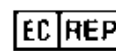# epoc

System Manual

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epoc Reader Quick Start Guide

Appendix D.   Ref: 51003903
epoc Care-Fill Capillary Tube Package Insert

Appendix E.   Ref: 51011873
User Guide: Enhanced QA Features for the epoc System

01 Introduction

1.1 General

The epoc® System Manual describes the proper use and operation of the epoc Blood Analysis System. System operators and the system administrator should familiarize themselves with the applicable sections in the manual prior to conducting testing.

All operators and the system administrator require training by Epocal Inc. ("Epocal") authorized personnel prior to conducting patient testing. This training is based upon the information contained in this manual. The System Manual should be made available to the administrator and operators at all times while the epoc Blood Analysis System is in use.

1.2 Cautions

Cautions are identified throughout the manual using the "Caution, risk of danger" or "Caution, consult accompanying documents" symbol. The operator and administrator need to pay special attention to the instructions accompanying this symbol to ensure that the epoc Blood Analysis System is used properly, reliably and safely.

The "Biological risks" symbol is used in the manual to identify potential biological risks associated with the handling of blood samples. Precautions, as stipulated by the facility where the epoc System is utilized, must be taken to ensure that the risk of transmitting blood borne pathogens is minimized.

Other symbols may also be used in the System Manual. The correct interpretation of these symbols is located in the Glossary Section.

1.3 Warranty

Epocal warrants to the original customer that the medical equipment manufactured by Epocal is free from defects in materials and workmanship, and under normal and proper use conditions, for a period of one (1) full year from the date of shipment. Upon receiving notice from the customer of any defects within this warranty period, Epocal shall, at its option and sole discretion, either repair, replace or modify this medical equipment or part thereof, which proves to be defective. Epocal shall repair or replace software media and firmware which does not execute as intended due to such defects. These replacements, repairs, or alterations will in no case extend the specified herein warranty period. Epocal does not warrant that the operating of the software, firmware or hardware shall be uninterrupted or error free.

If Epocal is unable, within a reasonable time, to repair, replace or modify any product to a condition as warranted, the customer shall be entitled to a refund of the purchase price upon return of the product to Epocal, together with a copy of the dated itemized purchase receipt and the original packaging.

The test card warranty is limited to, and prorated in accordance with the "use by" date indicated on the test card labeling. The customer must inform Epocal immediately upon receipt if it is evident that the test cards were improperly stored or handled during shipment. Epocal is not responsible for test cards that have been handled and stored outside the specified requirements stated in the System Manual after delivery to the customer.

The warranty does not cover these parts that deteriorate, or which are in any case considered consumables, or those parts or items, which by their nature are normally required to be replaced periodically consistent with normal maintenance .

Note: Warranty rights may vary from state to state, province to province and country to country.

1.4 Warranty Limitations

The foregoing warranty shall not apply to defects resulting from:

1. Improper, inadequate, insufficient or negligent storage, care or maintenance by the customer or an unauthorized person,
2. Misuse due to carelessness, negligence or inexperience,
3. Using accessories and/or consumables that are not approved by Epocal,
4. Unauthorized use of buyer-supplied hardware, software or interfacing,
5. Unauthorized repairs, modifications, misuse, or damage caused by disposable batteries, or rechargeable batteries not supplied by Epocal,
6. Failure to use the device and accessories in accordance with operating instructions,
7. Operating outside of the environmental specifications of the product,
8. Improper site preparation or maintenance, or
9. Expiration of test card "use by" date.

NO OTHER WARRANTIES, EXPRESS OR IMPLIED, ARE MADE. EPOCAL WILL NOT BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING DIRECTLY OR INDIRECTLY FROM THE FAILURE OF THE PRODUCT TO PERFORM IN ACCORDANCE WITH SPECIFICATIONS.

Some states do not allow the exclusion or limitation of other express or implied warranties or incidental or consequential damages, so the above limitations or exclusions may not apply.

No agent or employee of Epocal is authorized to extend any other warranty or to assume for Epocal any liability except as set forth above.

1.5 WEEE Compliance

Epocal complies with Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on waste electrical and electronic equipment (WEEE).

Compliance is indicated on the epoc hardware using the Wheelie Bin symbol.

Customers should contact their epoc distributer or Epocal, the manufacturer, to arrange for disposal of their epoc electrical and electronic hardware at the end of product life. Contact information is provided on the cover page of this instruction manual.

02 | epoc® Blood Analysis System

2.1 System Overview

The epoc Blood Analysis System
o Is a Portable Blood Analyzer comprised
  of 3 components:
  - epoc Reader
  - epoc Host mobile computer
  - epoc Test Card

The epoc Reader
o Is a Battery powered portable device
o Has an internal barcode scanner
o Has card slot for accepting test card
o Reads epoc test cards during blood test
o Has status indicators to inform user of test progress
o Measures electrical signals from test card sensors
o Transmits test results wirelessly via Bluetooth to the epoc Host

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

The epoc Test Card
o Is a single-use device with port for blood sample introduction
o Contains array of sensors on a Sensor Module
o Contains calibration fluid within sealed reservoir
o Generates electrical signals proportional to analyte concentrations in sample
o Uses Barcode to identify Card Type, "Use By" Date, Serial and Lot Number

2.2 Operation Overview

A single blood test is performed in the following way:

1 Use epoc Host to establish wireless connection with an epoc Reader.

2 Obtain a new Test Card and remove from pouch.

3 Insert Test Card into Reader. The Reader reads the barcode on the card. "Use By" date is checked and card lot number is linked to test result and any related patient data that was entered.

4 Internal motor of the Reader is actuated to start the calibration process. This process releases a calibration fluid in the card that flows across sensors within the card. User has time to prepare the patient and draw the blood sample.

5 User introduces the sample into the Test Card upon completion of calibration.

6 Reader sends test data to the Host. Results are calculated and displayed on the Host in about half a minute.

03 | epoc® System Operation

3.1 System Operation Overview

⚠ Follow set up instructions for the epoc Reader and epoc Host before conducting a test.

⚠ Only use the Test Cards that have been properly stored.

To complete a test, the following steps are required:

1. Turn "ON" the epoc Reader and epoc Host.
2. Log in to epoc Host software application.
3. Discover the epoc Reader by connecting wirelessly from the epoc Host.
4. Begin the test sequence.
5. Insert a new Test Card into the epoc Reader.
6. Enter patient information, select tests and sample type (if applicable).
7. Introduce a blood sample into the Test Card.
8. Observe and possibly print the Test Results.
9. Remove the Test Card and discard it as biohazard waste.

Once logged in and connected to an epoc Reader, steps 5 through 9 above are required to perform another test.

3.2 Turning "ON" the epoc Reader

Depress the Power Switch to turn "ON" the epoc Reader. The Power LED will turn green indicating the epoc Reader is "ON" and ready for use.

epoc Readers that are switched "ON" will be located by the epoc Host and display on its main screen. Dedicated Readers display on the screen regardless of whether or not they are turned on. However, connection will be successful only if they are "ON."

Turn "OFF" any epoc Readers not in active use to conserve battery power.

Power Switch
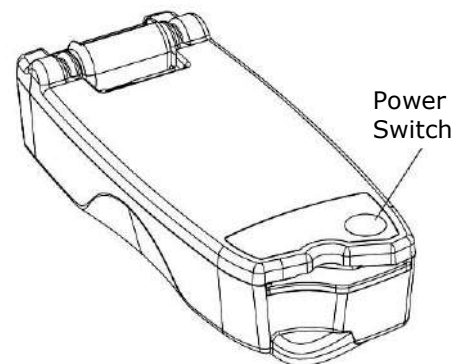
3.3   Turning "ON" the epoc Host

The **Power** button of the epoc Host mobile computer starts and stops the device. Press the **Power** button to wake up the epoc Host if the screen is blank.

The **Soft Reset (Warm Reset)** button reboots epoc Host application and displays the Login page.

Note: Refer to Appendix A "epoc Host Quick Start Guide" or Appendix B "epoc Host² Quick Start Guide" in the end of this manual to locate these buttons on your Host.

3.4   Logging in to epoc Host Software Application
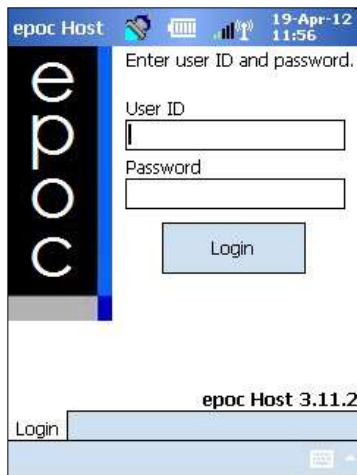
After a soft (warm) reset or logging out, epoc Host software application displays the Login Page.

Enter a valid **User ID** and **Password** and press the **Login** button.

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

3.5   Running a Test on a Dedicated Reader

If the epoc Host is already configured to connect with a single dedicated epoc Reader, the epoc Host will automatically connect to that epoc Reader to run a **blood test** and begin the Electronic QC Test.

A connection is cancelled by tapping the **Cancel** button.
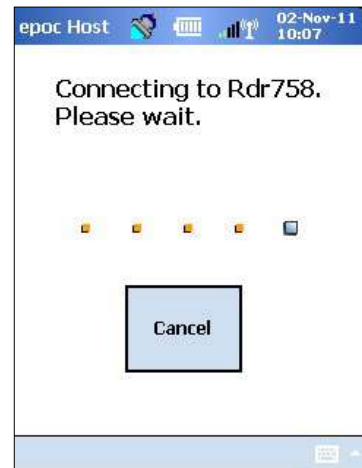
3.6   Alternate Means to Run a Test

If the system administrator has configured the system for multiple dedicated epoc Readers, all epoc Readers available for connection are listed. The Reader Icon displays the Reader name and the serial number below.
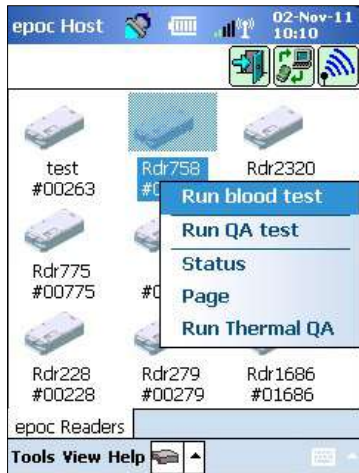
The **Discovery icon** can also be tapped to find ("discover") more Readers. Tapping the discovery icon when inactive will initiate this discovery process. Tapping the discovery icon while discovering will end the discovery process.

Once the desired Reader is displayed, press and hold its **Reader Icon** to select it for testing. A dropdown menu will be displayed. For a blood test, select **Run blood test**. For a QA test (if authorized), select **Run QA test**.

You can also start a blood test by double-tapping the **Reader Icon**.

3.7 Reader Electronic Internal QC Test

Connecting to an epoc Reader displays a Reader Screen unique to the epoc Reader's serial number. The Reader name is displayed on the bottom tab, with the serial number in parentheses.

Every time a Host and Reader connect, the Reader begins a two-level Electronic QC Test. Configuration data is sent by the Host to the Reader, and preparations begin for a test. After completing the electronic QC test and configuration, the Reader Screen displays **Insert card to begin test**, and the Test Status Indicator of the Reader turns and stays green.

8-Hour Electronic QC Check: The epoc Host checks that an Electronic QC Test has been run within the past 8 hours. If a new Test Card is inserted after 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 to run another Electronic QC Test.

3.8 Reader Screen

The epoc Host and epoc Reader are ready to begin a test by inserting a Test Card.

The Reader Screen displays:

1. Type of test: ● Blood test or ● QA test.

2. Battery charge level of the Reader ▌.

3. Current Date and Time.

4. Patient ID or Lot Number field.

5. Additional tabs for accessing other test information entries that may be used to ensure a complete test record. Requirements may vary according to the policy of the healthcare institution.

⚠ 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.

⚠ The policy of the healthcare institution may require the user to select the Analytes, Sample Type, and/or Hemodilution Correction Factor for testing.

⚠ 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.

3.9   Obtaining the Test Card

1. Select a properly stored Test Card.

2. Starting at the Notch, tear open the Test Card pouch as shown.

3. Carefully (read the cautions below) remove the Test Card from the Test Card pouch.

4. Place the Test Card directly into the epoc Reader's Card Insertion Slot.

5. Discard the empty pouch.

Tear Direction

Notch

Sensor Module's contact surface
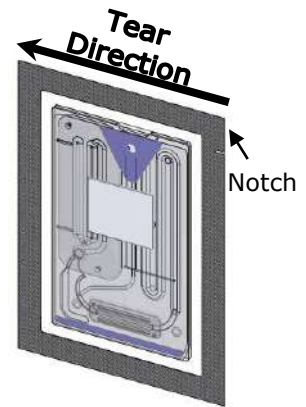
⚠ Never touch the Sensor Module's contact surface or Blood Sample Entry Port.

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

⚠ Always take the Test Card directly from the pouch before inserting into the Reader.

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

epoc
BLOOD ANALYSIS

REF epoc BGEM
CT – 1006 – 00 – 00
IVD pH   Na+   Glu
pCO2   K+   Lac
pO2   Ca++   Crea
Hct   Cl–
⌛ 2013 – 04 – 11
LOT 01 – 12299 – 00
SN 401770
Epocal, Inc.
Ottawa, ON Canada
www.epocal.com
50007224 – 00
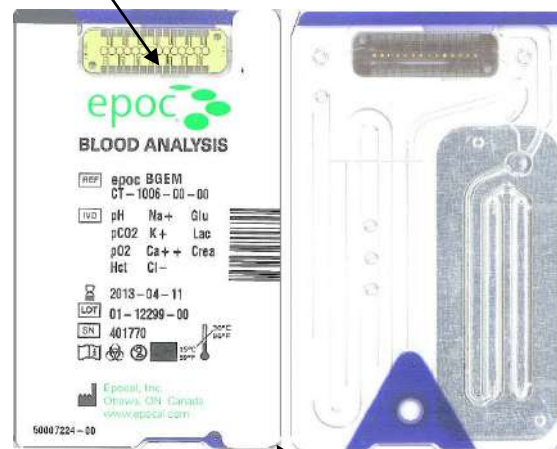
Blood Sample Entry Port

3.10 Inserting the Test Card

⚠️ 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.

This side up
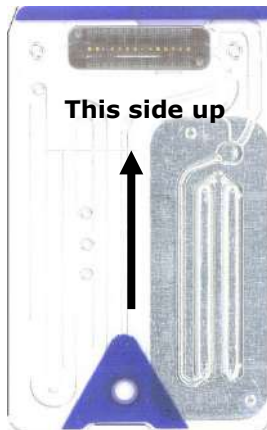
Position the Test Card with the Blue Label side facing upwards and the Sensor Module towards the Reader. Test Cards are "keyed" using a notch in the corner to ensure correct card orientation during insertion. Insertion of a Test Card causes the Barcode Reader in the Reader to turn "ON."

Insert the Test Card into the Reader's Card Insertion Slot at the front of the Reader with a smooth single motion to enable the Barcode on the Card Label to be correctly read by the Reader during insertion.
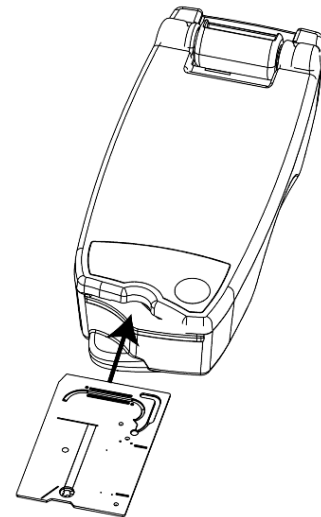
Continue inserting the Test Card until slight resistance is felt. Push the Test Card past this point to "lock" it into place. This is the final Test Card position. Avoid abrupt stops or unevenness in speed during Test Card insertion.

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. The Reader beeps once, and the Test Status Indicator turns solid green to notify the user that the Test Card has been successfully inserted.

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. Reinsert the card for successful insertion confirmed by a solid green Test Status Indicator.

3.11 Calibration Sequence

Once the Test Card is successfully inserted, a motorized mechanism in the Reader can be heard as the 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 displaying the calibration progress.
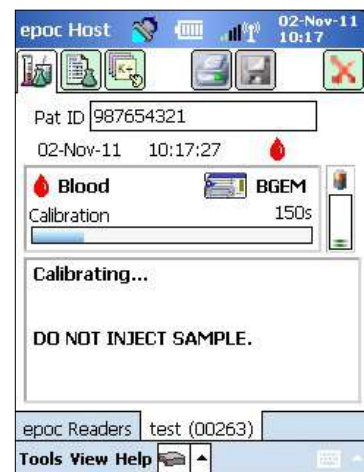
The calibration process takes approximately 165 seconds to complete. During this time, the user can prepare the patient and obtain a blood sample.

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

3.12 Entering Patient Information (or Lot Number) and Test Selection

The Patient ID and related information can be entered 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** (not shown), the QA fluid Lot Number is entered instead of the Patient ID.

Select the Test Information Tab on the Reader Screen to enter the patient information. The Administrator may require Sample Type or Hemodilution entries.

Using the arrow, additional settings related to respiratory therapy, age, and gender may be entered.

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.

The Test Information Page for performing QA test 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.

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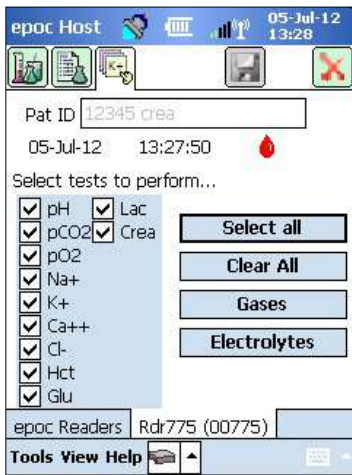
Select the Test Selection Tab on the Reader Screen to select or deselect analytes to display in the test results. The system administrator settings may require analyte selection before results are displayed. Additional analytes may be selected after test completion. Once test results are displayed, analytes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

3.13 Using Barcode Scanner to Enter Patient ID

Press the stylus in the Patient ID field. A cursor appears.

Activate the Barcode Scanner by pressing any of the **Scan** buttons on the epoc Host. The Barcode Icon at the top of the screen indicates when the barcode scanner is ready to scan. Point the light coming from the top of the Barcode Scanner towards the desired barcode until a beep is heard. The scanner turns off. The scanned text appears in the field where the cursor was left.

 Warning: Never look directly at the laser light. Point the laser only at a barcode and away from the eyes at all times.

The Patient ID may also be entered using the stylus and the **Onscreen Keyboard** accessible from bottom of screen via the Text Input button.

3.14 Collecting a Blood Sample

 Read information on Sample Collection in the BGEM Test Card Specifications section of this Manual to ensure that blood samples are properly collected and handled for testing.

3.15 Timing of Sample Introduction

After about 165 seconds 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.
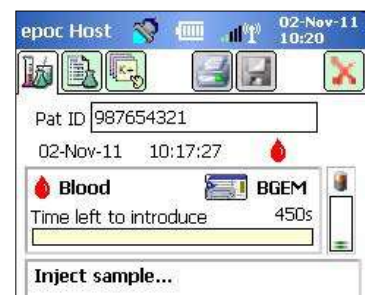
 Introducing the sample too soon or too late will cause an error and abort the test. A new Test Card must be inserted and the test procedure started again.

3.16 Sample Introduction

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

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

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

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

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

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

   ⚠ 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 end of the Test Card waste chamber and possibly into the epoc Reader.

   ☣ Never attempt to clean inside the 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.

The Reader automatically analyzes the test sample. The analysis process takes about half a minute.

Figure 1

Figure 2

Figure 3

3.17 Test Completion

Once the analysis is complete, the epoc Host displays the Test Results from the Reader Screen (tab on the left).
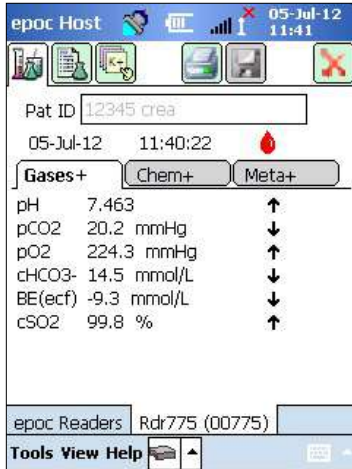
The Patient ID must be entered before the test results are displayed. Once saved, the Patient ID textbox and Save button are disabled again.

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.

