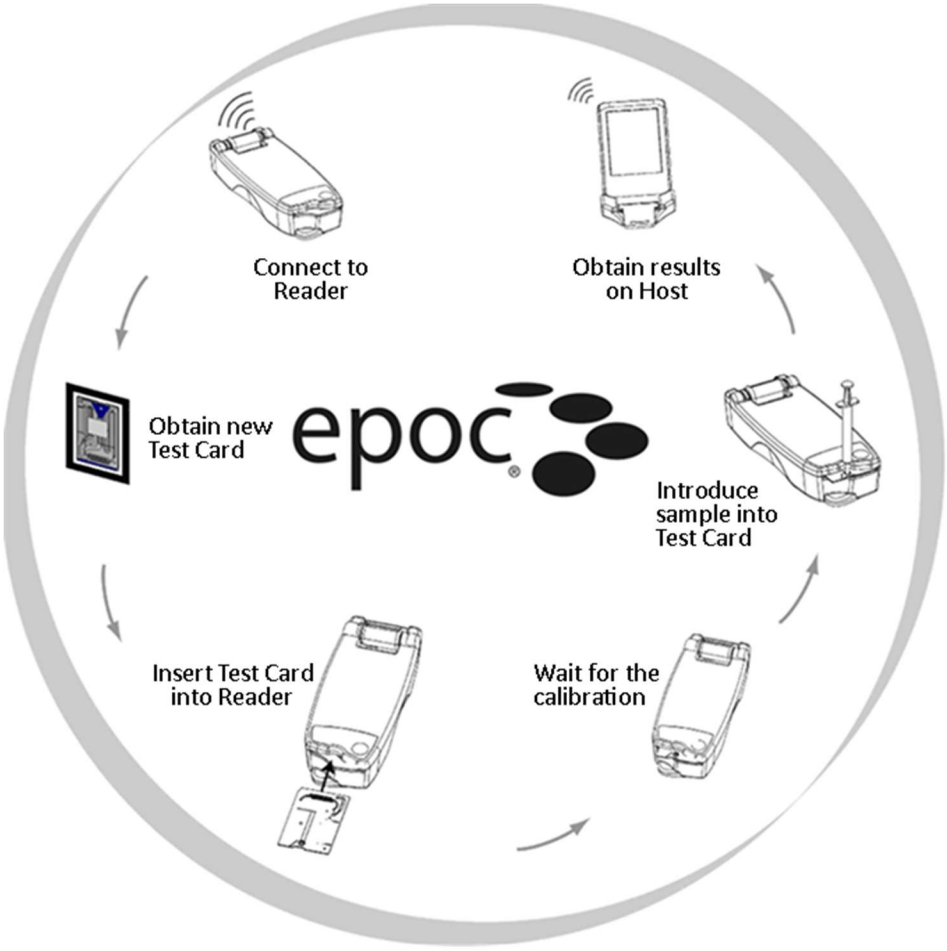

Figure 5

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 (approximately) 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 45 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.

4.0 User Interface

The epoc Host Application has a simple, intuitive user interface, similar to that of a smartphone.

Navigate the epoc Host Application software as you would any touch screen device:

- Tap on an item to select it.
- Scroll down or up by swiping your finger along the screen.

There are two (2) possible methods to enter text: scanning a barcode or using the soft keyboard.

Using the Barcode Scanner

The Barcode Scanner allows the User to scan text, such as a Patient ID, directly into the Host. It is located at the top of the Host and is activated by Barcode buttons on the sides of the Host. (*Figure 4*)

Always point Barcode Scanner away from eyes.

Tap on the field where the scanned text is to be entered.

Press the Scan button at either side of epoc Host or tap on the on-screen Scan button (*Figure 7*) to initiate scanning.

Point the red light coming from the scanner at the top of the Host towards the desired barcode until a beep is heard and the red light stops. The scanned text appears in the selected field. (*Figure 6*)

Figure 6

Using the Soft Keyboard

- The soft keyboard is normally hidden. Touch any text entry field to open it
- Tap on characters in sequence until all required text is entered
- To hide the keyboard, use the Go Back button  on the Android navigation bar

<u>Note:</u> During the test, the Scan button changes to Next when you start typing on the soft keyboard. Tap Next to confirm the currently entered text.