3.18 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 question **Recall data from previous test?** may appear in place of the Patient ID entry. The user can select **Yes** or **No** to proceed. If neither option is selected before the test ends, the previous test data will not be recalled.
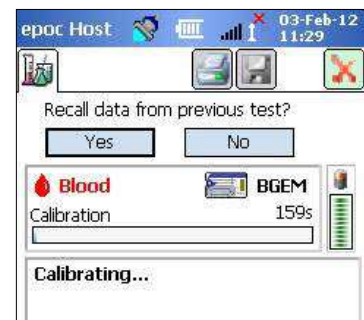
3.19 Closing the Test and Disconnecting the Reader

When all testing with the Reader is complete and all data entries are made, the test is closed by tapping on the **Red X** [icon] at 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.

3.20 EDM Synchronization

For epoc Enterprise Data Manager (EDM) users only:

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

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

3.21 Logging Out and Turning the Power "OFF"

Log out of the epoc Host Application when finished testing and viewing test results. Select "Tools," then "Logout" on the menu at the bottom left corner of the screen, or press the **Logout** button [icon]. Use the **Power** button on the Host to turn the device "OFF."

Note: _Upon epoc Host logout, users will be notified of expiring user account privileges. Notifications to users begin at 30 days before the expiration date._

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.

3.22 Multiple Reader Testing

The epoc System allows multiple Readers to connect to a single Host and run multiple tests simultaneously. The Host displays a unique Reader Screen for each Reader connected to a Host. Up to seven (7) Readers can be connected to a Host at the same time. Up to four (4) of these Readers can perform tests concurrently.

Discover all required Readers using the Host before running multiple tests. Discovery is not permitted while the Host is connected to one or more Readers. Disconnect all connected Readers before attempting to discover additional Readers.

Once discovered, a Reader can be connected to the Host at any time. Connect to each Reader at any time before starting a test on each Reader. Run tests for each Reader using the same instructions for running a test as when using a single Reader.

04 | epoc® Test Cards

4.1 General Test Card Information

A Test Card is comprised of an array of sensors on a sensor module mounted in a credit-card sized fluidic housing with a sample entry port, and a sealed calibrator fluid reservoir.

Test Card – TOP   Test Card – BOTTOM
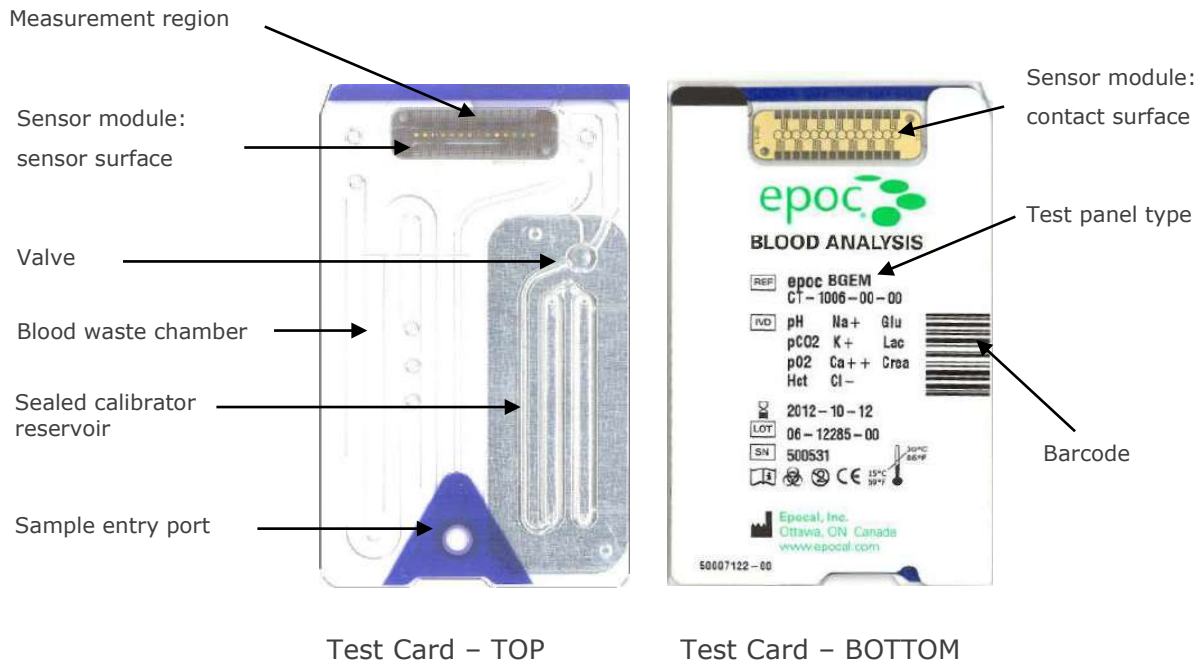
Refer to BGEM Test Card Specifications Section of this Manual for more information.

4.2 Test Card Physical Characteristics

Size	L86 mm × W54mm × H1.4mm
Weight	6.3 ± 0.3 grams
Materials	• Co-polyester body; • Polypropylene adhesive labels; • Polyethylene-coated aluminum foil; • Water-based calibration fluid; • Fiberglass-reinforced epoxy tape with an array of nickel-gold-coated copper electrodes.

4.3 Test Card Packaging, Storage, and Shelf Life

4.3.1 Packaging

Each single use Test Card is packaged by the manufacturer into a card pouch, which also contains one (1) strip of desiccant. Fifty (50) card pouches are packed into boxes of 50 cards. Quantities of 50 Card Boxes are packed into larger shipping cartons.

4.3.2 Shipping Controls

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

Test Card shipping cartons include two (2) Temperature Monitors, which change color when the shipping temperature is outside the specified range. A Low Temperature Monitor turns red below 2° C. A High Temperature Monitor turns red above 30°C.

Temperature monitors must be checked when Test Cards are received to verify that the temperature limits were not exceeded during shipment. If one or both of the temperature monitors indicate any RED, place the card shipment on "Hold" and isolate from possible use. Contact Technical Services.

High Temperature Monitor   Low Temperature Monitor

FAIL: Cards Stored above 30°C

PASS: All 3 windows are white

FAIL: Cards Stored below 2°C

PASS: Window is white

Temperature Monitors

Shipping Carton

Box of 50 Test Cards
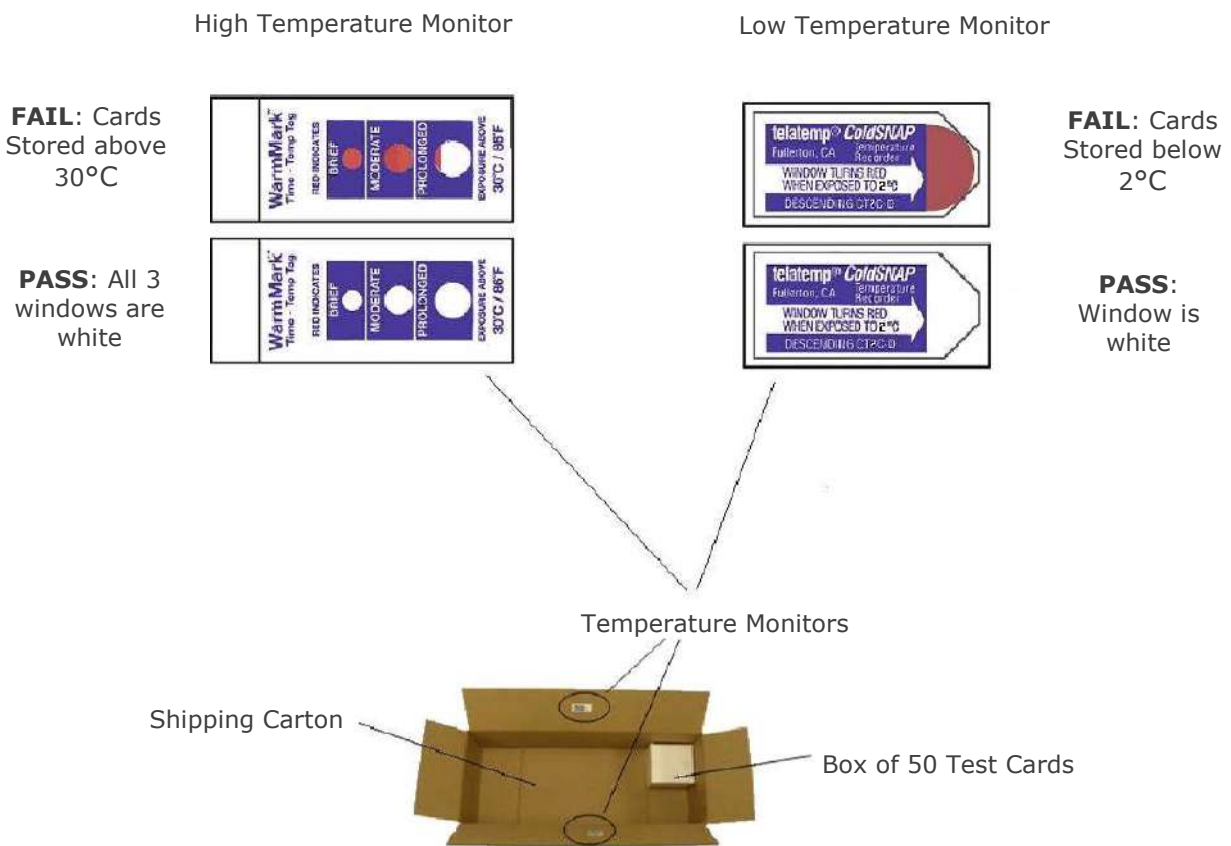
⚠ Never use Test Cards shipped outside the specified temperature limits (2°-30°C).

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

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

4.3.3 Card Pouch

The card pouch contains one (1) Test Card and one (1) strip of desiccant. A tear notch is used to tear open the pouch.

Card Pouch

Tear Notch

Test Card

Desiccant Strip
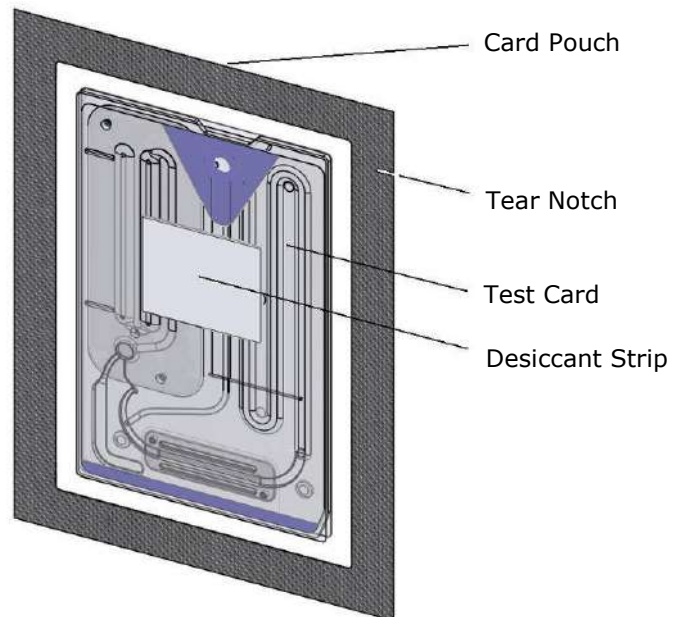
4.3.4 Test Card Storage

⚠ Always store Test Cards at room temperature (15°-30°C).

⚠ 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.

⚠ The 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 subject Test Cards to excessive shock (dropping, throwing, shaking) during storage.

4.3.5 Removing Cards from the Card Pouch

⚠️ 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.

4.3.6 Test Card Use

⚠️ 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.

4.3.7 Test Card 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.

⚠️ Shelf life is affected if Test Cards are stored outside specified storage temperature limits.

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.

"Use by" date

Storage temperature range
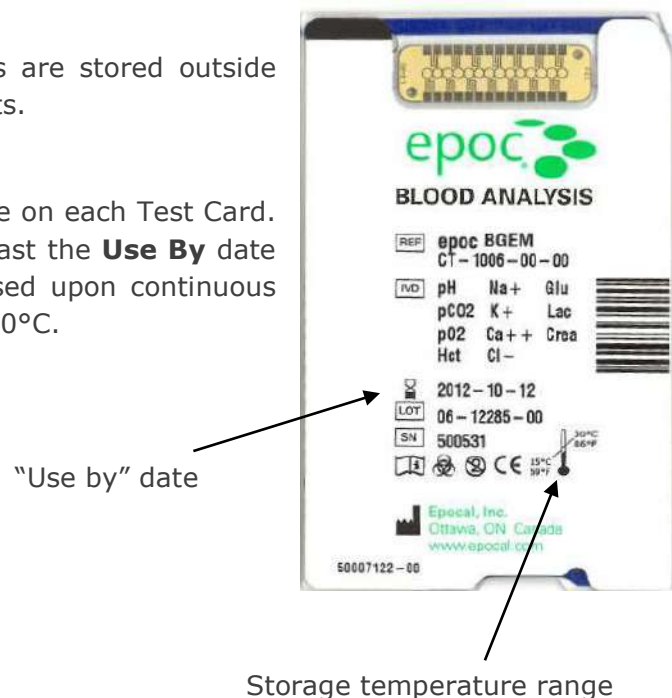
05 | epoc® Reader

5.1 Overview

The epoc Reader is a simple-to-use raw-signal acquisition peripheral. The Reader and Host mobile computer together comprise all of the subsystems generally found in a traditional blood analyzer that operates on single use sensors and reagents.

The Reader has a card slot for accepting a Test Card, and an Electro-Mechanical Actuation Assembly for engaging the Test Card after it is inserted into the Card Slot. When the internal Motor Drive is activated, a Push Pin in the Reader breaks the Valve in the Test Card and drives Plungers causing the Calibration Fluid to flow across the Sensor Module. The Reader includes circuits for amplifying, digitizing and converting the raw sensor signals to a wireless transmittable Bluetooth format. At the rear of the Reader is a Docking Pivot with a slot for the epoc Host. The Docking Pivot provides a charging connection for the Host battery.

⚠ The epoc Reader has no user serviceable parts, with the exception for the lithium battery and battery door. Never disassemble the Reader or place any foreign objects into the Card Insertion Slot or the Docking Pivot.

Membrane Switch Layout

Indicators:
battery status (amber)
test status (green or red)
power (green)

Docking Pivot

Power Button

Membrane Switch

Card Insertion Slot

epoc Reader – Front View

Maintenance Port (covered)

epoc Reader AC Adaptor

epoc Reader – Rear View

Power Jack
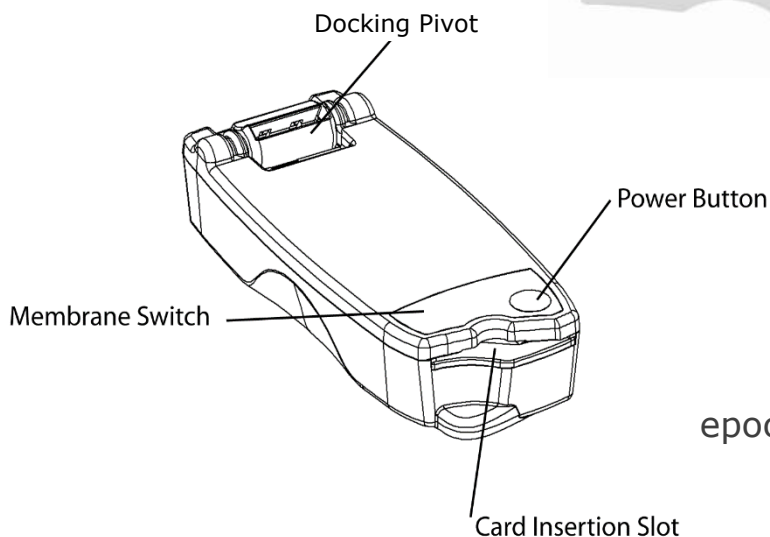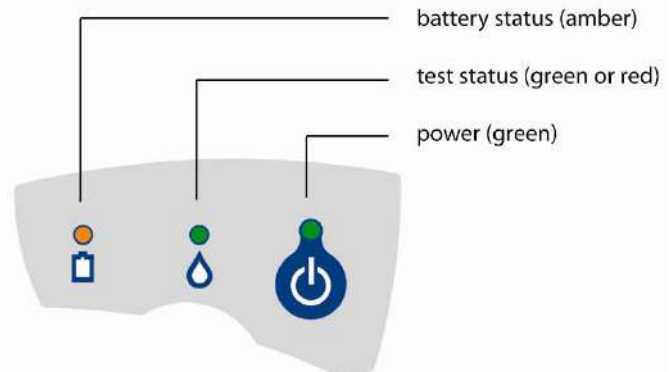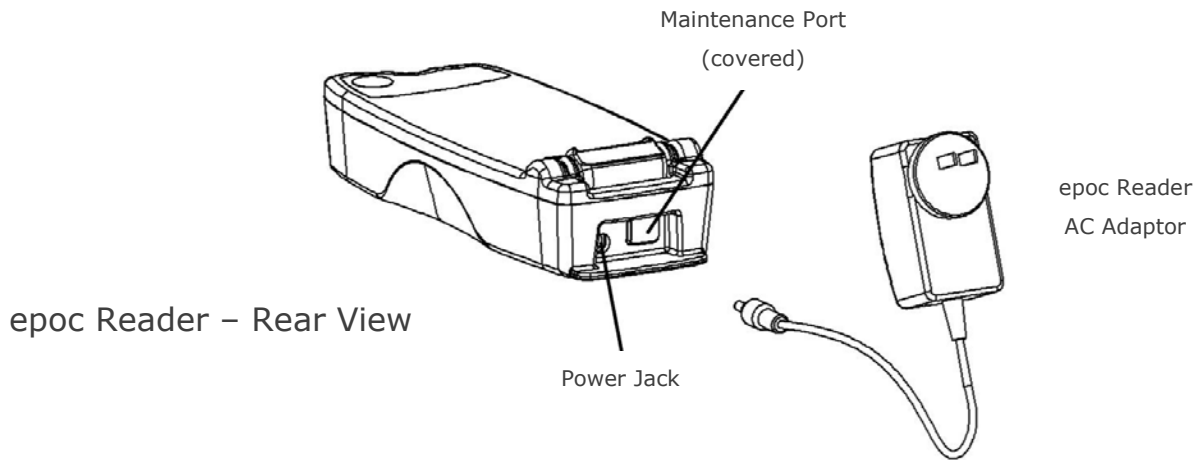
5.2 Power Requirements

The Reader operates on a rechargeable battery inside the Reader. The Reader can be operated on battery power only or while the battery is being charged using the AC Adapter provided with the Reader.

The AC Adapter plugs into the Power Jack located at the rear of the Reader.

⚠ Use only the AC Adapter, as specified in "epoc Reader and Host Specifications" section of the epoc System Manual.

⚠ Exercise caution if using an Extension Cord or Power Bar for use with the Reader AC Adaptor. These devices may void the product safety certification if not appropriately certified or approved for medical use.

⚠ Never remove the AC Adapter from an electrical outlet by pulling the cord or by pulling it out at an angle. Otherwise, the plug may break and potentially be left in the electrical outlet.

⚠ Should the plug ever break in the electrical outlet, remove the broken plug from the wall while wearing electrical safety gloves. This adds extra protection to the user from electric shock.

Power Button		
⏻	🟢 solid green	reader is on
	○ off	reader is off

The Power Button is located on the Membrane Switch. Press the button to power up the Reader. The Power Indicator turns solid green indicating that the Reader is "ON." Press and hold the Power Button for several seconds to turn 'OFF' the Reader when not in use to conserve battery power.

The AC Adapter recharges the Reader when the Reader is either "ON" or "OFF."

5.3 Rechargeable Battery

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 for instructions on replacing the battery and the battery door.

Fully charged, the Reader can process about fifty (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 requires approximately four (4) hours to recharge a fully discharged Reader Battery.

5.4 Reader Status and Firmware Version

Use the epoc Host to obtain the Reader status. Use "Tools" → "Status" when connected to the Reader or press on a Reader icon from the Main Reader Screen and tap "Status" on menu that appears. The epoc Reader Status is displayed.