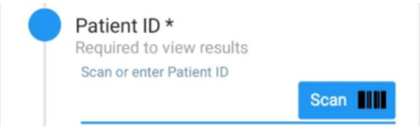

Figure 7

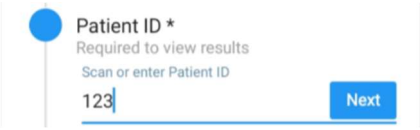

Figure 8

Additional Functionality

- Toggle between upper- and lower-case characters by tapping  before the next character
- Toggle between text and number/symbol screens by tapping ?123
- Select text already entered by pressing gently on the screen while sweeping across one or more characters
- The Backspace key  removes the last character
- The Enter key  confirms the currently entered text

5.0 Test Cards

5.1. Storage and Handling

Always store Test Cards at room temperature (15°C - 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°C and below 30°C.

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°C and 30°C.

5.2. epoc BGEM Test Card Specifications

5.2.1. Measured Analytes

Test Name	Acronym	Units	Measurement Range
pH	**pH**	pH units	6.5 - 8.0
Carbon Dioxide Partial Pressure	***p*CO₂**	mm Hg	5 - 250
		kPa	0.7 - 33.3
Oxygen Partial Pressure	***p*O₂**	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	

Test Name	Acronym	Units	Measurement Range
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
Total Carbon Dioxide	**TCO_2**	mmol/L	5 - 50
		mEq/L	5 - 50
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
Blood Urea Nitrogen	**BUN**	mg/dL	3 - 120
Urea	**Urea**	mmol/L	1.1 - 42.8
		mg/dL	7 - 257
		g/L	0.07 - 2.57
Creatinine	**Crea**	mg/dL	0.30 - 15.00
		µmol/L	27 - 1326
Hematocrit	**Hct**	% PCV	10 - 75
		L/L	0.10 - 0.75
		mEq/L	1 - 85

5.2.2. Calculated Analytes

Test Name	Acronym	Units	Measurement Range
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
Calculated Total Carbon Dioxide	**$cTCO_2$**	mmol/L	5 - 50
		mEq/L	5 - 50
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.

6.0 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**.**

6.1. General Information

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.

6.2. Sample Collection Methods

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

Test	**Syringes** *1 or 3ml plastic*	**Evacuated Tubes** *With Li or Na heparin* *Without anticoagulant must be run immediately*
***p*O₂**	• Non-iced syringes • Test in less than 30 min	• Not recommended
pH/*p*CO₂	• Test in less than 30 min	• Test in less than 30 min
TCO₂	• Test in less than 30 min to avoid possible air contamination and/or artifacts of metabolic activity	• Do not underfill • Test in less than 30 min to avoid artifacts of metabolic activity
Ca++	• With Li or Na heparin only if <10 IU/ml • With balanced heparin only if <70 IU/ml • Test in less than 30 min to avoid artifacts of metabolic activity	• With Li or Na heparin only if <10 IU/mL • Test in less than 30 min to avoid artifacts of metabolic activity
Glu	• Test in less than 30 min to avoid effects of glycolysis	• With Li or Na heparin only (do not use NaF) • Test in less than 30 min to avoid effects of glycolysis
Lac	• Test in less than 5 min to avoid effects of glycolysis	• With Li or Na heparin only (do not use NaF) • Test in less than 5 min to avoid effects of glycolysis

Test	Syringes *1 or 3ml plastic*	Evacuated Tubes *With Li or Na heparin* *Without anticoagulant must be run immediately*
Hct	• Immediate testing is recommended in order to avoid red blood cell (RBC) settling. *Note: Re-suspension of RBC requires an air bubble of significant volume.*	• With Li or Na heparin only (do not use EDTA). *Note: Cat blood should be drawn into anticoagulant to prevent clotting.*
All other tests	• Test in less than 1 h to avoid effects of glycolysis and electrolyte shifts	• With Li or Na heparin • Test in less than 1 h to avoid effects of glycolysis and electrolyte shifts

7.0 Running a Test

7.1. Power Up epoc Reader

Press the Power Button to turn "ON" the Reader. (*Figure 3*)

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.

7.2. Power Up epoc NXS Host

Press and hold the Power Button to turn on the epoc NXS Host. (*Figure 4*)

Briefly press the Power Button to wake up a running epoc NXS Host if the screen goes dark.

7.3. Login to epoc Host Software

After a reset or signing out, epoc Host software application displays the Sign In page. (*Figure 9*)

Enter a valid User ID (and Password, if required) and tap SIGN IN.

Note: User ID and Password requirements may vary depending upon how the Administrator has set up the sign in settings.

The epoc Host will display the Home page. (*Figure 10*)

- Tap Run Blood Test to continue with a blood test
- Tap QA Testing to continue with a QA test (if authorized)

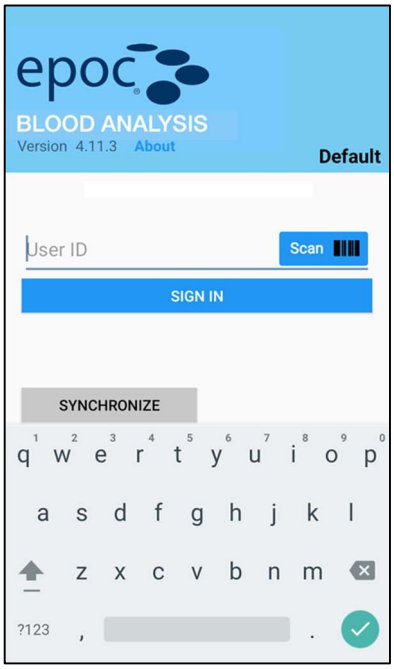

Figure 9

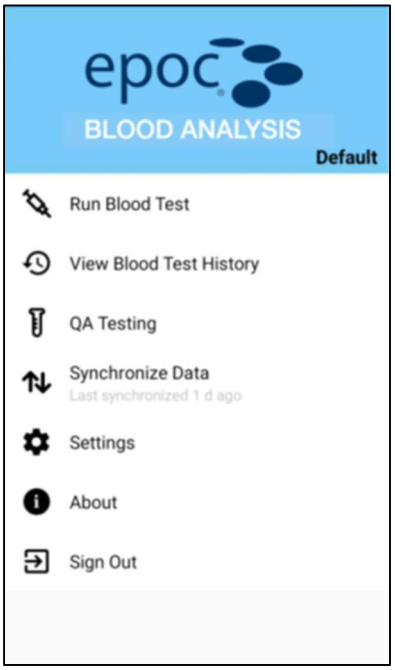

Figure 10

7.4. Begin Test

7.4.1. Establishing Connection Between Host and Reader

If the epoc Host is configured to use a single dedicated epoc Reader, the epoc Host will automatically connect to that epoc Reader and start the test.

If the Host not configured with a single dedicated Reader, a list of available Readers will be displayed. A Reader now may be selected to run a test.

Tapping Refresh will update the list. (*Figure 11*)

Connecting to an epoc Reader displays a Test Screen. A message, "Configuring <Reader Name> Do not insert card" is displayed on the top of the screen.

The screen is split up in two parts: test progress information on the top and data entry on the bottom. At appropriate times, test progress information may be enlarged to display visual aids.

After completing Reader configuration, the Reader Screen displays a message, "Insert new Test Card," and the Test Status Indicator of the Reader turns and stays green. Reader configuration includes running an electronic QC and storing an electronic QC record.

Any time during Reader configuration, you can start entering test data, such as Patient ID, hemodilution settings, sample type, etc. as required by the policy of your healthcare institution.

Figure 11

<u>Note:</u> Do not insert a Test Card until Reader configuration is complete (about 15 seconds).

7.4.2. Electronic Quality Control (QC) Check

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.

<u>Note:</u> Unlike QA Test Records, Electronic QC records are removed from the Host after each Synchronization.

7.4.3. Check Test Information

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.

If running Test Cards on the Use By date identified by the Hourglass Icon on the bottom of the Test Card, allow sufficient time to complete the test before midnight. Test results do not display after midnight of the Use By date.