The third tab [icon] provides the Reader firmware version.
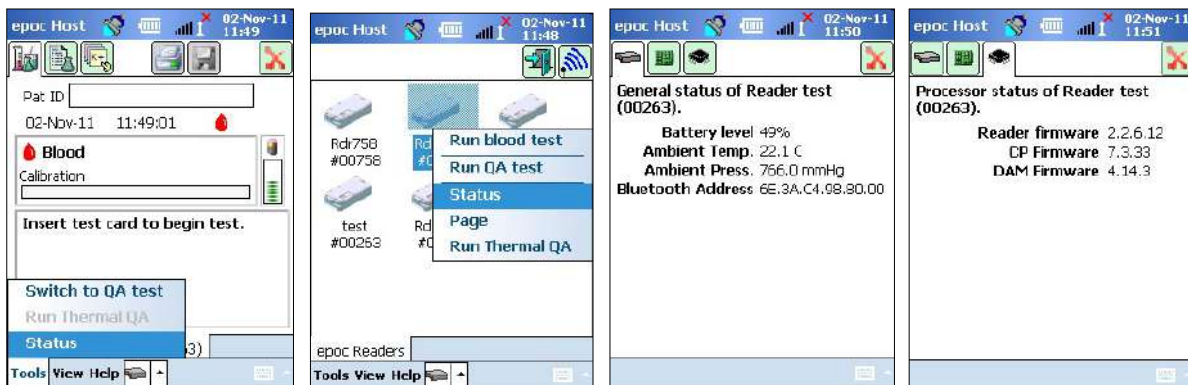
5.5 Test Status

The Test Status Indicator informs the user of the test status. When the indicator is "OFF" the Reader is not connected to a Host. When a Host first connects to a Reader, the indicator will turn solid **green** to inform the user that the Reader is ready for use. When the indicator begins to flash **green**, it indicates that the Reader is busy processing and the user should wait. When the Indicator turns solid **red**, it notifies the user of an error condition. The required user action is determined from the context of the test.

Solid **Green** when:	Required User Action
Test card is first inserted	Fully insert card
Calibration is complete	Inject sample
Test is complete. Results are available	Remove card
Reader is being paged (slow flash with beeps)	No action required
Solid Red when:	
Error has occurred	Check the Host for further action

5.6 Audible Signals

The epoc Reader uses a "beeping" sound to provide user feedback.

Audible Signal	Interpretation
Normal Beep	Test Card is first inserted and Card Barcode is successfully read. Adequate sample has been introduced into Test Card OR Sample introduction window has timed out
Quick Beeps	Calibration is complete and test sample may be introduced
Long Beeps	Reader is paged from a Host

5.7 Card Insertion Slot
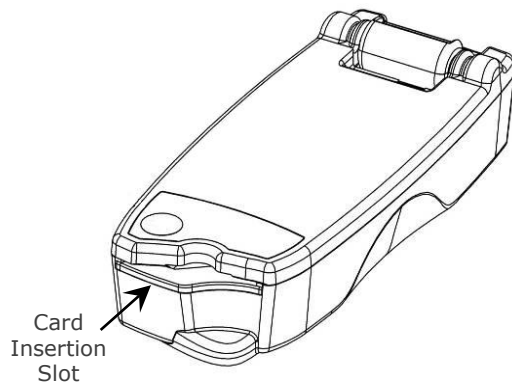
The epoc Reader has a Card Slot for inserting the Test Card. Within the Card Slot there is a Card Entry Switch, a Barcode Scanner, an Electrical Contact for contacting the Test Card Sensor Module upon insertion, and a Thermal Subsystem for heating the card's measurement region to 37°C during the test.

The Test Card has a Notch, allowing only a correctly orientated Test Card insertion into the Card Slot. A properly orientated card requires minimal force for insertion and encounters minimal resistance up to full insertion.

Card Insertion Slot

Notch in Test Card

⚠ Never force a Test Card into the Card Slot. If correctly orientated, the Test Card should enter easily with minimal effort.

⚠ Never insert any object other than a Test Card into the Card Slot.

⚠ Never use a Test Card that may be contaminated (wet or with foreign material attached).

⚠ Avoid placing the Test Card on any surface prior to test. Insert Test Card directly from the Test Card Pouch and insert into the Card Slot.
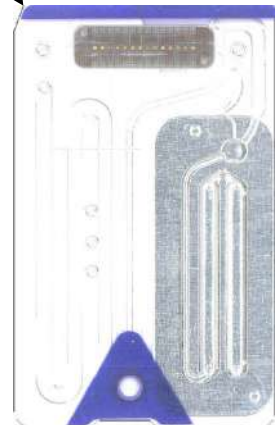
5.8 Docking Pivot

The Docking Pivot provides a physical link between the epoc Reader and epoc Host. A pocket in the Docking Pivot accepts the blade section of the Host Cradle. When docked in the open position, the Host sits with its Screen at 15 degrees from vertical. When in the closed position, the Host is rotated flat against the top surface of the Reader, an internal spring latch provides a holding force, and an edge of the Cradle fits into a pocket in the Reader cover preventing removal of the Host.

An Internal Spring contact in the Docking Pivot makes an electrical connection to the Host via Contact Strips on the surface of the Cradle Blade. When docked to a Reader connected to the AC Adapter, the Host Battery is recharged through this connection.

Cradle Blade

Docking Pivot
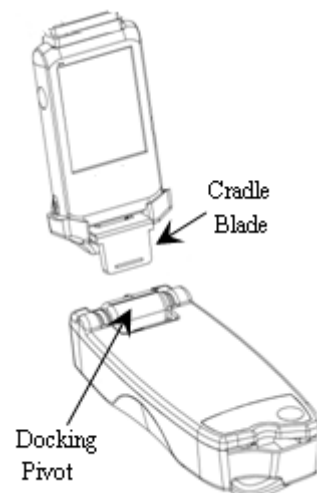
5.9 USB Maintenance Port

The USB Maintenance Port at the rear of the Reader is **for use by Epocal authorized personnel only**. The connection to this port is blocked with a cover that must not be removed by the user.

USB Maintenance
Port Cover
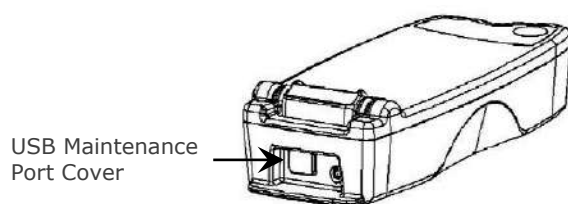
5.10 Motorized Mechanism

A Motorized Mechanism inside the Reader releases the calibration fluid from the reservoir in the Test Card to the sensor region of the Test Card. This mechanism operates automatically during a test. The motor can be heard operating at two (2) different times:

1. When a new Test Card is completely inserted into the Reader.

2. At the end of a test.

5.11 Wireless Module

Potential interference may occur with other sensitive diagnostic and measuring equipment used for detecting low level signals. Always keep the epoc Reader at least one (1) meter away from other medical equipment.

The Reader uses an embedded Bluetooth module for communication with an epoc Host. Bluetooth is a wireless communication standard designed for low power, short range communication between wireless devices.

In order to communicate, the wireless module must be connected to a Host. Once connected, the Bluetooth module forms a bond with the epoc Host as if both devices were connected by a wire. When connected, access to the epoc Reader by other Hosts is blocked.

5.12 Barcode Scanner

Within the epoc Reader, there is an internal Barcode Scanner that is used to read the Test Card Barcode during card insertion. The Barcode Scanner is activated upon entry into the Card Insertion Slot where a red light inside is visible. Each Test Card has a Barcode printed on the bottom white label that contains the card lot number, serial number, "use by" date and card type.

The test card must be inserted smoothly and completely into the Reader to read the barcode. Any abrupt stops or unevenness in the speed of insertion may prevent proper reading of the barcode.

Successful reading of the barcode is indicated with an audible "beep". A solid **red** Test Status Indicator informs the user of an unsuccessful reading of the barcode. The card must be removed from the Reader and reinserted with a steady, smooth motion. Multiple insertions of an unused Test Card are allowed if the Card has not been damaged or the calibration sequence initiated.

5.13 Thermal System

The epoc Reader is equipped with a Thermal System that provides a temperature controlled environment for Sensors during a test. The Heaters are two (2) Metal Heating Blocks located above and below the Test Card near the sensor module.

When a Test Card is fully inserted into the Reader, the Heaters are brought in contact with the Test Card. Efficient thermal contact of the Heaters with the Test Card is provided by a spring loaded mechanism. The heating cycle begins upon successful insertion of a Test Card and is controlled by algorithms present in the Reader's Microcontrollers. The Heaters are calibrated so that the fluid over the pO$_2$ sensor is at 37°C.

5.14 Operating Environment

Temperature

The Reader can be operated between 15°C-30°C. There is an internal Ambient Temperature Monitor that will disable the Reader function if room temperature falls outside of this range. A Reader brought from a warm or cool environment, such as during shipment, must be allowed to equilibrate before use.

Atmospheric Pressure

The Reader can be operated at atmospheric pressures between 400–825 mmHg. An internal Barometric Pressure Sensor monitors atmospheric pressure and disables the Reader function if outside this range.

Relative Humidity

The Reader must be used where the relative humidity is less than 85% at 30°C, non-condensing. The Reader's Electronic QC checks leakage current within the Reader to detect compromised performance due to high humidity.

Test Position

The Reader is designed to be portable and to be used at the point-of-care (POC). It may be used within the patient vicinity, but it is not intended for direct patient contact.

⚠ The Reader must rest on a flat horizontal surface without being moved during the entire testing process.

Water Ingress

The epoc Reader has not been evaluated to protect against the ingress of water.

Degree of protection against ingress of water: IPXO

⚠ Always keep the epoc Reader in a dry location. Immediately wipe away any liquids on the outside Reader surfaces (using appropriate Biohazard protection). Always follow the recommended cleaning procedure.

06 | epoc® Host

6.1 Overview

The epoc Host is a dedicated use mobile computer. When loaded with the epoc Host Application Software by the manufacturer, the epoc Host is ready for use. The Host comes assembled in a Cradle that features a Cradle Blade designed to mate with the Docking Pivot on the epoc Reader.

The epoc Host mobile computer is intended for use as part of the epoc Blood Analysis System and not as a general purpose computing device. Some hardware and software functions have been disabled in the device, including several buttons on the front of the device. The Host runs only the epoc Host Application Software to ensure that it can communicate with epoc Readers and execute the blood analysis calculations effectively.

The Touch Screen is used for almost all user navigation and interfacing. A removable Stylus pointer is included with the Host to "tap" on elements of the user interface located on the Touch Screen for software navigation.

6.2 Rechargeable Battery

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 is 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 Appendix A "epoc Host Quick Start Guide" or Appendix B "epoc Host[2] Quick Start Guide" in the end of this manual for more information.

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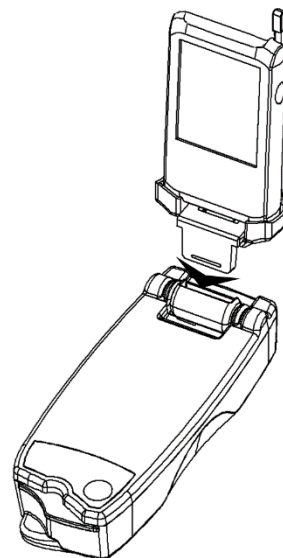
6.3 Barcode Scanner

The Barcode Scanner (included with the epoc Host) 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. Refer to Appendix A "epoc Host Quick Start Guide" or Appendix B "epoc Host[2] Quick Start Guide" in the end of this manual for exact locations of Barcode buttons.

Always point Barcode Scanner away from the eyes. Laser light may be harmful to eyesight if viewed directly.

The Barcode Scanner Icon at the top of the screen indicates that the scanner is ready to use.

To use the Barcode Scanner:

1. Place the software cursor into field where the scanned text is to be entered.

2. Press the Barcode Button at either side of epoc Host to turn it "ON."

3. Direct the red light coming from the scanner at the top of the Host towards the desired barcode until a beep is heard.

The scanner turns "OFF," and the scanned text appears in the field previously selected.

6.4 Soft (Warm) and Hard (Cold) Reset

A soft (warm) reset acts like rebooting a desktop computer. The software stops running and is reloaded. All saved data are safe. A boot-up sequence is initiated, and epoc Host application is loaded automatically. The soft (warm) reset can be used to restart the Host application if the epoc Host stops functioning and/or responding.

If the soft (warm) reset does not help, perform the hard (cold) reset. Refer to Appendix A "epoc Host Quick Start Guide" or Appendix B "epoc Host² Quick Start Guide" in the end of this manual for exact locations of the Reset buttons.

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

Always verify that date and time are correct after performing a hard (cold) reset.

6.5 Navigation

Navigate the epoc Host Application software by pointing and gently tapping the Touch Screen using the Stylus included with the epoc Host. Use the Stylus to tap or press software buttons, switch between software tabs, and to place the cursor into text fields.

Tap an item: Use to select an option, similar to left-clicking a computer mouse.

Press and hold an item: A pattern of dots will encircle the Stylus and a menu appears, if available. Similar to right-clicking a computer mouse.

6.6 Entering Text

Almost all interfacing with the epoc Host is performed through the touch screen using the Stylus included with the epoc Host.

There are four (4) possible methods to enter text (Keyboard, Block Recognizer, Letter Recognizer, Transcriber). It is recommended to use the **Keyboard Method** with the epoc System. Refer to Appendix A "epoc Host Quick Start Guide" or Appendix B "epoc Host[2] Quick Start Guide" for more information.
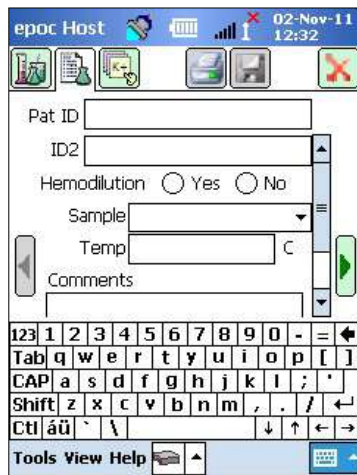
1. Tap the Stylus to locate the cursor into the desired field.

2. The Onscreen Keyboard is normally hidden. Tap the Text Input Button ⌨️◢ at the bottom right hand corner of the screen to enable text input functionality.

3. If the Onscreen Keyboard does not appear, then tap the triangle at the right side of the Text Input Button. A menu of the four (4) text input methods appears. Select "Keyboard".

4. Tap on characters in sequence until all required text is entered.

Additional functionality:

- Toggle between upper and lower case characters by tapping "Shift" before the next character, or "CAP" before tapping multiple characters.
- Toggle between text and number/symbol screens by tapping "123."
- Relocate the cursor as required for text editing.
- Select text already entered by pressing gently on the screen while sweeping across one or more characters.
- The "Backspace" and "Enter" keys function like on a desktop computer.
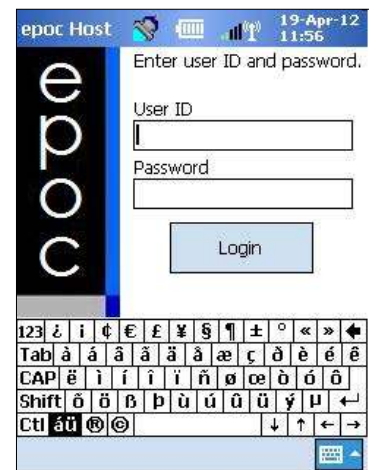
Additional foreign language functionality:

- For additional foreign language keyboard characters, tap the áü key. See illustration.

6.7 Date / Time Clock

The current Date and Time are displayed at the top right hand corner of the screen. This is the Date and Time applied to the Test Record.

⚠️ Always verify that Date and Time are correct before starting a Test.

If Date and/or Time are incorrect, synchronize with your data manager to update Date and Time. Otherwise contact your System Administrator to set correct Date and Time before proceeding with a test.

Note: Only approved data managers like the epoc Enterprise Data Manager (EDM) may be used with the epoc System. When using the epoc System with an approved data manager, epoc Host messages that reference "EDM" refer to all approved data managers.

6.8 Status Indicators

A line of Status Indicators appears at the top of the epoc Host screen.

Status Indicator	Interpretation
🔵	Host Barcode Scanner is ready for use.
🔴	Host Barcode Scanner is NOT ready for use.
🔋	FULL Battery charge (as shown). Fewer bars are shown as charge is depleted.
📶	Wi-Fi Indicator – Wi-Fi OFF.
📶	Wi-Fi Indicator – NOT connected to network.
📶	Wi-Fi Indicator – connected (low signal).
📶	Wi-Fi Indicator – connected (strongest signal).
02-Nov-11 10:39	Current Date and time (as set by Administrator).

6.9   User Accounts

The epoc Host Application supports two (2) types of users: **Administrator** and **Operator**.

The Administrator has access to customizable features of the epoc Host Application and is able to exit the program to change settings in the Host operating system, outside of the Host Application.

Operators have the ability to perform tests and view test results. Some Operator options are limited by the Administrator settings.

The **Administrator** has the ability and responsibility to manage user accounts and maintain the software using appropriate customized settings.

The epoc Host distinguishes between Operators and the Administrator by their unique User ID and Password.

6.10 epoc Host Application User Interface

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

Tabs within the software allow the user to navigate to different parts of the application using the Stylus.
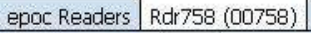
Buttons perform actions and enable fields for text input.

The Example Screenshot below shows the basic elements of the user interface.
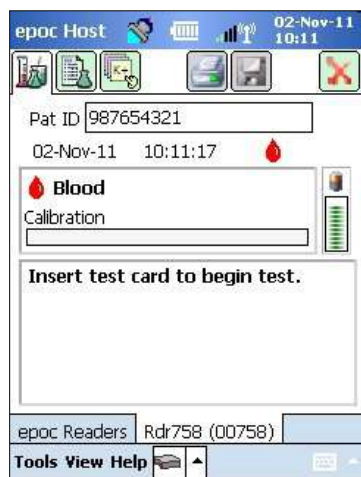
The user interface is context dependent; it changes depending on where and what a user is doing.

There is always a **Toolbar** at the bottom of the Screen that contains Menu Items and Toolbar Buttons. The Text Input Button is located here.

Select different screens by tapping **Screen Tabs** near 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 **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. The remaining information in this Section describes the user interface for an Operator Account.

Information for the Administrator Account is described in Section 7 "epoc Host Administration" of this manual.

6.11 Startup Screen

After any Reset, the epoc Host Application displays a Startup Screen while it initiates the program, reads files and configures the software.

6.12 Login Screen
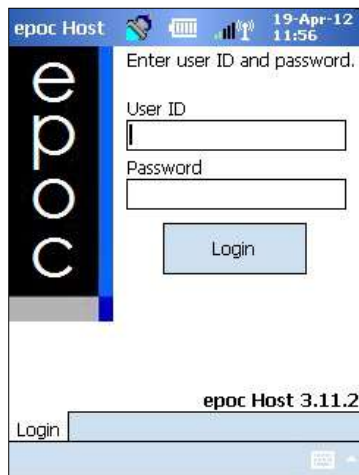
The Login Screen appears after any Reset or after the user logs out of the epoc Host Application.

6.13 Operational Modes

The following Operational Modes are available to the Operator by tapping the [icon] access button:

1. Testing Mode (the **Run Test** option).

   - Run and view tests in progress;
   - Open multiple Reader Screens to view tests on Readers concurrently

2. Viewing Tests Mode (the **View Test** option).

   - Review previous Test Results;
   - View multiple Tests in a List. Select Tests to view on separate screens.

3. Viewing Electronic QC Mode (the **View EQC** option).

   - Review latest electronic quality control records (since the last EDM synchronization);
   - View multiple electronic quality control records in a List. Select records to view on separate screens.

4. Viewing Thermal QA Mode (the **View Thermal QA** option).

   - Review latest thermal quality assurance records (since the last EDM synchronization);
   - View multiple thermal quality assurance records in a List. Select records to view on separate screens.

6.14 Testing Mode

The following information is displayed when conducting a Test:

1. **Test Type** ([icon] Blood Test or [icon] QA Test).

2. **Reader Battery Level** [icon] - (Red indicates a Low Battery Level).

3. **Progress Bar** [bar] displays the progress of timed events during a Test.

4. **Message Box** displays Text and Error Messages. (For example, "Calibrating… DO NOT INJECT SAMPLE").

Appearance of this information may vary depending upon the test type performed and stage of the testing process.

6.15 Main Reader Screen

Access the Main Reader Screen by pressing the **epoc Readers** tab: [epoc Readers] . The Screen displays all Readers available for use.