7.5. Obtain Test Card

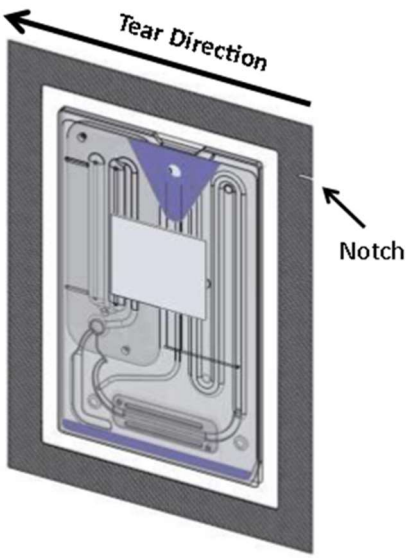

Figure 12

Select a properly stored veterinary Test Card.

Starting at the notch, tear open the card pouch as shown. (*Figure 12*)

⚠ The card pouch should be opened only when conducting blood or QA testing to assure a low humidity environment for the Test Card.

Carefully remove the Test Card from the card pouch.

Place the test card directly into the epoc Reader's Card Insertion Slot.

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.

Figure 13

⚠ Never place the Test Card on any surface before running a test.

7.6. Insert Test Card into Reader

Insert a Test Card to start a test. Visual aids can be shown by tapping "Show me how."

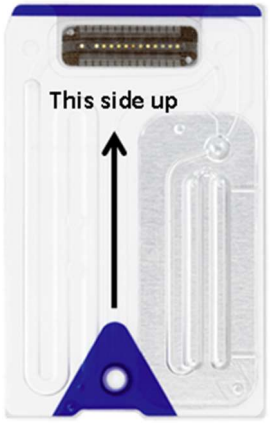

Figure 14

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

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.

Push the Test Card into the Reader's Card Insertion Slot at the front of the Reader with a smooth, swift, single motion. Continue inserting the Test Card until the slight resistance is felt. Push the Test Card past this point to "lock" it into place. This is the final Test Card position.

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.

7.7. Test Sequence

7.7.1. Test Card Calibration

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

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

The calibration process takes approximately three (3) minutes to complete. During the calibration sequence, the User can prepare the patient and obtain the blood sample.

<u>Note:</u> Do not inject the sample until calibration is complete, about three (3) minutes.

Refer to Blood Collection, above, to ensure that blood samples are properly collected and handled for testing.

7.7.2. Entering Test Information

Test details can be edited at any time during the test.

For a Blood Test, the Patient ID number is entered to identify the test results for the Test Card used for the test.

For a QA Test, the QA fluid Lot Number is entered instead of the Patient ID.

Patient information entered prior to completion of the test is saved automatically. If mandatory information is not entered before the test is complete, you will be prompted to enter it before the test results can be viewed.

Exercise care when entering Patient ID and other information.

Ensure the correct Reader is selected by verifying that the Reader name corresponds with the Reader used to conduct the test. The Reader name is displayed at the bottom of the Visual Aids page.

Select or deselect analytes to display in the test results. The system administrator settings may require analyte selection before results are displayed. Additional analytes may be selected after test completion. Once test results are displayed, analytes can no longer be de-selected.

7.7.3. Using the Barcode Scanner

Press the Patient ID field. A cursor appears.

Activate the Barcode Scanner by pressing either of the Scan buttons on the sides of the epoc Host. Point the light coming from the top of the Barcode Scanner towards the desired barcode until a beep is heard.

Always point Barcode Scanner away from eyes.

The Scanner turns off. The scanned text appears in the field where the cursor was left.

The Barcode Scanner can also be activated by tapping the Scan button. The Scan button is located to the right of applicable text fields.

Alternatively, the Patient ID may also be entered using the soft keyboard activated by tapping the entry field.

Note: The Scan button changes to Next when you start typing on the soft keyboard.

7.7.4. Sample Introduction Window

After about three (3) minutes of calibration, the Test Status Indicator stops flashing green indicating that the Test Card is ready to receive a test sample. 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 Test Card during this 450-second (or 7.5-minute) period.

Visual aids can be shown by tapping on "Show me how."

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.

7.7.5. Sample Introduction Method

Always wait until the Host displays the message, "Inject sample…" before engaging the syringe with the Test Card sample entry port.

1. Hold the syringe barrel vertically between fingertips and thumb (*Figure 15*).

   Keep the 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.

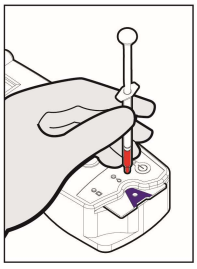

Figure 15

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 ¼-turn to ensure a good seal (*Figure 16*).

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

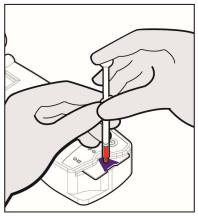

Figure 16

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 17*).

   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.

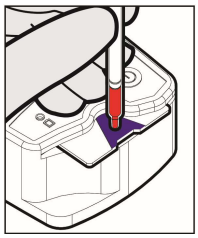

Figure 17

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 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.

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.

Never attempt to clean inside the Reader.

7.7.6. Test Completion

Once the analysis is complete, the epoc Host displays the Test Results.

The Patient ID must be entered before the test results are displayed. If mandatory information is not entered before the test is complete, you will be prompted to enter it before the test results can be viewed.

When the Reader has completed a test, the Test Status Indicator on the Reader will flash green, indicating the Test Card can be removed. The motorized mechanism is heard briefly as the calibration fluid plungers are disengaged.

Remove the card from the Reader and dispose of it using appropriate biohazard precautions.

Always wear protective gloves when removing a Test Card from the Reader.

Never reuse a Test Card. Test Cards are for single use only.

Press SAVE & CLOSE to complete the test.

7.7.7. Running Another Test

After removing the used Test Card, the Reader's Test Status Indicator will turn solid green, indicating that the Reader is ready to perform another test.

Repeat the same procedure to complete another test.

Starting a new test permanently saves the previous test record. Changes to that test are no longer possible.

If the system is configured to allow data recall on incomplete tests, the messages SAME PATIENT, NEW PATIENT will appear above Edit Test Details fields. The User can either tap the message to use previous entries or enter new data to proceed. If the message is not tapped before the test ends, the previous test data will not be recalled.

7.7.8. Closing Test and Disconnecting Reader

When all testing with the Reader is complete and all data entries are made, the test is closed by tapping on the X at the top of the Reader Screen. A confirmation message will be displayed. Press No to return to the Results screen or Yes to close the test.

Closing the test and disconnecting the Reader permanently saves the test and changes to that test are no longer possible.

7.7.9. Synchronization with a Data Manager

When using a compatible data manager, the device will automatically transmit completed tests and QC records to the data manager after closing the test.

<u>Note:</u> When using a data manager, CLOSE & TRANSMIT is displayed on the Test Results page instead of SAVE & CLOSE.

Users can also initiate a full synchronization with the data manager as follows.

- From the Sign In page, tap SYNCHRONIZE, or
- From the Home page, tap Synchronize Data.

During a full synchronization:

1. epoc Host uploads Test Results (both Blood and QA Tests), Electronic QC records, and Raw Data (if applicable) to the data manager.
2. epoc Host retrieves Configuration Information from the data manager such as Units, Ranges, and Operator Lists (if required), as well as current Date and Time.
3. epoc Host may receive a software upgrade if a new version exists in the data manager, and the System Administrator has enabled the automatic upgrade feature.

When synchronization is complete, leave the screen by tapping X at the top left.

7.7.10. Logging Out and Turning Power "OFF"

Sign out of the epoc Host Application when finished testing and viewing test results by pressing Sign Out on the Home page.

Note: Upon signing out, Host users will be notified of expiring user account privileges. Notifications to users begin at 30 days before the expiration date.

You can suspend the Host device by briefly pressing the Power button.

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.

8.0 Routine Procedures

8.1. Reset

If the epoc NXS Host stops functioning or stops responding, press and hold the Power button for at least 10 seconds; the device will then restart.

Never perform a reset during a test. This ends the test immediately.

8.2. Charge Reader Battery with AC Adaptor

The epoc Reader contains a Lithium Ion Rechargeable Battery. The battery and the door to the battery compartment may be replaced by the User.