Locate Readers by pressing the **Discovery** button: [icon] . During the Discovery Mode, the Host searches for Readers in the vicinity. Blue waves imitating the radio signal are visible in the icon. The Discovery Mode is cancelled by pressing the Discovery button again. Discovery can be performed again to locate additional Readers, but not while a connection already exists between a Host and Reader, such as during a test.
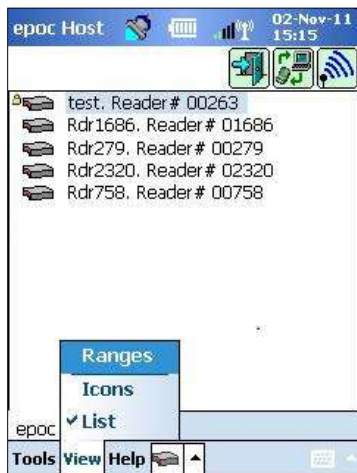
Dedicated Readers are always listed and are indicated by the **Lock** icon: [icon] . Available Readers are displayed on the Main Reader Screen either as Icons or in a List. The Serial Number and name for each Reader are displayed. Select View on Toolbar menu to change the way how Readers are displayed.

When a data manager is present, the **EDM Synchronization** button [icon] is used to exchange information (test results, configuration information) between epoc Host and EDM.

Tap the **Logout** button [icon] to logout and display the Login screen again.

Gently press and hold Stylus on Reader Icon or List Item to open **Options Menu** for each Reader. Select an activity for Reader to perform**:**
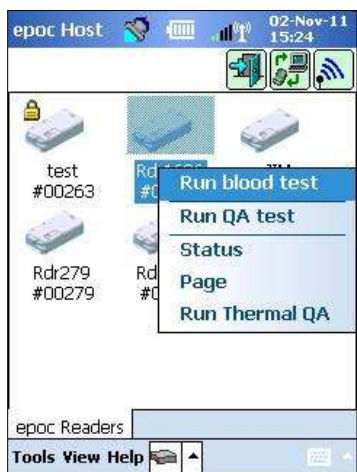
Run blood test – Connect to Reader to perform Blood Test.

Run QA test – Connect to Reader to perform QA test (available for Operators authorized to run QA tests).

Status – Reader reports to Host with Reader status information.

Page – Reader beeps five (5) times. Reader Indicator illuminates to help locate Reader.

Run Thermal QA – available for Operators authorized to run QA tests. Thermal QA records may be saved for later viewing or printing. Saved Thermal QA records will be sent to your data manager during synchronization, and can then be viewed and printed from the EDM.

6.16 Reader Screen

A tabbed **Reader Screen** appears for the Reader once a Test is started.

Reader name and serial number are displayed on the **Reader Screen** tab ⌊Rdr319 (00319)⌋ at the bottom of the screen.

Three (3) buttons may appear at the top right corner of the Reader screen:

1. The **Print** button appears only if there are printers configured. Tap the **Print** button to send test results to a printer connected to the Host. The Print button is not enabled during a test;

2. The **Save** button is enabled only after a test completes. Information entered during a test is automatically saved as the test completes. Information entered after the test completes must be saved by pressing the Save button;

3. Tap the **Red X** button to cancel the test and close the Reader connection.

Note: *If the initial Reader connection fails, the **Blue Lightning Bolt** icon appears next to the Patient ID field. Tap this icon to reconnect to the Reader.*

6.17 Reader Screen Pages

There are three (3) pages for each Reader screen:

1. The **Test Results** page displays all messages and starts information about a test in progress and the results of a test once it is complete.

2. The **Test Information** page allows for user input for optional information for the test (some calculated or corrected results may not be available unless these data are completed).

3. The **Test Selection** page permits for the selection of analytes for testing.
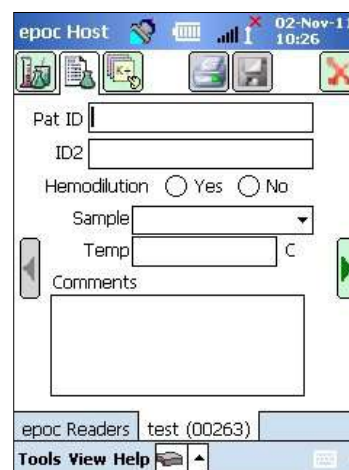
Test Date and Time are displayed on each page, as well as Patient ID (Blood Test) or Lot Number field (QA Test).

Note: If the Operator is authorized for QA Testing, use Tools menu to:

1. Switch between Blood Test and QA Test;

2. Perform Thermal QA.

The screenshot on the right shows the Reader Screen on the Test Results page, with the **Switch to QA test** option being accessed from the Tools menu.
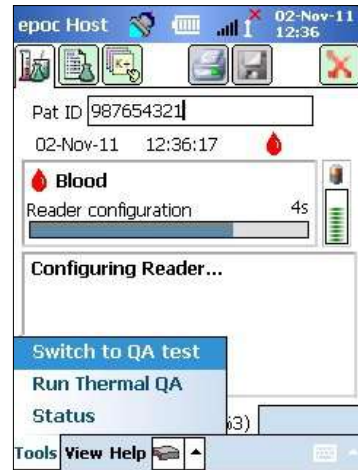
6.18 Test Results Page

While a Test is in Progress:

The Progress Bar displays the progress of timed events and their title. The color of the Progress Bar varies with each event. The Message Box displays all instructions, errors, and messages during the Test.

When a Test is Complete:

Three (3) Tabs [Gases+] [Chem+] [Meta+] show test results. Click on Tabs to display each set of results data. Results displayed depend upon the Test Card type (see the bottom side of the Test Card) and tests selected.
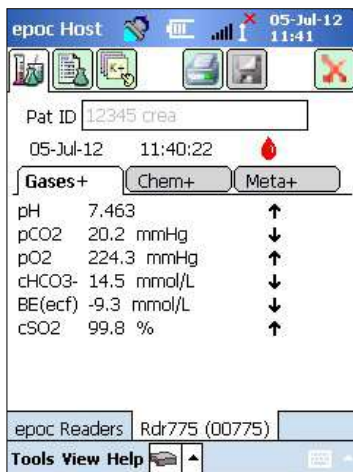
Gases+	**Chem+**	**Meta+**
Test results for Gases+ include:	Test results for Chem+ include:	Test results for Meta+ include:
pH	Na+	Glu
pCO$_2$	K+	Lac
pO$_2$	Ca++	Crea
pH(T)	Cl-	eGFR, eGFR-a
pCO2(T)	cTCO2	
pO2(T)	AGap, AGapK	
cHCO$_3$-	Hct	
BE (ecf)	cHgb	
cSO$_2$	BE (b)	
A		
A-a		
a/A		
A (T)		
A-a (T)		
a/A (T)		

Messages

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

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

Additional Documentation

If the Host has been configured to allow additional information to be recorded with the results, then the **Additional Information** button will be displayed next to the results.
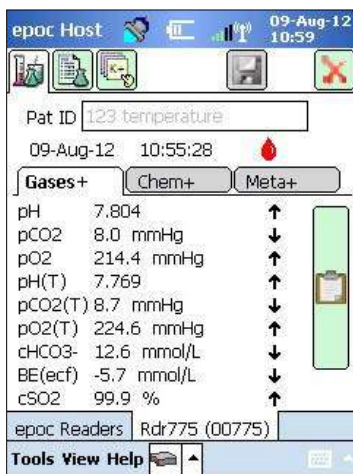
Tap the Clipboard button to open the **Additional Documentation Window**.
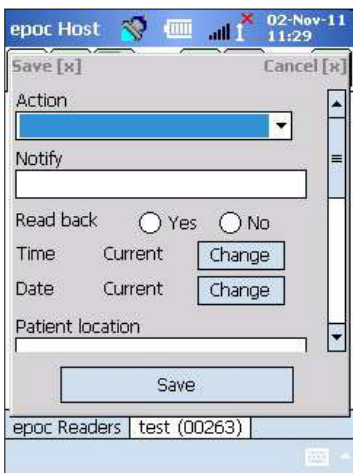
Action dropdown contains selections for Notify physician, Notify RN, Repeated test, Sent to lab, Expected values, and Other.

Select **Notify** to enter text information such as the name of the Physician who was notified. If **Action** was selected, then a text entry is required for valid action.

Read back? Select "Yes" or "No" to record action of reading back test results.

Time, **Date** of action is automatically recorded using current Time and Date. Tap **Change** to edit Time and Date.

Use the Scroll Bar on the right to access additional fields.

Text can be entered in **Patient Location, Ordering Physician,** and **Collected By** fields.

Order Time and Date and **Collection Time and Date** are automatically recorded using current Time and Date. Tap **Change** to edit Time and Date.

Tap **Save** to keep all text entered. The Window closes after the **Save** operation.

Tap **Cancel [x]** to close the Window. **Additional Documentation** action changes will not be saved.

6.19 Critical Values Actions

After completing a test, if one or more of the test results fall outside of its critical range and the Host has been configured to flag critical results, the result will appear in **bold red** with out-of-critical-range indicator ↑↑ ! and the **Critical Actions** button displayed.
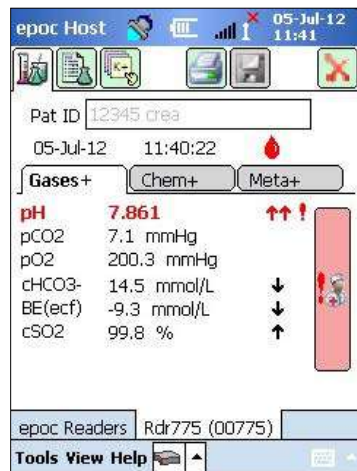
Tap the Doctor button to open the **Critical Actions Window,** where actions taken by the Operator may be entered.

Critical Actions Window
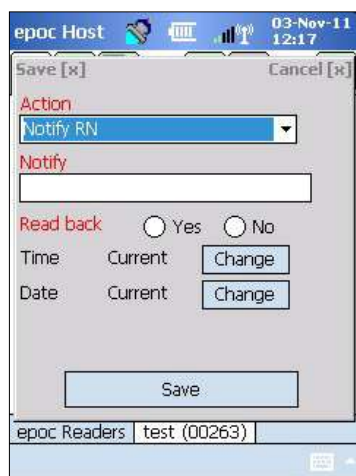
Mandatory fields appear in **red** in the Critical Actions Window.

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. If Action was selected, then a text entry is required for valid action.

Read back? Select "Yes" or "No" to record action of reading back test results.

Time, **Date** of action is automatically recorded using current Time and Date. Tap **Change** to edit Time and Date.

If the Host has been configured to **Allow Additional Documentation fields**, a Scrollbar will appear to the right, providing access to additional fields. Consult the Additional Documentation subsection for the list of fields.

Tap **Save** to keep all text entered. The Window closes after save operation.
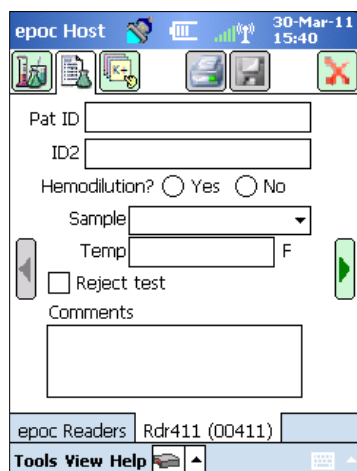
Tap **Cancel [x]** to close the Window. Critical Values action changes will not be saved.

6.20 Test Information Page

Use the Optional fields on this Page to enter Test specific data.

Enter **Patient information** at any time during the Test. Information entered prior to end of Test is saved automatically with Test Results when test is completed. Save any Information entered after the test completion before next test begins by tapping **Save Button**. Once Test Screen is closed, patient information can no longer be entered.

Use **Pat ID** and **ID2** fields to enter sample identifiers. Pat ID field can be accessed from any Page. ID2 may be used to enter alternate sample identifier such as an order number.

Use **Hemodilution** field to select hemodilution correction factor for Hematocrit. Selecting "Yes" corrects Hematocrit result for amount of hemodilution.

Note: Refer to 11.5.1 "Measurement Method" in Section 11 "Theory of Operation" and 12.13 "Hematocrit (Hct)" in Section 12 "BGEM Test Card Specifications" of this manual for details on Hematocrit measurement.

Select **Sample Type** to stamp Test Record for identification purposes. Associated with each sample type are unique reference and critical ranges that are applied to the test results and are configured by the System Administrator.
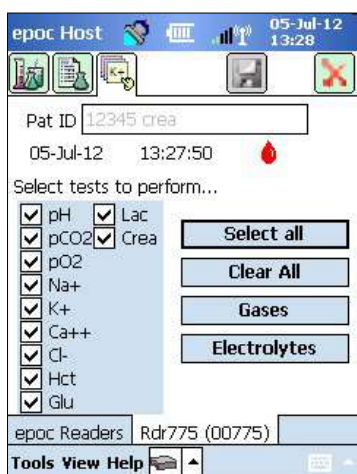
Sample Types: Unknown, Arterial, Venous, Mixed-Venous, (Umbilical) Cord, (Umbilical) Cord Arterial, (Umbilical) Cord Venous, Capillary.

Use **Temp** to enter Patient's Body Temperature to obtain temperature corrected values for pH, pCO_2, and pO_2. Temperature measuring units are set by the Administrator to ºF or ºC.

If allowed to reject tests, the user can do so by checking the **Reject Test** box. The EDM will mark this test record as "Rejected" and not send it to the Lab Information System.

In the **Comments** text box, enter test-related comments to save with the Test Record.

6.21 Test Selection Page

Use the check boxes to select Analytes for testing.

Use four (4) quick buttons to make multiple selections as described: **Select All, Clear All, Gases, Electrolytes**.

Healthcare Institution policy may require selection of analytes for testing. Policy is set in the Host Application by System Administrator.

When required, analytes must be selected before end of Test.

6.22 Respiratory Therapy Parameters

Use the **Green Arrows** at the sides of main Test Information page for entry of Respiratory Therapy parameters. Many of the fields contain **Dropdown Boxes** with choices. Different text may be entered in these fields using the Onscreen Keyboard. Select Text and tap the Backspace key from the Onscreen Keyboard to delete Text from these fields.

Values are recorded for reference only. Values do not impact Test Results.

Dropdown Box Choices:

Draw site: Art Line, R Radial, L Radial, R Brach, L Brach, R Fem, L Fem, Central Line, R Heel, L Heel, R Finger, L Finger, R Toe, L Toe, PICC, PA, RA, RV, Swan Ganz, UAC, and UVC.

Allen's test: Positive, Negative, and N/A.

Del. system: Adult Vent, AeroMask, AeroTx, AquinOx, Bagging, BiPAP, Cannula, CPAP, ET Tube, FaceTent, HFJV, HFNC, HFOV, Incubator, Neo Vent, NRB, Optiflow, Oxy Hood, Oxy Mask, Pedi Vent, PRB, Room Air, T Collar, T Tube, Vapotherm, and Venti Mask.

Mode: AC, BiLevel, CPAP/PS, PAV, PC, PC/PS, PRVC, PRVC/PS, PS, SIMV, SIMV/PC, SIMV/PS, TC, VC, BiVent, NCPAP, NIV, SIMV(PC)+PS, SIMV(PRVC)+PS, SIMV(VC)+PS, VS.

Units (beside FiO$_2$)**:** % and lpm.

FiO2, **VT**, **RR, RQ:** require numeric data entry.

Note: *For FiO$_2$, the % option must be used if calculating Alveolar Oxygen and related parameters (A, A-a, a/A).*

TR, **PEEP**, **PS**, **IT**, **ET**, **PIP**, and **MAP** require numeric data entry.

⚠ Always tap the **Save** button to retain Test Information, additional Test Selections, or Respiratory Therapy Parameters entered <u>after</u> the Test is complete.

Terminology for Respiratory Therapy Parameters

Draw Site:

Art Line	Arterial Line
R Radial	Right Radial
L Radial	Left Radial
R Brach	Right Brachial
L Brach	Left Brachial
R Fem	Right Femoral
L Fem	Left Femoral
Central Line	Central Line
L Heel	Left Heel
R Heel	Right Heel
R Finger	Right Finger
L Finger	Left Finger
R Toe	Right Toe
L Toe	Left Toe
PICC	Peripherally Inserted Central Catheter
PA	Pulmonary Artery
RA	Right Atrium
RV	Right Ventricle
Swan Ganz	A catheter that is threaded through the right side of the heart to measure pulmonary artery pressure
UAC	Umbilical Arterial Catheters
UVC	Umbilical Venous Catheters

Delivery System:

Adult Vent	Adult Ventilator
AeroMask	A mask that is worn over the mouth and nose when humidified O_2 is needed
AeroTx	Aerosol Treatment
AquinOx	Heated and Humidified, High Flow Nasal Cannula
Bagging	Bagging (manual ventilation of a patient)
BiPAP	Bi-Level Positive Airway Pressure
Cannula	Cannula
Optiflow	Type of cannula for delivering oxygen
CPAP	Continuous Positive Airway Pressure
ET Tube	Endotracheal Tube
FaceTent	Face Tent
HFJV	High Frequency Jet Ventilation

HFNC	High Flow Nasal Cannula
HFOV	High Frequency Oscillatory Ventilation
Incubator	Incubator
Neo Vent	Neonatal Ventilator
NRB	Non-Rebreather
Oxy Hood	Oxygen Hood
Oxy Mask	Oxygen Mask
Pedi Vent	Pediatric Ventilator
PRB	Partial Rebreather
Room Air	Room Air
T Collar	Tracheostomy Collar
T Tube	Tracheostomy Tube
Vapotherm	Heated and Humidified, Nasal Cannula
Venti Mask	Venturi mask

Mode:

AC	Assist Control Ventilation
BiLevel	Bi-Level Ventilation
CPAP/PS	Continuous Positive Airway Pressure/Pressure Support
PAV	Pressure Assist Ventilation
PC	Pressure Control
PS	Pressure Support
PC/PS	Pressure Control/Pressure Support
VS	Volume Support
VC	Volume Control
PRVC	Pressure Regulated Volume Control
PRVC/PS	Pressure Regulated Volume Control/Pressure Support
SIMV	Synchronized Intermittent Mandatory Ventilation
SIMV/PC	Synchronized Intermittent Mandatory Ventilation/Pressure Control
SIMV/PS	Synchronized Intermittent Mandatory Ventilation/Pressure Support
SIMV(PC)+PS	Synchronized Intermittent Mandatory Ventilation (Pressure Control) + Pressure Support
SIMV(VC)+PS	Synchronized Intermittent Mandatory Ventilation (Volume Control) + Pressure Support
SIMV(PRVC)+PS	Synchronized Intermittent Mandatory Ventilation (Pressure Regulated Volume Control) + Pressure Support
BIVENT	Airway Pressure Release Ventilation (APRV)
NCPAP	Nasal Continuous Positive Airway
NIV	Non-Invasive Ventilation
TC	Tracheostomy Collar

Other Parameters:

FiO2	Fraction of inspired oxygen
VT	Tidal Volume
RR	Respiratory Rate
RQ	Respiratory Quotient
TR	Total Rate
PEEP	Positive Expiratory End Pressure
PS	Pressure Support
IT	Inspiratory Time
ET	Expiratory Time
PIP	Peak Inspiratory Pressure
MAP	Mean Airway Pressure

6.23 Age and Gender
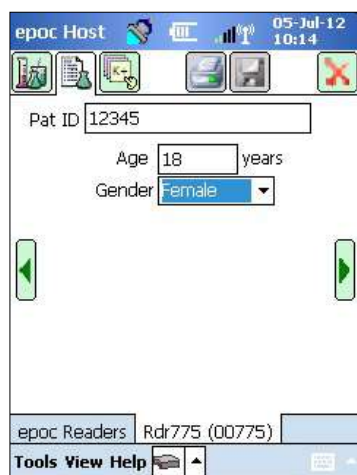
Use the **Green Arrows** at the sides of the Test Information page for entry of **Age** and **Gender** of the Patient.

6.24 EDM Synchronization

Tap **EDM Synchronization** button (or select **Sync with EDM** from the Tools menu) to synchronize with a data manager.
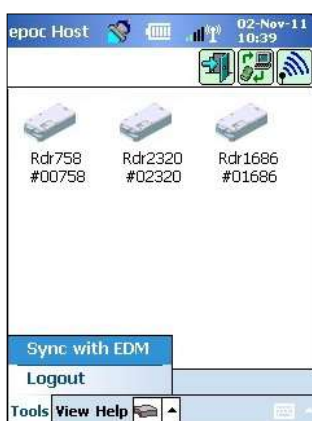
Note: The System Administrator may configure the system for automatic EDM Synchronization when closing the Test. In this case, EDM synchronization takes place

automatically after the Test is completed and the Reader Screen is closed via the Red X ![red x icon]*.*

During synchronization:

1. epoc Host **uploads Test Results** (both Blood and QA Tests), Electronic QC records, and Raw Data (if applicable) to EDM.