Please refer to the Care and Maintenance of the epoc System section of the epoc System Manual with epoc NXS Host for instructions on replacing the battery and the battery door.

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

Fully charged, the Reader can process about 50 Test Cards before recharging. If the Reader is left 'ON' for prolonged periods of time between tests, this amount will be reduced.

- When the Reader is charging, the amber Battery Status Indicator will flash.
- When charging is complete, this indicator will stay solid amber.
- When the indicator is OFF, it indicates that the AC Adaptor is not connected and the Reader is operating on battery power.

It takes approximately four (4) hours to recharge a fully discharged Reader Battery.

Use only the AC Adapter, as specified by the label on the bottom of the Reader.

The Reader Battery must be replaced by authorized Epocal service personnel only.

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.

8.3. Host Battery

8.3.1. Charge Host Battery using Reader

The epoc Host contains a Lithium Ion Rechargeable Battery.

To re-charge the battery, insert the epoc Host Cradle Blade into the epoc Reader Docking Pivot.

Connect the Reader AC Adapter to the Power Jack at the rear of the Reader and also into the wall receptacle.

An LED charging indicator shows when the battery is charging and when charging is complete. Refer to “epoc NXS Host Quick Start Guide” for more information.

Several hours may be required to fully recharge the battery. The Host can be operated normally while it is being charged.

9.0 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 Enterprise Data Manager.

QC Fluids Recommended for Verification of epoc Test Cards

Manufacturer	Description	Level	REF No.
Eurotrol Inc., Ede, The Netherlands	Eurotrol GAS-ISE-Metabolite QC	1	179.001.010
		2	179.002.010
		3	179.003.010
		1	266.001.010
		2	266.002.010
		3	266.003.010

Note: Some Control Fluids may not be approved for sale in all countries.

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°C - 25°C). Equilibration time for blood gas QC Fluids is four (4) hours minimum;
2. Immediately before use, shake the Ampoule vigorously for five (5) to 10 seconds to equilibrate liquid and gas phases;
3. Always hold the Ampoule at the tip and the 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 14 - 20-gauge blunt tip needle. When loading the syringe, slowly draw about 1 mL 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 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 Datasheets 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°C - 17°C	18°C - 20°C	21°C - 23°C	24°C - 26°C	27°C - 28°C	29°C - 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
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°C - 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.

Also, to establish Target Values, samples are analyzed at approximately 760 mmHg atmospheric pressure. The pCO_2 readings will be insignificantly affected by the barometric pressure, BP. The pO_2 readings will decrease by (2 mmHg + 6%) per 100 mmHg barometric pressure under 760 mmHg. Therefore, before comparing the gas readings with the published value assignments, the pO_2 readings need to be corrected as follows:

$$pO_2^{corrected} = pO_2^{reading} + (2\ mmHg + 6\% \cdot pO_2^{reading}) \cdot (760\ mmHg - BP\ [mmHg]) / 100 mmHg$$

For example, if pO_2 reading is 150mmHg and BP = 630mmHg the corrected pO_2 reading for this altitude would be

$$pO_2^{corrected} = 150 + (2 + 6\% \cdot 150) \cdot (760 - 630) / 100 = 150 + (2 + 9) \cdot 1.3 = 164.3\ mmHg$$

Value Assignment Datasheets (VAD)

The Value Assignment Datasheets (VAD) contain target values and acceptable ranges for aqueous control and calibration verification fluids specific to the epoc System. To obtain current VAD, contact your epoc distributor.

Each VAD is identified by Fluid Name, Level, Lot Number and epoc System Sensor Configuration Version. Ensure 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 with epoc NXS Host.

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

10.0 Reference Ranges

<u>Note:</u> These reference ranges have been provided by Woodley Equipment Company Ltd.

Acronym	Units	Reference Range					
		Dog		Cat		Equine	
		Arterial	Venous	Arterial	Venous	Arterial	Venous
pH	pH units	7.35 - 7.45	7.35 - 7.45	7.25 - 7.40	7.25 - 7.40	7.32 - 7.44	7.35 - 7.45
pCO_2	mmHg	34 - 40	40 - 50	28 - 34	33 - 51	36 - 46	38 - 48
pO_2	mmHg	85 - 100	30 - 42	90 - 110	27.6 - 39.6	90 - 100	37 - 56
Na+	mmol/L	139 - 150	139 - 150	147 - 162	147 - 162	128 - 142	128 - 142
K+	mmol/L	3.4 - 4.9	3.4 - 4.9	2.9 - 4.2	2.9 - 4.2	1.9 - 4.1	1.9 - 4.1
Cl-	mmol/L	106 - 127	106 - 127	112 - 129	112 - 129	100 - 111	100 - 111
Ca++	mmol/L	1.12 - 1.4	1.12 - 1.4	1.2 - 1.32	1.2 - 1.32	1.25 - 1.75	1.25 - 1.75
	mg/dL	4.5 - 5.6	4.5 - 5.6	4.8 - 5.3	4.8 - 5.3	5 - 7	5 - 7
Glu	mmol/L	3.3 - 6.4	3.3 - 6.4	3.3 - 7.2	3.3 - 7.2	3.4 - 7.4	3.4 - 7.4
	mg/dL	60 - 116	60 - 116	60 - 131	60 - 131	62 - 135	62 - 135
Lac	mmol/L	0.6 - 2.9	0.6 - 2.9	0.5 - 2.7	0.5 - 2.7	0.3 - 1.5	0.3 - 1.5
	mg/dL	5.4 - 26.1	5.4 - 26.1	4.5 - 24.3	4.5 - 24.3	2.7 - 13.5	2.7 - 13.5
BUN	mg/dL	10 - 26	10 - 26	15 - 34	15 - 34	11 - 27	11 - 27
Urea	mmol/L	3.6 - 9.3	3.6 - 9.3	5.4 - 12.1	5.4 - 12.1	3.9 - 9.6	3.9 - 9.6
	mg/dL	22 - 56	22 - 56	32 - 73	32 - 73	23 - 58	23 - 58
Crea	µmol/L	44 - 115	44 - 115	88 - 195	88 - 195	35 - 195	35 - 195
Hct	%	35 - 50	35 - 50	24 - 40	24 - 40	30 - 45	30 - 45
cHgb	g/dL	12 - 17	12 - 17	8 - 13	8 - 13	10 - 15	10 - 15
	mmol/L	7.4 - 10.6	7.4 - 10.6	5 - 8.1	5 - 8.1	6.2 - 9.3	6.2 - 9.3
$cHCO_3$-	mmol/L	20 - 24	15 - 23	16 - 20	13 - 25	24 - 30	25 - 30
TCO_2/ $cTCO_2$	mmol/L	17 - 25	17 - 25	16 - 25	16 - 25	24 - 32	24 - 32
BE(ecf)	mmol/L	(-5) - 0	(-4) - 4	(-5) - 2	(-10.7) - (-0.7)	(-5) - 5	(-5) - 5
BE(b)	mmol/L	(-5) - 0	(-4) - 4	(-5) - 2	(-10.7) - (-0.7)	(-5) - 5	(-5) - 5
cSO_2	%	90 - 100	90 - 100	90 - 100	90 - 100	90 - 100	90 - 100
AGapK	mmol/L	8 - 25	8 - 25	10 - 27	10 - 27	5 - 15	5 - 15
AGap	mmol/L	(-15) - 96	(-15) - 96	(-15) - 96	(-15) - 96	(-15) - 96	(-15) - 96
BUN/ Crea	mg/mg	0.2 - 400	0.2 - 400	0.2 - 400	0.2 - 400	0.2 - 400	0.2 - 400
Urea/ Crea	mmol/mmol	0.8 - 1615.4	0.8 - 1615.4	0.8 - 1615.4	0.8 - 1615.4	0.8 - 1615.4	0.8 - 1615.4
eGFR	mL/m/1.73m²	1 - 401	1 - 401	1 - 401	1 - 401	1 - 401	1 - 401
GFRmdr, GFRmdr-a GFRckd, GFRckd-a, GFRckd21, GFRswz	mL/m/1.73m²	1 - 401	1 - 401	1 - 401	1 - 401	1 - 401	1 - 401
A	mmHg	4 - 801		4 - 801		4 - 801	
A-a	mmHg	0 - 801		0 - 801		0 - 801	
a/A	%	(-1) - 101		(-1) - 101		(-1) - 101	