2. epoc Host **retrieves Configuration Information** from EDM 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 EDM, and the System Administrator has enabled the automatic upgrade feature.

When Synchronization is complete, Tap the Red X ![red x icon] to close the Screen or **Logout** ![logout icon] to log out.

6.25 Viewing Tests Mode
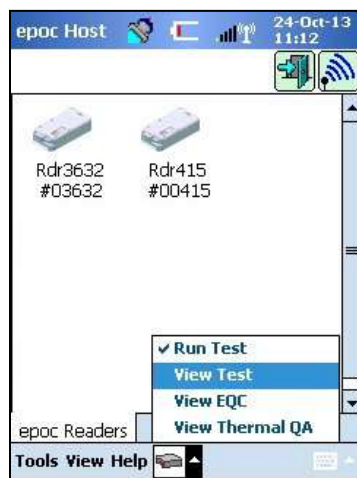
Tap the **Toolbar** button ![toolbar icon] at the bottom of the screen to open the Menu with four (4) options.

Select **View Test** to display the list of Tests Results.

Fields viewed on the **List** page ![list icon] can be selected from the View menu on the Toolbar. Check or uncheck fields to display on the List Page.
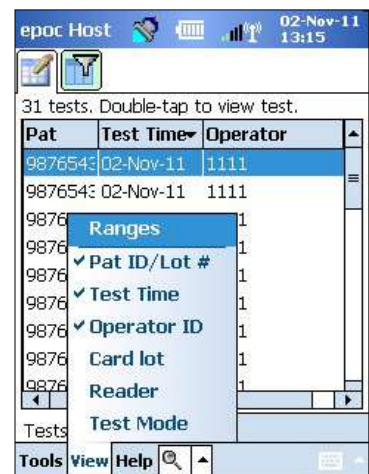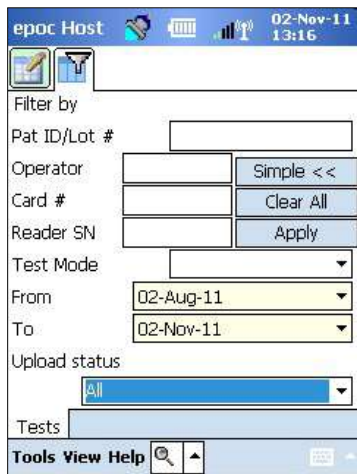
Narrow test results by using the **Filter** page . Enter search parameters such as Operator and/or Date Range to limit the results.

Toggle between "**Simple <<**" or "**Advanced >>**" **Filtering Mode** to limit/enhance search parameters.

Tap **Clear All** to remove all entered Text.

Tap **Apply** to view Filtered Results directly.

To **view** a complete Test Result:

1. Hold the Stylus on the desired Test Result row momentarily.

A new Menu Window opens.

2. Select **View this test** from the Menu.
3. Go back to the list by tapping **Tests** at the bottom left corner of the screen to select another Test to view.

Multiple Tests open on separate Tabs at the bottom of the Screen.

4. Tap Tabs to move between multiple Test Results.

Select All, Mark as unsent (used to re-send test to EDM) and **Remove this test** are only available to the System Administrator.
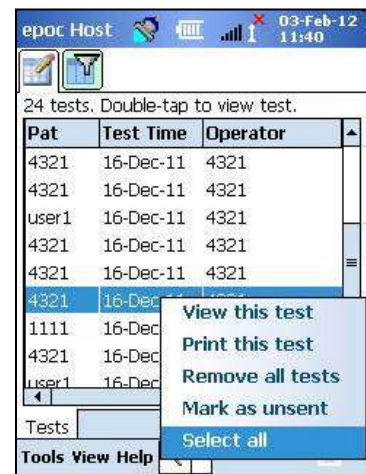
To **print** a complete Test Result:

1. Hold the Stylus on the desired Test Result Row momentarily.

    A new Menu Window opens.

2. Select **Print this test** from the Menu.

    (OR print a Test Result by tapping the **Print Icon** while on the Test Result Tab).

Test Results are available on four (4) Pages:

1. **Test Results Page** – Measured, Calculated, and Corrected Results.
2. **Test Information Page** – Data as entered with the Test and date/time of the last Electronic QC.
3. **Reference Ranges Page** – Reference Ranges for each Analyte at the time of the Test.
4. **Critical Ranges Page** – Critical Ranges for each Analyte at the time of the Test.
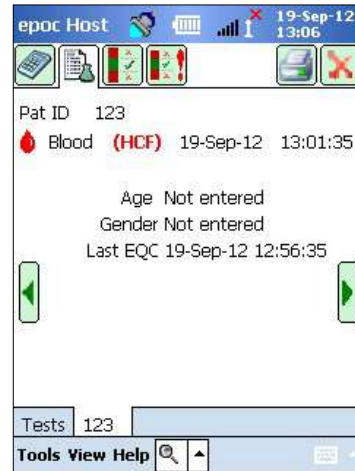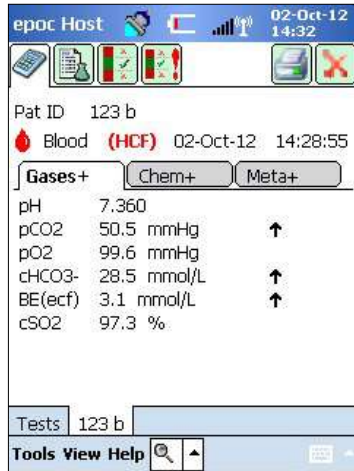
6.26 Viewing Electronic QC Mode

Tap the **Toolbar** button ![icon] at the bottom of the screen to open the Menu with four (4) options.

Select **View EQC** to display list of Electronic QC Records.

To **view** an Electronic QC record:

1. Press and hold Stylus momentarily on the Row with the desired Record.

   A new Menu Window opens.

2. Select **View this record** from the Menu.

3. Go back to the list by tapping **Electronic QC** at the bottom left corner of the screen to select another Record to view.

   Multiple Records open on separate Tabs at the bottom of the Screen.

4. Tap Tabs to move between multiple Electronic QC Records.

Refresh List by tapping the **Refresh** button ![icon] if required.

To **print** an Electronic QC Record:

1. Hold the Stylus momentarily on the Row with the desired Record.

   A new Menu Window opens.

2. Select **Print this record** from the Menu.

   (OR Print an Electronic QC Record by tapping the **Print Icon** while on the Electronic QC Record Tab).

Each Electronic QC Record is available on two (2) pages:

1. **Electronic QC Results Page** – contains Pass/Fail result flag, error codes, and other information for the Electronic QC Record.

2. **Versions Page** – contains Hardware and Software Versions for the Electronic QC Record.
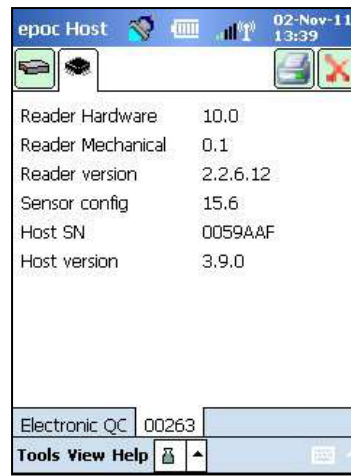
Note: Unlike Test Records, Electronic QC Records are removed from the Host after each EDM Synchronization.

6.27 Viewing Thermal QA Mode
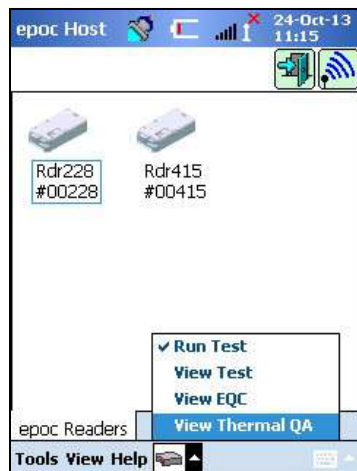
Tap the **Toolbar** button at the bottom of the screen to open the Menu with four (4) options.

Select **View Thermal QA** to display list of Thermal QA Records.
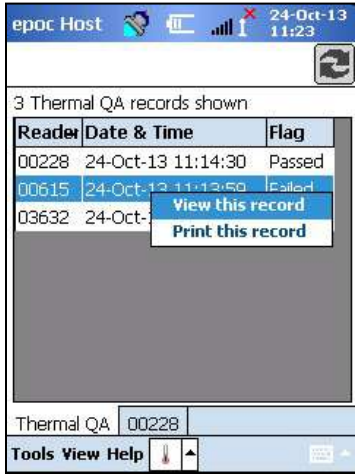
Thermal QA Records can be viewed or printed in the same way as Electronic QC Records above.

Refresh List by tapping the **Refresh** button if required.

Each Thermal QA Record is available on two (2) pages:

1. Thermal QA **Results Page** – contains Pass/Fail result flag, bottom heater temperature, top heater temperature, and other information for the Thermal QA Record.

2. **Versions Page** – contains Hardware and Software Versions for the Thermal QA Record.

Note: Unlike Test Records, Thermal QA Records are removed from the Host after each EDM Synchronization.
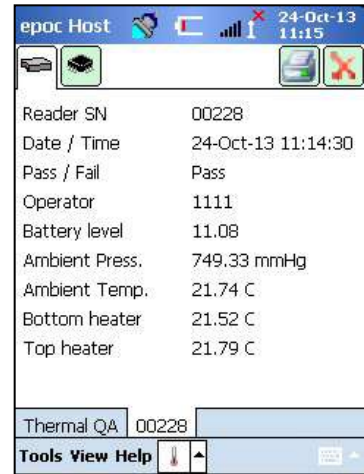
6.28 Personal Options Page

Use the **Personal Options** page to change Password.

This page is not available if using EDM. In this case, the User must change the password using EDM. Changes are effective with the next EDM synchronization.

Access the Personal Options page from the **Tools** menu. Enter **Old Password** and **New Password**. Enter the new password again in the **Verify** field. Tap the **Save** button to retain the changes.

6.29 Positive Patient ID Lookup

The real-time Positive Patient ID Lookup feature relies on Admission, Discharge and Transfer (ADT) information stored on the EDM. It can help reduce patient identification errors and automatically retrieve patient age and gender for eGFR calculations.

Note: Refer to Section 8 "epoc Enterprise Data Manager" of this manual for more details about ADT Interface.

When the Positive Patient ID Lookup feature is enabled, the Lookup icon will appear next to the Patient ID field.

When the operator scans the Patient ID from the patient's barcoded wristband, the epoc System will automatically query your data manager for ADT Information. If the Patient ID is found, the operator will be presented with a Patient ID confirmation screen containing the patient's name, date of birth, and gender.

With this information, the operator can confirm that the epoc test is being performed on the correct patient by tapping on **Use this ID** or **Scan/enter new ID** if it is incorrect.

If the Patient ID is not found, the operator has the option to continue with the scanned ID by tapping on **Use this ID** or **Scan/enter new ID**.
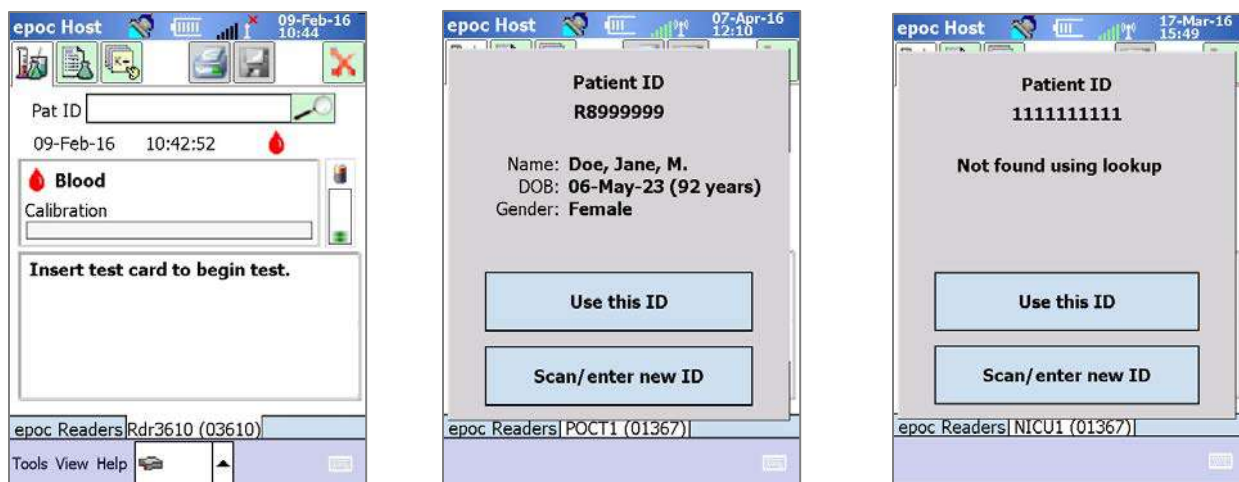
When performing Creatinine testing with the real-time Positive Patient ID Lookup feature, the operator no longer needs to manually enter patient age or gender to obtain the calculated eGFR values. The operator simply scans the patient's barcoded wristband, the epoc System will then retrieve the Patient's ADT Information from your data manager. If the operator confirms that the Patient ID is correct, this patient's age and gender will be automatically entered into the appropriate fields.

Note: The patient's age is calculated as a whole number from the date of birth obtained from the facility's ADT Feed.

Note: If the lookup does not provide the patient's date of birth, the operator can manually enter the age. If the lookup does not provide the patient's gender, the operator can manually enter the gender. See 6.23 "Age and Gender" above.

07   epoc® Host Administration

7.1 General

The Administrator Account is a special type of User Account in the epoc Host Application that allows access to customize and administer system settings. There is **only one Administrator Account**. The System Administrator requires additional training to manage critical settings not available to Operators, as this can affect the performance of the epoc System.

7.2 First Time Administrator Login

The first time, the System Administrator must log in using factory defaults for Administrator Account:

User ID: administrator

Password: administrator

Administrator should change the password after logging in for best security practices. Retain the New Password in a secure location. The Administrator cannot access the Administrator Account if the Administrator password is changed and subsequently misplaced and forgotten.

> ⚠ Contact Technical Services for a temporary password if the Administrator Password was changed and is no longer available for use.

7.3 Limitations for Use

> ⚠ The epoc Host is intended for use with the epoc Blood Analysis System. The epoc Host is not a general purpose computing device. Use only mobile computer functions described in the epoc System Manual.

> ⚠ Never install "off the shelf" software on your mobile computer without written authorization from Epocal Inc. Epocal has no control over the use of unauthorized software which may impact the operation of the epoc System.

> ⚠ The epoc System is designed and tested for use only with approved accessories and data management systems. Do not synchronize or connect the epoc System to any unapproved computing devices.

> ⚠ Wi-Fi capabilities of the epoc Host are factory disabled. Wi-Fi capabilities should be enabled and configured for use only with data managers approved for use with the epoc System or epoc compatible Printer.

> ⚠ The epoc Host supports downloading data only to data managers approved for use with the epoc System. Test results are intended to be viewed only on epoc Host screen or printed using epoc compatible Printers.

> ⚠ Exercise caution when changing settings within Administration Options. Always verify that changes made provide intended results before any patient testing.

Note: Only approved data managers like the **epoc Enterprise Data Manager (EDM)** *may be used with the epoc System. When using the epoc System with an approved data manager, epoc Host messages that reference "EDM" refer to all approved data managers.*

7.4 Administrator Access

The Operator using the epoc Host Application has limited system access and is not permitted to exit this application to access other software in the mobile computer Operating System. This ensures that the Operator is not able to change important settings in the epoc Host Application or in the Windows Mobile Operating System.

Log in to the Administrator Account to access additional settings in the epoc Host Application and in the operating system that may be changed.

As the Administrator, tap the **Tools** menu on the Toolbar and then **Exit** to access the Windows Mobile operating system.

Perform a Soft (Warm) Reset to return to the Login screen to log in as the Administrator. Refer to Appendix A "epoc Host Quick Start Guide" or Appendix B "epoc Host^2 Quick Start Guide" in the end of this manual for specific instructions on resetting the Host.

The epoc Host is factory set for optimal performance. Any changes to Software Settings or installation of unauthorized Software may adversely affect epoc System performance.

7.5 Windows Mobile Operating System

This section describes only those aspects of the operating system that are necessary for using the mobile computer as the epoc Host. The Administrator must review this information and establish appropriate settings in the epoc Host prior to releasing it for patient testing. The epoc Host comes ready to use with Windows Mobile Operating System for Pocket PC already installed.

7.5.1 Power Settings

Power and Backlight settings are overridden by the epoc Host software for optimal battery life using "Automatic logout after inactivity" epoc Host setting. Adjusting these in the operating system has no effect.

7.5.2 Regional Settings

Regional settings are to be set within the epoc Host and are described in 7.7.1 "Identification and Language Page" below.

Do not adjust regional settings within the operating system. These settings are automatically adjusted by the epoc Host software depending on language selection.

7.5.3 Wireless Settings

Bluetooth® is a short-range wireless communications technology. Devices with Bluetooth capability can exchange information over a distance of about 10 meters (30 feet) or more without a physical connection.

The epoc Host includes built-in Bluetooth technology dedicated to wireless communication with one or more epoc Readers. The epoc Host software automatically activates Bluetooth when required. In the rare event the Bluetooth radio does not appear to be functioning, a soft reset should be performed.

Wi-Fi is a longer range wireless networking communication technology used for connecting with and transferring information between epoc Host and data managers approved for use with the epoc System.

If using a data manager, epoc Host software ensures Wi-Fi is activated. However, particular Wi-Fi connection settings, including security settings, must be configured depending on the policy and the network of the Healthcare Institution.

Additional information about Wi-Fi Settings is available in Appendix A "epoc Host Quick Start Guide" or Appendix B "epoc Host[2] Quick Start Guide" in the end of this manual.

7.6   Administrator User Interface

There are a number of additional options available to configure the epoc Host.

If using a data manager, epoc Host can be configured for **EDM present?** ("Yes" or "No"). Tap **Tools, EDM Options** from the Toolbar.

If "Yes," a data manager is present, and Host Administration is performed using your data manager.

If using the epoc Enterprise Data Manager, refer to 8.29 "Configurations" in Section 8 of this manual.

All Host Administration options configured on the data manager will be transferred to each Host every time it is synchronized.

If "No," no data manager present, and Host Administration is performed using the Host by logging into the epoc Host Application as the Administrator. Use instructions that follow to configure an epoc Host with no data manager present.

7.7 Administrator Options

To access Administrator Options, tap **Tools, Admin Options** from the Toolbar.

Five (5) pages of options are available.

Navigate options using Page Tabs at the top of the screen.

Press the **Save** button after making any changes for the changes to become effective. A **Confirmation Message** appears when changes are successfully saved.

Press the **Red X** to exit Administrator Options.

A **Warning** box appears if changes were not already saved.

7.7.1 Identification and Language Page

Input the Hospital Name and desired Host Name.

Press the **Change language** button to change the language for the epoc Host. After changing the language and pressing **Save** , the epoc Host will reset to make this change effective.
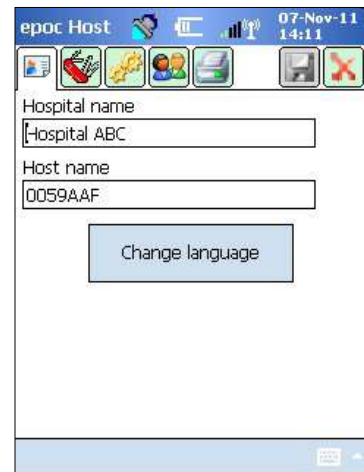
7.7.2 General Configuration Page

A. User Authentication Levels

i) Login/Run tests

Set user Login requirements by choosing an appropriate Radio Button:

ID / Password: All users require both a valid User ID and a Password to log in.

ID only: All users need only a valid User ID to log in.

None: Any User ID entered into the User ID Login field is accepted. No password is required, but the User ID field cannot be left blank.

⚠ Always require both User ID and Password for Login when in multiple user environments.

ii) View Tests

Select an appropriate Radio Button under **View Tests**. The choice must be at least the same level as the Login Authentication.

The following Table shows all possible combinations of Login / View Tests User Authentication Levels and how they impact the User.

Login	View Tests	Description
ID / Password	ID / Password	Valid User ID and Password is entered at Login allowing the User to perform Tests and to view previous Test Results.
ID only	ID / Password	Only valid User ID is entered at Login allowing the User to perform Tests. The User must log out and log in again with valid User ID and Password to view previous Test Results.
ID only	ID only	Only valid user ID is entered at Login allowing User to perform Tests and view previous Test Results.
None	ID / Password	Any User ID is entered at Login allowing User to perform Tests. User must log out and log in again with valid User ID and Password to view previous Test Results.
None	ID only	Any User ID is entered at Login allowing User to perform Tests. User must log out and log in again with only valid User ID to view previous Test Results.
None	None	Any User ID is entered at Login allowing User to perform Tests and to view previous Test Results.

B. Save Raw Data

Options to **Save Raw Test Data** enable the epoc Host Application to save additional Test Data for diagnosing a testing problem.

There are **three (3) settings** available: **Always**, **Never**, and **On failure**. The additional data saved are not available to the User or Administrator. They can only be retrieved by Epocal authorized personnel.

Saving raw data consumes significant amounts of additional memory in the Host and causes application to run slower. Only enable the saving of Raw Data when requested to do so by Epocal technical personnel.

Press the **Purge** button to remove all saved Raw Data files.

C. Allow Use of Expired Cards?

By default, this option remains unchecked. Expired Test Cards are rejected.

The epoc System checks "Use By" date on Test Card when it is inserted into the Reader. If User inserts expired Test Card, Card is rejected.

Under normal test circumstances, the following message is displayed:

<p align="center">"Expired test card. Insert new test card."</p>

Check the option to **run expired cards for training purposes only**.

When checked, the Test runs in the normal manner, but the Test Results are not displayed and not saved with the test record.

The following message is displayed briefly:

<p align="center">"Expired test card. Results will not be shown."</p>

D. Additional Wireless Options

Additional wireless options **Enable Wireless Roaming**, **Certificate Validation**, or **Enable FIPS mode?** may be available, depending on your epoc Host hardware, as well as on Wi-Fi network infrastructure in the installed environment for epoc Host network communications with your data manager.

These option settings are determined during the site implementation process.

E. Close completed tests after 15 min

Check option to automatically disconnect from epoc Reader and close a test after 15 minutes of inactivity when a successful test has been completed. This allows for automatic synchronization with your data manager if applicable. For a successful test to be completed all required data entry must be entered.

F. Allow user to reject test?
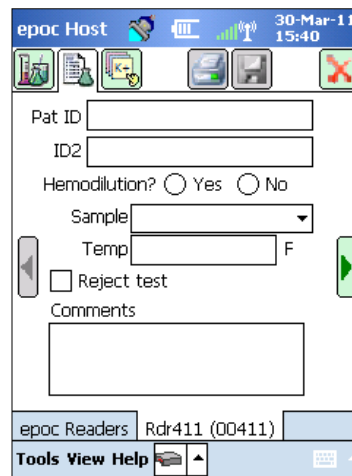
If enabled, the check box option for the user to reject a test is displayed on the **Test Information** page. The EDM will mark this test record as "Rejected" and not send it to the Lab Information System.

Administrator screen   **User screen**

7.7.3 Patient and Security Page

A. Fixed length patient ID?

Check option to set fixed length for Patient ID field of Test Record. Select field length of 1 to 23 characters from Drop-down Selector.

B. Temperature units

Set the unit of temperature measurement for use in epoc Host Application to Fahrenheit (F) or Celsius (C).

C. Automatic logout after inactivity [1-5 min]

Check this option to enable an automatic User Logout after a set period of no Host activity. Select the number of minutes before logout from the dropdown selector. If the epoc Host is operating on **battery power** without external power, it will **turn off** after logging out. This option should be used to **preserve battery power**.

D. Automatic logout after power off

If selected, Host Application automatically logs out the User when turning power "OFF" from the Power button (upper right on epoc Host).

E. Action When Closing Test

There are three (3) settings available: **None**, **Synchronize**, **Sync and log out** (one test mode).

When set to **None**, no action is taken.

When set to **Synchronize**, synchronization will take place when either

1. The Reader screen is closed with the **Red X** ;
   OR
2. The User is inactive for 15 min after the end of the test (only when the **Close completed tests after 15 min** option is enabled).

After synchronization, the User may either use **Red X** to return to the main Reader screen, or use the Logout button to log out.

When set to **Sync and log out** (one test mode), the User will only be allowed to perform one successful test. Synchronization will take place when either

1. The Reader screen is closed with the **Red X** ;
   OR
2. The User is inactive for 15 min after the end of the test (only when the **Close completed tests after 15 min** option is enabled);
   OR
3. The Operator inserts a new Test Card into the slot.

After synchronization, the User can *only* use the **Logout** button to log out (there is no **Red X** button on the screen in this case).
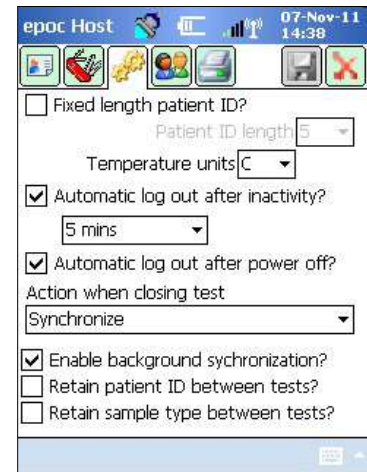
F. Enable Background Synchronization?

When enabled, the Host automatically connects to your data manager after each completed test to send all unsent Test Results.

Background synchronization does not synchronize electronic QC Tests or Host configuration settings.

G. Retain Patient ID/Sample Type between tests?

When enabled, the Host retains previously entered information. Inserting a new Test Card will automatically recall the Patient ID and Sample Type selection from the previously run test record.

7.7.4 User Accounts Page

Go to the **User Accounts** page to **add, remove,** or **modify** User Accounts when not using a data manager.

Select a user from dropdown selector to **display User Accounts** in epoc Host. Tap on a User Name to view User information including:

Name – User Name

Status - enabled or locked

Created – date User Account created

Expiration – date User Account expires

Can run QA – Yes or No

The Administrator account is not shown.

Press the **Add** Button to **add** a new user account. The Administrator is required to provide entries for all information including:

User ID – primary User Account identifier. User ID must be unique and is not case sensitive.

Name – User Name associated with User ID

Password – Login Password. Password is case sensitive.

Expiration – date User Account expires
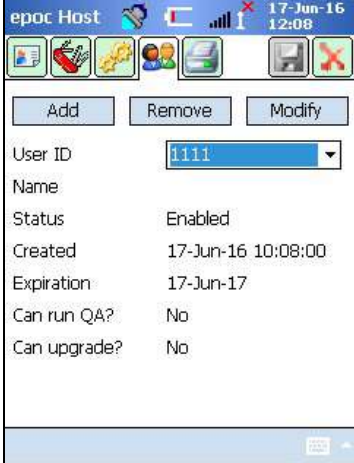
Allow user to run QA tests? – Select to enable

Allow user to upgrade Host? – Select to enable ordinary users to perform software upgrades in addition to the Administrator.

When complete, press the **Add** Button. Press the **Save** Button after adding one or more Users.

Press the **Remove** Button to **remove User**.
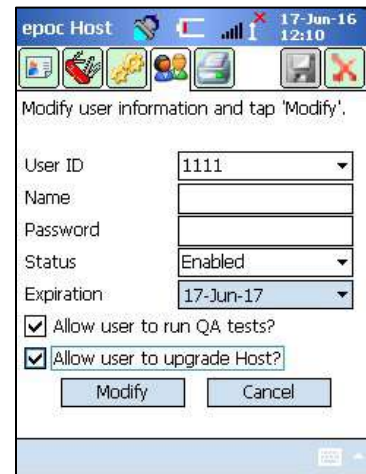
Press the **Save** Button after removing one or more Users.

Press the **Modify** Button to **change User Account**.

Press the **Save** Button [icon] after completing single or multiple changes.

Press the **Red X** [icon] to **exit User Accounts Page**.

7.7.5 Printer Set Up Page [icon]

Note: Epocal lists all Printers authorized for use with epoc Host in Section 13 "epoc Reader and Host Specifications" in this manual.

Go to the **Printer Set Up** page to **add, remove**, or **modify** Printers.

To select a printer:

Press the dropdown selector to list printers. Tap on a selected printer to view current Printer Settings.

To add a printer:

Press the **Add** button to add a new printer. The Administrator is required to provide entries for all information including:

Name - Name associated with the printer

Address – Select **Bluetooth Address** for a Bluetooth printer or enter an **IP Address** for a Wi-Fi printer. Refer to respective printer specifications to find Bluetooth Address and default IP address.

Print calculated results? – Check the check box to enable, uncheck to disable.

Print corrected results? (blood gas results corrected for patient temperature) - Check the check box to enable, uncheck to disable.
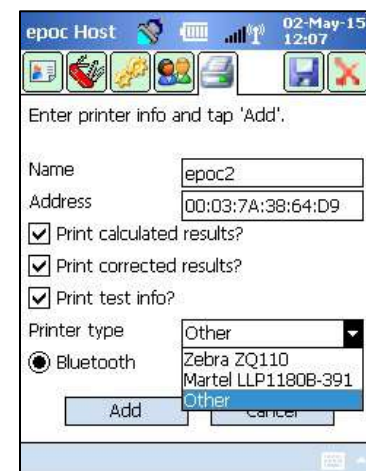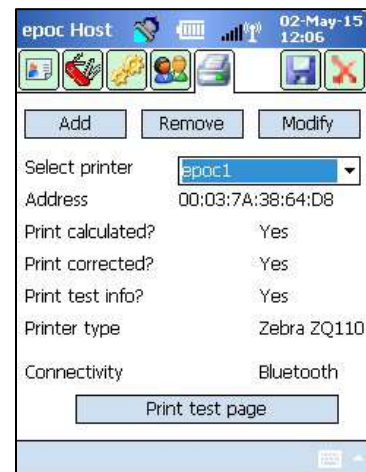
Print test info? (respiratory therapy parameters that were entered) - Check the check box to enable, uncheck to disable.

Printer Type – Select Zebra ZQ110, Martel LLP1880B-391, or Other, depending on the printer model in use.

Connectivity – Select Bluetooth or Wi-Fi by tapping the corresponding radio button.

Press the **Add** button to change Printer Settings and return to the **Printer Set Up** page.

From the **Printer Set Up** page, tap **Save** [icon].

To remove a printer:

Select a printer from the dropdown selector. Tap the **Remove** button to change Printer Settings and return to the **Printer Set Up** page**.**

From the **Printer Set Up** page, tap **Save** 💾 .

To modify a printer:

Select a printer from the dropdown selector. Press the **Modify** button to change Printer Settings and return to the **Printer Set Up** page.

From the **Printer Set Up** page, tap **Save** 💾 .

To test the connection after changing Printer Settings:

To connect to a printer, Bluetooth or IP Address of the printer must be set according to the printer specifications. Refer to the Instructions for Use included with your Printer for additional information, including information on wireless setup.

Turn the printer "ON," and then print a test page by tapping **Print test page** to confirm that the printer is connected and working.

⚠ Only Printers listed in this manual are authorized for use with epoc Host.

⚠ Printers are Information Technology (IT) Grade Devices not approved for use within Patient Vicinity. Patient vicinity is the space having surfaces that may be subject to contact by the Patient. This encloses a space no less than 6 feet (1.8 m) in all directions beyond the Patient or beyond the Bed's perimeter when applied to a Patient Room.

7.8   Barcode Options Page

Tap **Barcode Options Page** from **Tools Menu** to setup certain text entry fields to only allow certain Barcode Symbologies or automatically remove leading or trailing digits from Scanned Barcode.

Field type – Select the text entry field to which the settings are applied. Field choices include:

User ID – User ID

Password – User Password

Pat ID - applies to Patient ID ("Pat ID") for blood test

Lot # - applies to Lot Number ("Lot Num") for QA test.

ID2 – second ID field ("Id2") (blood test only)

Comments – Comment Field

Other – Use for Barcode Settings for all other possible text entry fields.

*Note: For **Patient ID**, Barcodes will be rejected if they do not meet length requirements after cropping.*
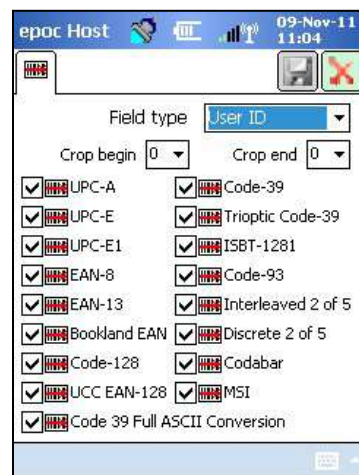
Fill the **Crop begin** and/or **Crop end** fields with the number of digits to remove from the beginning and/or end of the scanned barcode.

Note: *For Host[2], both 1D and 2D barcodes are supported, hence two tabs on the Barcode Options screen. The administrator needs to enter the crop settings for 1D and 2D barcodes separately, on their respective pages.*
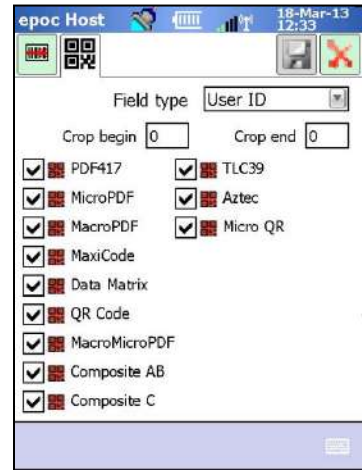
Select one or more check boxes for **Barcode Symbologies** to apply selected symbologies to a particular **Field Type**.

Always press the **Save** button after making any changes for these changes to become effective.

7.9 EDM Options Page

Use the **EDM options** page to set up connection to your data manager. Indicate "Yes" or "No" as appropriate. If "Yes," set correct **EDM Address** (IP address or server name) and **Port Number** for the EDM Server location. The IP address must be set using the XXX.XXX.XXX.XXX format, each of the four XXX numbers ranging between 0 and 255, and the port number value must be between 1 and 65535.
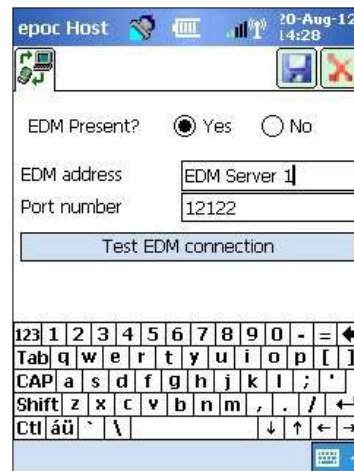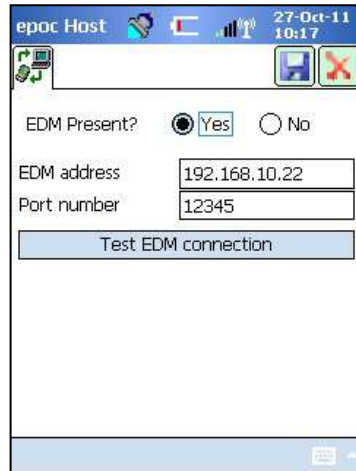
Tap the **EDM options** page from the **Tools** menu to begin.

Always press the **Save** button after making any changes for these changes to be effective.

7.10 Card Options 1

The **Card Options 1** page can be used to enable/disable individual sample types, to set the default Test List, high and low Reference and Critical Range limits for each analyte reported by Host Application, and Units of Measurement for each reported value.

The **Default Reference Ranges** are factory set in accordance with the Reference Ranges in Test Card Specifications. The **Default Critical Ranges** are factory set to values outside the reportable ranges, and this effectively disables the Default Critical Ranges. To use them, the Administrator must narrow them down to desired critical values.

Tap the **Card options 1** page from the **Tools** menu to start. Press Tabs at the top of the screen to navigate between five (5) pages of options available.

Always press the **Save** button ![save] after making any changes for these changes to become effective.

7.10.1 Sample type Selection Page

Check/uncheck boxes to **enable/disable individual sample types** in the first tab ![tab].

Press the **Save** button ![save] for these changes to become effective.

The **Require sample type selection?** option is automatically disabled when all boxes are unchecked.
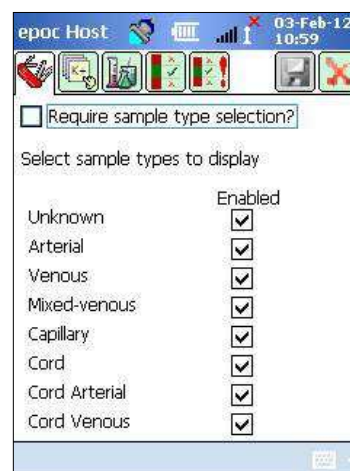
7.10.2 Test Selection Settings Page

Select the **Test Selection Settings** page tab ![tab] to **enable/disable** or **select/deselect** analytes for the test.

Click on the appropriate **Check Box** for test selection.

Enabled - Choose only those analytes that can be used for Testing. Only **Enabled** analytes are available for obtaining test results when running a test.

Selected – Choose analytes to initially default as **Selected** when running a test.

Enabled/Not Selected – The analyte is available, but must be selected during the test to provide a test result.
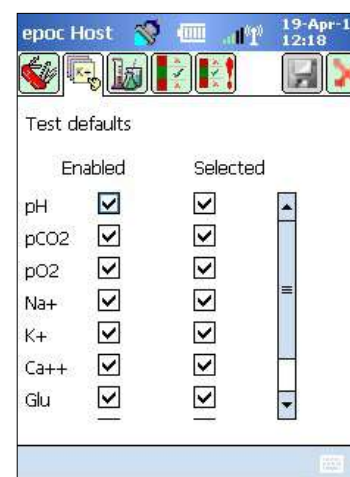
Note: *Any measured, calculated, or corrected analyte may be enabled or disabled.*

Note: *When running a QA test, all enabled analytes will be automatically selected by default.*

7.10.3 Units and Reportable Ranges Page

Select the **Units and Reportable Ranges** page tab [icon] to set the analyte units of measurement and customize reportable ranges.

Select appropriate units from the dropdown box beside the analyte. Values of the reference and critical ranges are automatically converted to correspond with the new units of measurement.

Use the onscreen keyboard and stylus to modify reportable ranges, depending on the policy of the Healthcare Institution.

Note: Custom reportable ranges may not be wider than measurement ranges. Please refer to Section 12 "BGEM Test Card Specifications" in this manual for epoc measurement ranges.

Use the scrollbars to the right and in the bottom of the screen to access all units and ranges.
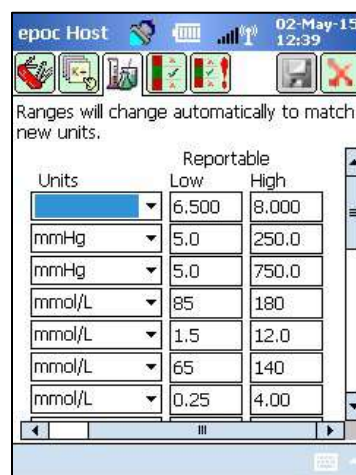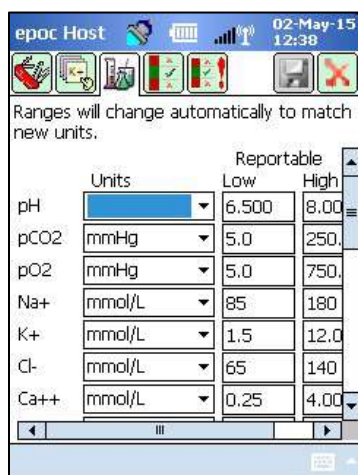
Note: Regardless of whether the ranges are customized or not, symbols ">" and "<" are used to mark the test results outside of their reportable range, when running a blood test. For example, if the reportable range is 10-75, and the test result is lower than 10, "<10" is displayed, while if the test result is greater than 75, ">75" is displayed.

7.10.4 Reference Ranges Settings Page

Select the **Reference Ranges Settings** page tab [icon] to set the reference ranges.

Select an appropriate **Sample Type** from the **Reference Range** dropdown box.

Use the **Scroll Bar** to view information not displayed on the screen.

To change a Low or High Reference Range value, tap the **Text Field** where the value is displayed. Highlight and edit values using the Text Input Keyboard [icon].
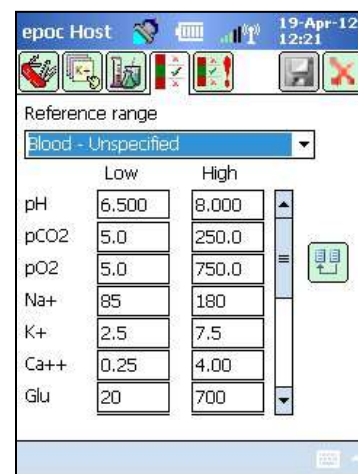
When changes are complete, tap the **Save** Button ![save] to retain these changes. If values are outside of allowable Range, a Warning Notice appears with Allowable Range Values.