11.0 Troubleshooting

The epoc System has no User serviceable parts or adjustments with the exception for the Reader battery and battery door. 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. For a complete list, refer to the epoc System Manual with epoc NXS Host. 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 (E64)	Verify that the Reader is turned "ON"; Verify that the Reader is not connected to another Host. If used by another Host, wait until test is complete; Verify that that the Reader is within range; 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; If still unable to connect, reset the Host and log into epoc Host application again. Attempt reset and discovery sequence twice if necessary.
Connection Failure: Connection to Reader lost (EXX)[1]	Verify the Reader is turned "ON" and within range; 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 (EXX)[2]	Remove the Test Card; 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 (E70)	Remove the Test Card and insert it again with a smooth, swift, single motion. If unsuccessful after multiple attempts, use another Test Card.
Invalid barcode (E71)	Remove the Test Card and 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 smooth, swift, single motion. If unsuccessful after multiple attempts, use another Test Card.
Ambient temperature too low to use Reader (E60) **OR** **Ambient temperature too high to use Reader (E61)**	Move the Reader to a location where the ambient temperature is within acceptable limits described in this User Guide; Allow the Reader enough time to adjust to the new temperature; If the actual ambient temperature is within specified limits, contact Technical Support at Woodley.

[1] Error may be E10, E14, E20, E23, E29, or E32.

[2] Error may be E7, E9, E17, E19, E26 or E28.

Error Message	Action
Ambient pressure too low to use Reader (E62) **OR** **Ambient pressure too high to use Reader (E63)**	Move the Reader to a location where the atmospheric pressure is within acceptable limits; 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 (E67)	Close the Reader Tab, turn the Reader "OFF" and "ON," and then try again. If this message persists, contact your Technical Support representative.
Failed Reader Electronic QC (E65)	If a Reader fails electronic QC, then first confirm failure. Close the Reader Screen; Turn the Reader "OFF" and "ON," and then try to connect to the Reader again; If the Reader connects successfully (and therefore passes the electronic QC) it is acceptable for use.
Failed iQC: **Calibration fluid not detected (E3)** **Fluidics check (EXX)[3]** **Humidity check (E53)** **Resistance check (E54)** **Sensor check (EXX)[4]**	Remove the Test Card and insert a new Test Card to begin another test. If this message persists, use a different Reader or contact your Technical Support representative.
Failed iQC: **Thermal check (EXX)[5]**	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: **Early sample (E55)**	Remove the Test Card. Insert a new Test Card and repeat the test. Make sure calibration is completed before injecting sample.
Failed iQC: **Fast sample injection (E34)**	Remove the Test Card. Insert a new Test Card and repeat the test. Inject the test sample a little slower.
Failed iQC: **Insufficient sample detected (E35)**	Remove the Test Card. Insert a new Test 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 (E49)**	Remove the Test Card. Insert a new Test Card and repeat test. Ensure a smooth, steady injection. Avoid injecting air into the Test Card.
Fluid detected on sensors (E80)	Remove and discard the old Test Card. Insert a new Test Card into Reader. *<u>Note:</u> Examine the Test Card to check whether fluid is present in the measurement region (see Section 4.1 of the epoc System Manual with epoc NXS Host). If failure occurs on the same Reader with multiple cards and no fluid is present on Test Card sensors, then the failure may be due to internal Reader failure. Contact Technical Support at Woodley.*

[3] Error may be E50 or E56.
[4] Error may be E13, E22, or E31.
[5] Error may be E38, E39, or E40.

Error Message	Action
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: • Is the Control Value Assignment Datasheet correct? • Has the Use by Date of Controls been exceeded? • Have the Controls been handled correctly? • Have Test cards and Controls been stored correctly? Repeat the test. If the repeat results are in range, the Test 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 fluids and/or Test Cards.
Failed iQC on Result Display	Remove the Test Card. Insert a new Test Card and repeat the test. *Note: 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 Test Card and repeat the test. *Note: This message means "Could not calculate. 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.*

12.0 Revision History

Revision	Description of Changes
00	New document