Transfer values from other Sample Types using the **Transfer** button ![transfer] . Tap the Transfer button and, select a range of values to copy from the dropdown box. Tap **Copy** and **Save**.

![warning] Changing reference ranges affects ranges applied to *future* test results, and does not affect past, stored test results.

![warning] Factory set values for the reference ranges for each analyte are based on values specified for Arterial Blood Sample in BGEM Test Card Specifications.

7.10.5   Critical Ranges Settings Page

Critical Ranges are entered the same way as **Reference Ranges**. Critical Ranges values are factory set to outside the reportable ranges for each analyte. Values outside the reportable ranges do not flag as "Critical." Therefore, the User must set Critical Ranges according to internal procedures at the Healthcare Institution.

Select the Critical Ranges Settings page tab ![tab] to set **Critical Ranges**.

Select an appropriate **Sample Type** from the Critical Range dropdown Box.

Use the **Scroll Bar** to view information not displayed on the screen.

Factory Set Critical Ranges (Selected Units)			
Analyte	Low	High	Units
pH	5.500	9.000	
pCO$_2$	4.0	251.0	mmHg
pO$_2$	4.0	751.0	mmHg
Na++	84	181	mmol/L
K+	0.5	13.0	mmol/L
Cl-	64	141	mmol/L
Ca++	0.00	5.00	mmol/L
Glu	19	701	mg/dL
Lac	0.00	21.00	mmol/L
Crea	0.00	16.00	mg/dL
Hct	9	76	%
cHgb	2.3	26.0	g/dL
cHCO$_3$-	0.0	86.0	mmol/L
cTCO$_2$	0.0	86.0	mmol/L
BE(ecf)	-31.0	31.0	mmol/L
BE(b)	-31.0	31.0	mmol/L
cSO$_2$	-1.0	101.0	%
AGapK	-11	100	mmol/L
AGap	-15	96	mmol/L
eGFR, eGFR-a	1	401	mL/m/1.723m^2
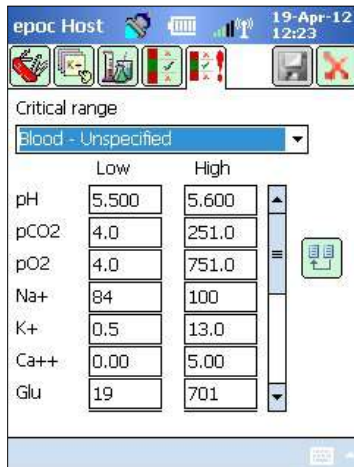
To change a Low or High Critical Range value, tap the **Text Field** where the value is displayed. Highlight and edit values using the Text Input Keyboard ![keyboard] ..

When the changes are complete, tap the **Save** button ![save] to retain these changes.

Transfer values to other Sample Types using the **Transfer** button ![transfer] . Tap the Transfer Button and select a range of values to copy from the dropdown box. Tap **Copy** and **Save**.

7.11 Card Options 2

Go to **Card Options 2** [icon] to edit test settings.

Use **Apply hemodilution** to correct **Hematocrit Results** for the amount of hemodilution in a patient sample. Choices are **Always**, **Never**, or **Force selection**, which requires User selection during the test.

Note: _Refer to 11.5.1 "Measurement Method" in Section 11 "Theory of Operation" and 12.13 "Hematocrit (Hct)" in Section 12 "BGEM Test Card Specifications" of this manual for details on Hematocrit measurement._

Select **Print ranges only if low/high?** to shorten the length of the thermal printer printouts from epoc Host. Ranges will be printed only where a result has flagged outside of its range.

Select **Print QA ranges?** to print ranges for QA tests. Deselecting this option omits these ranges from the thermal printer printouts, shortening the length of the printouts from epoc Host.

Select **Print QA info?** to include QA status at the time of the test in test results printouts.

Select **Enforce Critical Handling** to display the **Critical Actions** Doctor button when a result is outside of its critical range.

Select **Additional Documentation** to enable extra fields for recording additional test information.

When there are critical results, these fields are accessed through the red **Critical Actions** Doctor button.

When there are no critical results, these fields are accessed through the green **Additional Documentation** Clipboard button.

Select **Allow data recall on incomplete tests?** to retain all the information entered from the previous test if the previous test failed (has the "incomplete" status).
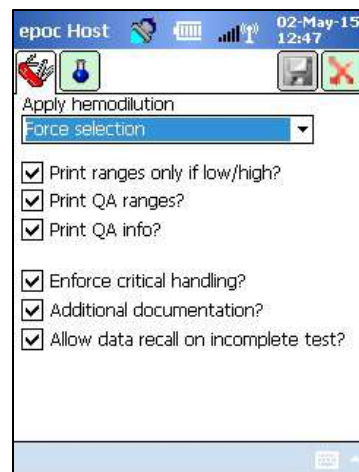
7.12 Personal Options Page

Use the **Personal Options** page to change the **Administrator Password**.

This page is not available if using a data manager. In this case, the Administrator can change the password using EDM. Changes become effective with the next EDM synchronization.

Access the Personal Options page from the **Tools** menu. Enter the **Old Password** and the **New Password**. Enter the new Password again in the **Verify** field. Press the **Save** button to retain these changes.

7.13 Software Upgrades

Note: epoc System software upgrades are required periodically. Also, epoc Host software **expires** eventually, and a software upgrade is required to continue testing. This is to assure that the epoc System is configured properly for the latest Test Cards being manufactured. Please check Product Update for a particular software revision or contact Technical Services for information regarding the expiration date of the installed software.

epoc System software is delivered via an "upgrade" file. Each upgrade file always contains 3 components: 1) epoc Host software 2) epoc Sensor Configuration 3) epoc Reader firmware. Sometimes 1, 2, or all 3 of these components are being upgraded (where unchanged components remain as in previous release).

All software upgrades are accomplished by first upgrading epoc Host, then (if applicable) epoc Reader. (The epoc Host upgrade process copies epoc Reader firmware and saves it on epoc Host for subsequent upgrading of epoc Reader).

Automatic Upgrade – The System Administrator can configure your data manager to automatically send the upgrade to epoc Host when it is synchronized, whereupon epoc Host then upgrades after the next logout.

The rest of this sub-section describes Software Upgrades when not using this Automatic Upgrade feature.

The System Administrator or ordinary user authorized to upgrade Host must be logged in to perform upgrades. **Perform upgrade option** on **Tools Menu** allows Administrator to upgrade epoc Host software by downloading new the upgrade file from EDM, from an SD Card, or from another upgraded epoc Host.

7.13.1 Perform Upgrade from EDM
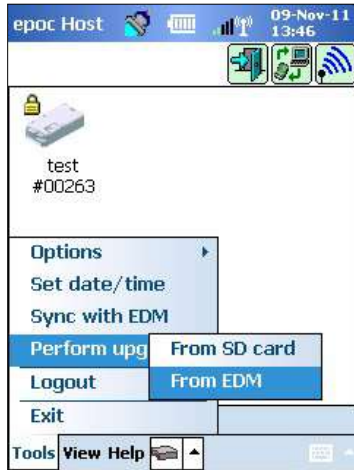
When using a data manager to upgrade, the **EDM present?** setting in the Host must be set to "Yes" and a proper upgrade file must be uploaded to EDM first.

Then select **Perform Upgrade** and **From EDM** on the **Tools** menu and follow the prompts.

Once the update is received, tap the Red X to initiate the upgrade process.   epoc Host Application then notifies the Administrator of the upgrade and immediately begins upgrading the epoc Host. When the upgrade is complete, epoc Host Application restarts and returns to the Login page.

7.13.2 Perform Upgrade from SD Card

Refer to Appendix A "epoc Host Quick Start Guide" or Appendix B "epoc Host[2] Quick Start Guide" in the end of this manual for SD Card Slot location and information on accessing the SD slot.

Insert the SD Card (containing the correct upgrade file) into the SD Slot. Select **Perform Upgrade**, then **From SD Card** on the **Tools** menu, and follow the prompts.

The upgrade process will then proceed (similarly to the **From EDM** method).

Some SD cards may not work on all mobile computers. Refer to Section 13 "epoc Reader and Host Specifications" in this manual for restrictions on SD cards that can be used with your hardware.

7.13.3 Perform Upgrade from Another Host

When upgrading from another epoc Host, the **EDM present**? setting in the Host must be set to "No," and the other epoc Host must already be upgraded.

Then select **Perform Upgrade** and **From Host** on **Tools Menu**. The epoc Host will immediately begin to discover other epoc Hosts in the vicinity via Bluetooth. As they are discovered, they will appear on the screen as shown below. Select **View**, then **List** to see full names of Hosts if required. Tap and hold the Host you wish to upgrade from and follow prompts.
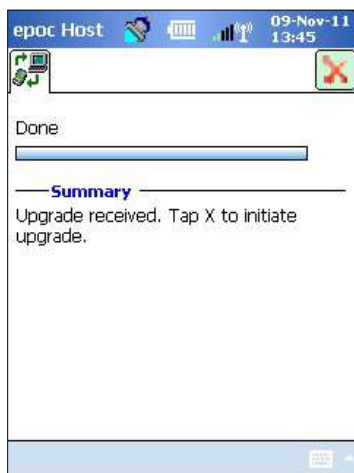
Once an update is received, tap the Red X to initiate the upgrade process. epoc Host Application notifies the Administrator of this upgrade and immediately begins upgrading the epoc Host. When the upgrade is complete, epoc Host Application restarts and returns to the Login page.

When the epoc Host upgrade is complete, the version number may be verified from the Login screen (lower right) or by tapping **Help**, then **About** in the bottom of the screen after logging in.

If the upgrade includes the epoc Reader, the epoc Host is able to upgrade Readers as described in 7.16 "Reader Configuration and Reader Software Upgrade" below.

7.13.4 Information Screen

The **About** screen can be accessed as follows:
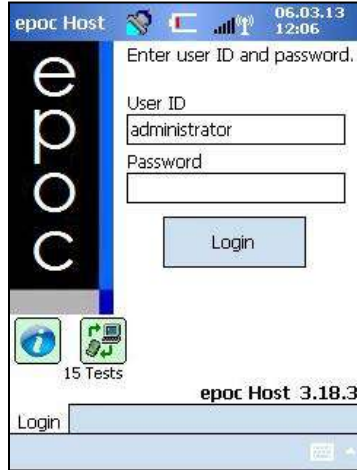
Tap on the Information icon on the Login screen

OR

When logged in, tap **Help** in the Toolbar menu, then **About.**
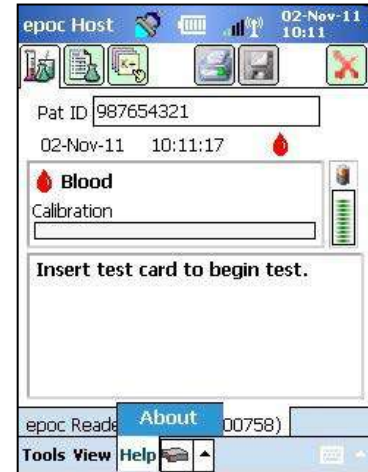
A screen with four tabs will open:
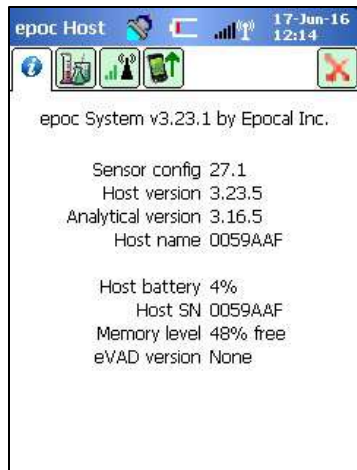
Tab 1 provides basic hardware and software information on the Host, including Sensor configuration and Host software version currently installed on the Host.

*Note: Use the Reader **Status** option to verify the firmware version currently installed on your Reader.*

Tab 2 shows how many blood tests and QA tests are stored on the Host.
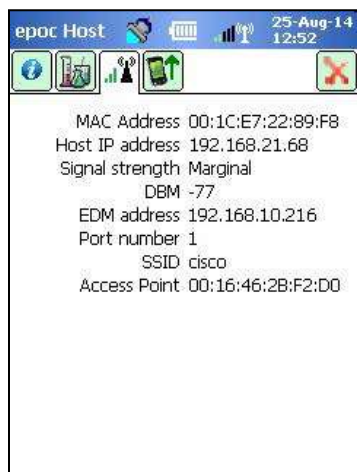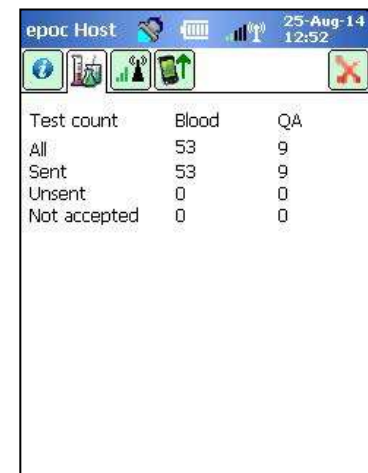
Tab 3 contains information necessary for establishing Wi-Fi and Bluetooth connections, including IP addresses for Host and EDM.

Tab 4 lists Host, Reader, and Sensor configuration versions that are available for upgrade from this Host.

Note: These are not necessarily the versions currently installed on this Host or Reader.

7.14 Set Date, Time, and Time Zone

Your data manager updates Date and Time in the epoc Host during synchronization. Any changes made on the Host will be overwritten during synchronization.

The Administrator can change Date and Time settings from the **Tools** menu by selecting **Set Date/Time**.

Use the dropdown boxes to select correct **Date** and **Time Zone**.

Use Up/Down Arrows to set correct **Time**.

Press **OK** to save changes and Exit. Press **Cancel** to ignore changes and Exit.
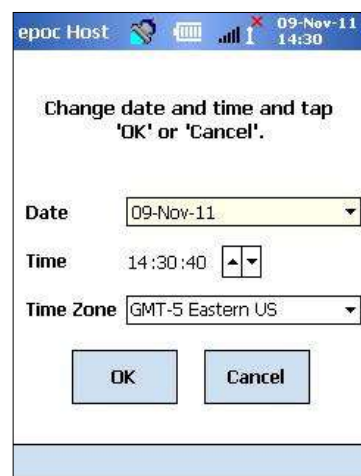
⚠ Changing Date, Time, and Time Zone directly affects Date and Time saved with each Test Record. Date and Time cannot be edited after the test is completed.

⚠ Periodically verify that epoc Host displays correct Date and Time to avoid errors with date and time recorded with Blood Tests.

⚠ Always verify the Host reports correct Time and Date after:
1. Changing to/from Daylight Savings Time.
2. Performing a Hard (Cold) Reset.

7.15 Reader Identifiers

There are three (3) Identifiers for epoc Readers:

1. Serial Number

The Serial Number is a fixed, factory set five (5) Digit Number unique to each Reader. Reader Serial Numbers are always displayeds in epoc Host software Application to identify Readers. The Reader Serial Number is permanently labeled on the Nameplate on Reader Bottom.

2. Name

The Reader Name is a custom Name identifying a Reader. It can be changed by the Administrator. The Reader Name is factory set to a default one corresponding to the Reader Serial Number. The Reader Name can be up to 17 alphanumeric characters in length, including spaces. The Administrator can establish meaningful Reader Names describing Reader locations, e.g. Department Name, Ward Name, Room Number, etc. After customizing the Reader Name, use Reader Name Labels supplied with the Reader to label Readers with new Reader Names for visual Reader identification.

3. PIN (Bluetooth)

The PIN is a Password that allows an epoc Host to connect to an epoc Reader via Bluetooth. The PIN is set in the Reader and in the Host. The Host requires a correct PIN for each Reader requiring connection. If the PIN is changed in a Reader, it is immediately changed in the Host used to change the Reader PIN. The Administrator needs to additionally update the PIN in other Hosts for them to connect to same Reader.

7.16 Reader Configuration and Reader Software Upgrade

The **Reader Configuration** function allows the Administrator to configure **Reader Name** and **Reader PIN**, and to perform **Reader Software Upgrades**.

To access Reader Configuration pages, go to the **Main Reader Screen**. Press and Hold a **discovered Reader** with the Stylus until the **Options** menu for the selected Reader appears. Tap **Configure** from the menu. The Reader Configuration Screen for the selected Reader will appear.
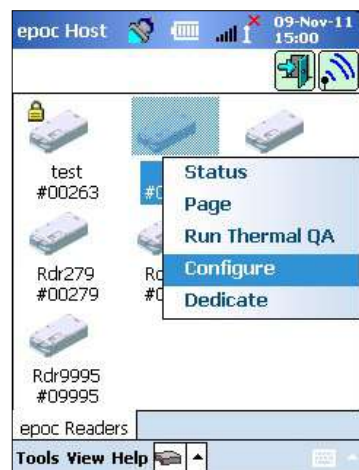
7.16.1 Reader Configuration Page

Use the **Reader Configuration** page to change the **Reader Name**.

To **change the Reader Name**:

1. Enter the desired Reader name in the **New Name** field (Upper Screen).
2. Tap **Send new PIN**.
3. Tap the Red X button to leave the Reader Configuration page. The new Reader name will now be sent to the Reader.
4. Refresh the main Reader screen by tapping the **Discovery** icon. to show the new Reader name.

Upper Screen

The Reader Configuration page is also used to set the Reader PIN, in the Reader or in the Host.

⚠ If the PIN is changed in any epoc Reader, only the Hosts with the updated PIN can connect to this Reader.

⚠ If the Reader PIN is changed and new PIN misplaced, it is impossible to retrieve the new PIN to communicate with the Reader.

⚠ Always maintain a separate Log of current Reader PIN's. If the PIN is lost, contact your Epocal distributor to arrange for the return of the Reader to reset its PIN.

To **change the Reader PIN**:

1. Enter a new PIN in the **New PIN** field (Upper Screen).
2. Tap **Send new PIN**.
3. **Tap "OK" when prompted.** The new PIN is sent to Reader. However, only the Host used to change Reader PIN is updated with this new PIN. Update other Hosts using procedure below.

To **change Reader PIN in other Hosts**:

1. Use the other Host to discover the Reader (with the changed PIN).
2. Navigate to the Reader Configuration Screen as previously described.
3. Use the **New PIN** field (Lower Screen) to enter a new PIN.
4. Tap **Change PIN**. Repeat this process for all remaining Hosts that require connecting to this Reader.
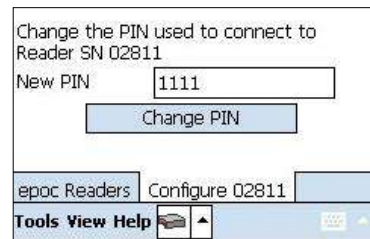
7.16.2 Reader Software Upgrade Page

The Administrator uses the **Reader Upgrade** page to update epoc Reader software.

Press the **Upgrade** button.

Upgrade is automatically executed in two (2) steps: 1. Download and 2. Upgrade. The entire process takes about four (4) minutes.

⚠️ Never interrupt the Reader upgrade process. Do not switch "OFF" Reader or Host during upgrade.
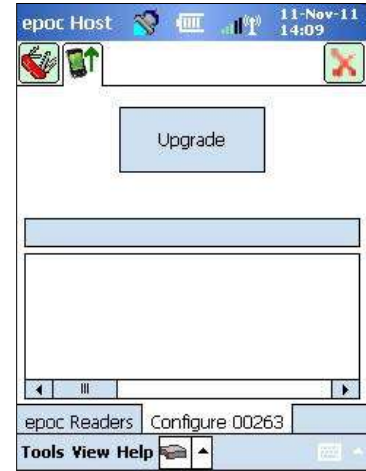
The Reader version is confirmed by tapping **Reader Status** (third tab).

7.17 Dedicating Readers

The Administrator has an option of **dedicating** specific Readers to the epoc Host.

Dedicated Readers always display on the Main Readers Screen of the epoc Host (regardless of whether or not they are turned on).

If only one Reader is dedicated to the Host, then the Host will automatically connect to this Reader to run a Blood Test after a successful Login.

Press and hold on the **Reader Icon** until the Menu appears.

Tap **Dedicate** on the Menu.

A dedicated Reader displays the **Lock Icon** 🔒 beside the Reader Icon on the Main Readers Screen.

To undedicate, follow the same steps as above. Tap **Undedicate** when the Menu appears**.**
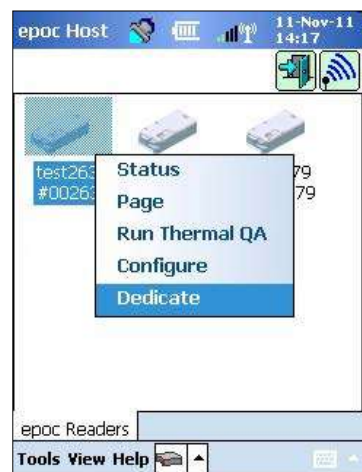
7.18 Test Record Administration

The Administrator can permanently **delete** a saved Test Result or mark a Test Result **as unsent** (to resend it to the data manager) from the epoc Host.

Tap the **Tests** button from the Toolbar to open the **Tests** menu, then navigate to **View Test**. The **Test List** page appears showing **Test Results** stored on the Host. Use the **Filter** page to narrow these results as required.

Press on the Test Result row to open the Menu.

Tap **Remove this test** to permanently delete the Test Result. Tap **Mark as unsent** to resend the Test Record to the data manager upon the next synchronization. A confirmation Window appears. When deleting a record, proceed only if sure about the record deletion.

To remove or resend multiple tests, **filter** the results first to reduce the list and then use **Select All** option to select all rows of test records currently shown in the table. Subsequent actions will apply to all displayed tests.
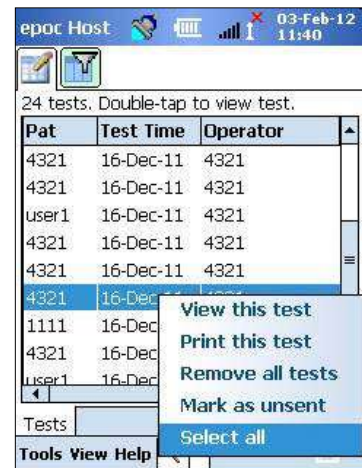
Electronic QC Records are deleted in a similar manner. First, enter the **Tests** menu, then navigate to **View EQC**. The **EQC List** page appears showing Electronic QC Records stored on the Host. The remainder of the procedure is the same as above.

> ⚠️ Deleting a saved Test Result or Electronic QC Record is permanent. Deleted records cannot be recovered after deletion.

08 | epoc® Enterprise Data Manager

8.1 Introduction

The epoc Enterprise Data Manager ("EDM") is a software package that is used with the epoc Blood Analysis System to collect Test Results and other information from multiple epoc Hosts, as well as to control and manage their usage and inventory.

The EDM is comprised of the epoc Database, epoc Enterprise Data Manager web application, and epoc Link client—server application. Additional software packages may be installed to facilitate exchange of data between the epoc Enterprise Data Management System and the Laboratory or Hospital Information Systems.

8.2 Deployment

The computing platform of the epoc Enterprise Data Manager is an Intel x86 or x64 based computer hardware in a typical LAN and Wireless networking environment. EDM components may be installed on a recommended computer hardware or PC workstation.

8.3 Hardware and Software Requirements

Hardware

Processor: 2.4 GHz or faster.

Memory: 70GB of hard disk space or higher.

Network interfaces: Ethernet network adapter.

Software

Operating System: Microsoft® Windows® Server 2008 R2, Microsoft Windows Server 2012 R2, Microsoft Windows 7, Microsoft Windows 8.1, Microsoft Windows 10.

Application Framework: Microsoft .Net Framework 2.0 SP2.

Database Server: Microsoft SQL Server 2008 R2 or 2012, Express or Standard Edition.

Web Server: Microsoft Internet Information Services (version dependent on OS).

Internet Browser: Microsoft Internet Explorer® 11, Chrome™ 48.0.x or higher, Firefox® 44.0 or higher.

8.4 Installation

All hardware and software requirements have to be met prior to installing the epoc Enterprise Data Manager. All components of the EDM are installed using EDM Installation package, configured and tested by Epocal personnel.

8.5 epoc Database

The epoc Database is installed on the Microsoft SQL Server 2008 or 2012. The relational database solution, along with properly designed data schema offers reliable, high performance data store, regular backups and controlled access.

The epoc Database stores test results, Electronic QC statistics, Usage Statistics data and Operators Statistics data. Stored data are accessible for user view via the epoc Manager Web Application.

When EDM is installed in an enterprise networked environment, IT personnel are asked to arrange for adding the epoc Database to the existing backup scheme.

8.6 epoc Link Application

Scope

epoc Link is a Software Application facilitating communication between epoc Hosts and the epoc Enterprise Data Manager. A single installation of epoc Link supports connections (identified by IP address or name, and port number) forwarding data to multiple data destinations (data sources). Installation, configuration, and ongoing support of epoc Link is performed by qualified Epocal and hospital IT personnel.

Starting epoc Link

The epoc Link is set up to start automatically when the EDM computer is started.

Connecting to the epoc Link

The connection between the epoc Host and epoc Link is made through a Wireless Access Point (WAP) of the Local Area Network (LAN), or it can be performed setting up a wireless ad-hoc (PC to PC) type of connection.

The epoc Host must be configured with the appropriate connection settings (IP address or name, and port number) of the epoc EDM PC.
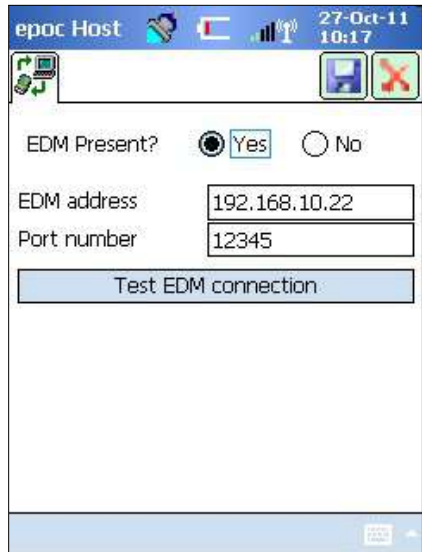
The screenshot from the epoc Host illustrates the connection settings for the epoc Enterprise Data Manager on the epoc Host (name may be substituted for IP address).

8.7 Using EDM Web Application

Scope

The epoc Enterprise Data Manager is an ASP .NET Web Application running on the Microsoft Internet Information Services (IIS) server engine. The application has direct access to the EDM Database, engineered to be a web portal to viewing and accessing test results from a client browser.

Starting epoc Enterprise Data Manager
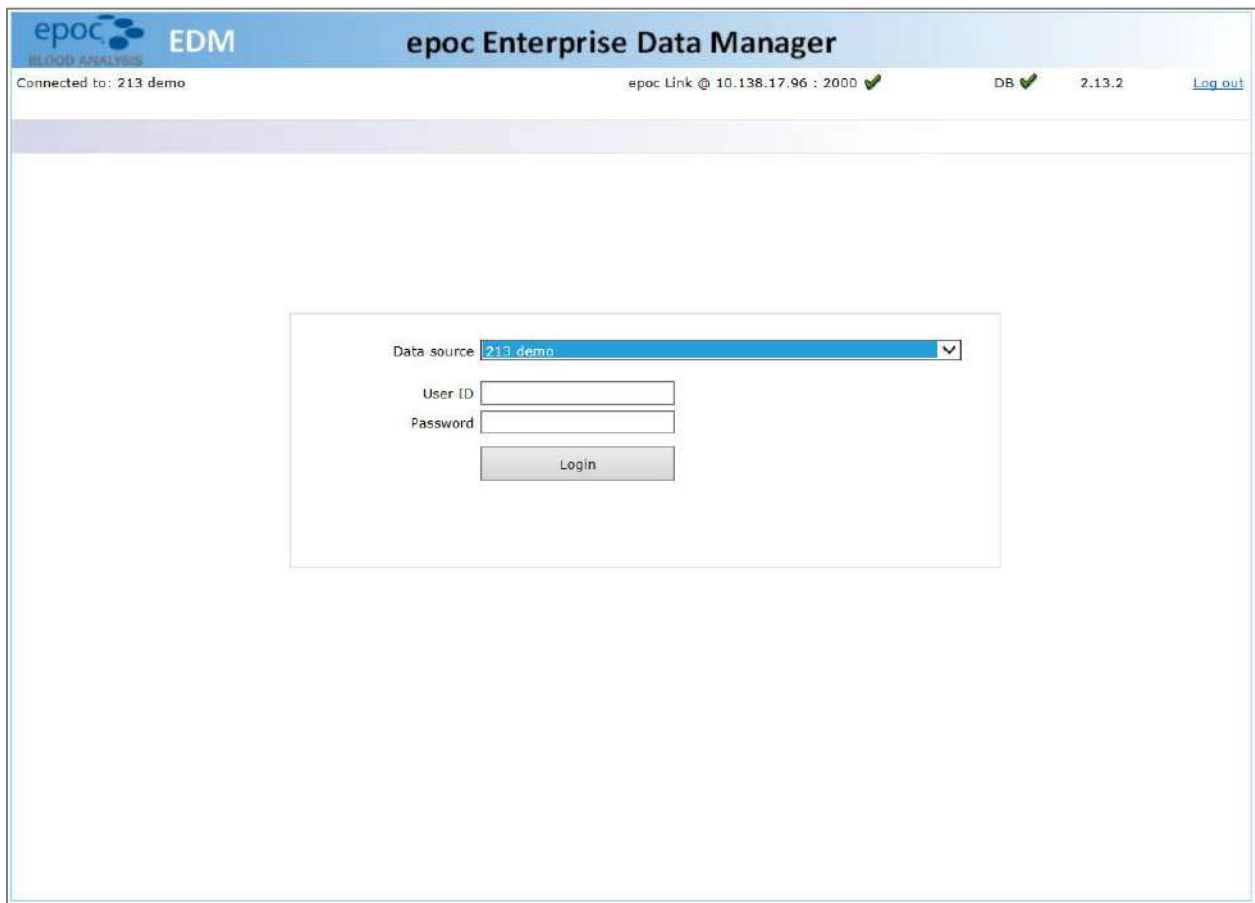
The epoc Enterprise Data Manager will start automatically when the EDM computer is started. Using a supported web browser, users can access the EDM Web Application from any LAN-connected computer by entering the EDM's web address (URL).

- http://<*EDMServerName*>/EpocManager
- http://<*EDMServerIPAddress*>/EpocManager

Note: *The System Administrator can restrict access to the EDM to specific computers.*

Login Page

Users must enter User Name and Password to login to the EDM. Contact your Epocal Distributor for your User Name and Password.

8.8 Blood Tests Page

After a successful login, the EDM will display the **Blood Tests** page. This page includes:

1. A Menu Banner near the top of the screen.
2. A Main scrollable table displaying blood tests from the last 7 days.
3. A series of buttons to save changes and print reports.
4. The test details for a selected test.

| Blood tests ▾ | QA tests ▾ | Reports ▾ | Inventory ▾ | Settings ▾ |

Blood tests (Last 7 days - 2/21)

Date/Time	Patient ID	ID2	Operator	Department	Host name	Reader name	Test Status	Critical	LIS
02-Feb-15 10:49:51	12		1111	Default	0059AAF	Rdr3610	OK	--	Not sent
02-Feb-15 10:43:29	12		1111	Default	0059AAF	Rdr3610	Incomplete	--	Not sent

Save as CSV file

Individual test details are displayed when the User selects a test from the Main Table. Single test details are displayed below the test table as shown in the following figure.

| Blood tests ▾ | QA tests ▾ | Reports ▾ | Inventory ▾ | Settings ▾ |

Blood tests (Last 7 days - 2/21)

Date/Time	Patient ID	ID2	Operator	Department	Host name	Reader name	Test Status	Critical	LIS
02-Feb-15 10:49:51	12		1111	Default	0059AAF	Rdr3610	OK	--	Not sent
02-Feb-15 10:43:29	12		1111	Default	0059AAF	Rdr3610	Incomplete	--	Not sent

Save as CSV file

Save changes | Cancel changes | Printable report | Send to LIS

Results | Equipment | QC status | CV status | RT parameters | Patient history | Test change log

Test record details

Test date/time	02-Feb-15 10:49:51
Patient ID	12
ID2	
Comments	
Operator name	1111
Operator ID	1111
Department	Default
Test Status	OK
LIS message	
Reject test	○ Yes ● No
Age	35
Patient gender	Female
Patient temperature	38.9 C
Sample type	Arterial
Hemodilution	Yes

Test results

Analyte	Result	Reference range	Critical range	Reportable range	Status
pH	7.794	7.350 - 7.450	5.500 - 9.000	6.500 - 8.000	High
pCO2	8.0 mmHg	35.0 - 48.0	4.0 - 251.0	5.0 - 250.0	Low
pO2	190.4 mmHg	83.0 - 108.0	4.0 - 751.0	5.0 - 750.0	High
Na+	139 mmol/L	138 - 146	84 - 181	85 - 180	
K+	3.8 mmol/L	3.5 - 4.5	0.5 - 13.0	1.5 - 12.0	
Ca++	1.01 mmol/L	1.15 - 1.33	0.00 - 5.00	0.25 - 4.00	Low
Glu	74 mg/dL	74 - 100	19 - 701	20 - 700	
Lac	2.42 mmol/L	0.56 - 1.39	0.00 - 21.00	0.30 - 20.00	High
cHCO3-	12.3 mmol/L	21.0 - 28.0	0.0 - 86.0	1.0 - 85.0	Low
cTCO2	12.5 mmol/L	22.0 - 29.0	0.0 - 86.0	1.0 - 85.0	Low
BE(ecf)	-6.2 mmol/L	-2.0 - 3.0	-31.0 - 31.0	-30.0 - 30.0	Low
cSO2	99.9 %	94.0 - 98.0	-1.0 - 101.0	0.0 - 100.0	High
pH(T)	7.761	7.350 - 7.450	5.500 - 9.000	6.500 - 8.000	High
pCO2(T)	8.7 mmHg	35.0 - 48.0	4.0 - 251.0	5.0 - 250.0	Low
pO2(T)	200.7 mmHg	83.0 - 108.0	4.0 - 751.0	5.0 - 750.0	High

Editable fields on the **Results** tab can be edited within the test record by typing in the information and pressing the **Save Changes** button. Every change to a test record is logged under the **Test change log** tab.

The **Equipment** tab provides information about the specific epoc Host, epoc Reader, and epoc Test card used to generate the selected record including serial numbers, software versions, card lot information and Quality Assurance information.

epoc Host		epoc Reader		Test card	
Host name	MED MALL CT	Reader name	Rdr8085	Card lot	06-15347-10
Host SN	14102521401207	Reader SN	08085	Card barcode	027911
Host SW version	3.22.6	Reader SW version	2.2.11.3	Card expiry date	29-May-2016
Sensor config	26.2	Ambient pressure	745.7 mmHg		
eVAD version	epoc16029.eVAD	Ambient temperature	73.8 F		
		Last EQC	15-Mar-2016 11:31		
		Thermal QA expiry			
		QC expiry			
		CV expiry			
		QA Schedule state	Schedule disabled		

The **QC Status** and **CV Status** tabs provide information about the quality assurance test results status at the time of the test. Green indicates Pass and red with "*" indicates Fail. Refer to Appendix E "User Guide: Enhanced QA Features for the epoc System" in the end of this manual for details.

Quality assurance status

Level	Date/Time	Results							
L1	13-Jul-2015, 14:08:47	pH*	pCO2*	pO2*	Na+*	K+*	Ca++*	Glu*	Lac*
L3	13-Jul-2015, 15:58:25	pH	pCO2	pO2	Na+	K+	Ca++	Glu	Lac

Users may review multiple test results for the same patient by opening the **Patient history** tab. The **Patient history** tab will display the last five results for the patient selected. The patient history is can be saved as a PDF file by clicking **Printable Report** or exported to **CSV**.

Date	pH	pCO2	pO2	pH(T)	pCO2(T)	pO2(T)	Na+
13-Jul-15 17:16:51	7.547 ↑	23.3 mmHg ↓	192.9 mmHg ↑				162 mmol/L
13-Jul-15 17:06:20	7.496 ↑	23.8 mmHg ↓	194.7 mmHg ↑	7.468 ↑	25.8 mmHg ↓	204.3 mmHg ↑	163 mmol/L
09-Jan-15 07:45:25	7.575 ↑	9.9 mmHg ↓	180.6 mmHg ↑				108 mmol/L
02-Feb-15 10:49:51	7.794 ↑	8.0 mmHg ↓	190.4 mmHg ↑	7.761 ↑	8.7 mmHg ↓	200.7 mmHg ↑	139 mmol/L
01-Feb-15 17:22:35	7.894 ↑	7.3 mmHg ↓	210.0 mmHg ↑				144 mmol/L

8.9 Blood Tests: Filtering Results

Use one or more of the following methods to filter Test Results in the Main Table:

1. Click on any of the column headers of the Table to order records based on the column content.

2. Click on same column header to change the order of results to ascending or descending.

Blood and QA tests can be filtered by the Date and Time these tests were performed. Recent results can be filtered using such menu items as: **Today**, **Last 7 days**, **Last 30 days**.

The EDM allows for advanced filtering: Users can select or enter a value from the filter type values existing in the database to narrow displayed Test Results to those with only selected attributes.

Blood tests (Custom dates - 18/21)

Select filter type ...					From 01-Feb-15		To 01-Feb-16		Refresh
Patient ID									
Operator									
Department		ID2	Operator	Department	Host name	Reader name	Test Status	Critical	LIS
Host name			1111	Default	0059AAF	Rdr3610	Incomplete	--	Not sent
Host SN			1111	Default	0059AAF	Rdr3610	Incomplete	--	Not sent
Reader name			1111	Default	0059AAF	Rdr3610	OK	--	Not sent
Reader SN			1111	Default	0059AAF	Rdr3610	OK	--	Not sent
Status			1111	Default	0059AAF	Rdr3610	Incomplete	--	Not sent
Critical			1111	Default	0059AAF	Rdr3610	Incomplete	--	Not sent
LIS			1111	Default	0059B53	Rdr3610	iQC	--	Not sent
ID2			1111	Default	0059B53	Rdr3610	OK	--	Not sent
Site									
02-Apr-15 13:32:19	123		1111	Default	0059B53	Rdr3610	OK	--	Not sent
02-Feb-15 10:23:18			1111	Default	0059AAF	Rdr3610	Incomplete	--	Not sent
01-Feb-15 17:22:35	12		1111	Default	0059AAF	Rdr3610	OK	--	Not sent

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8.10 Blood Tests: Printing Results

Press the **Printable Report** button above the test record details to display a printable view.

				Save as CSV file
Save changes	Cancel changes	Printable report	Send to LIS	

Results	Equipment	QC status	CV status	RT parameters	Patient history	Test change log

Test record details		**Test results**					
Test date/time	02-Feb-15 10:49:51	**Analyte**	**Result**	**Reference range**	**Critical range**	**Reportable range**	**Status**
Patient ID	12	pH	7.794	7.350 - 7.450	5.500 - 9.000	6.500 - 8.000	High
ID2		pCO2	8.0 mmHg	35.0 - 48.0	4.0 - 251.0	5.0 - 250.0	Low
Comments		pO2	190.4 mmHg	83.0 - 108.0	4.0 - 751.0	5.0 - 750.0	High
		Na+	139 mmol/L	138 - 146	84 - 181	85 - 180	

A PDF file with this test record is generated. The file may be opened or saved on disk for subsequent printing. Select **File**, then **Print** from the Adobe Top Menu or right click over the report and select **Print** from the Context Menu. See a sample test record below.

Test record (BGEM Blood)

epoc

Test date/time
02-Feb-15 10:49:51

Test record details		Equipment		RT parameters	
Patient ID	12	Host name	0059AAF	Allen's test	Positive
ID2		Host SN	0059AAF	Delivery system	Adult Vent
Operator name	1111	Host SW version	3.21.9		
Operator ID	1111	Sensor config	25.3	Draw site	Art Line
Department	Default	eVAD version	epoc15142.eVAD		
Test Status	OK	Reader name	Rdr3610JH	ET	
Reject test	No	Reader SN	03610	FIO2	
Age	35	Reader SW version	2.2.10.1	IT	
Patient gender	Female	Ambient pressure	756.9 mmHg	MAP	
Patient temperature	38.9 C	Ambient temperature	25.2 C	Mode	AC
Sample type	Arterial	Last EQC	02-Feb-2015 10:42	PEEP	
Hemodilution	Yes	Thermal QA expiry		PIP	
Critical action	Not entered	QC expiry		PS	
Critical notify		CV expiry		RQ	
Notify date		QA Schedule state		RR	
Read back	No	Card lot	07-14266-00	TR	
Patient location		Card barcode	032296	VT	
Collected by		Card expiry date	10-Mar-15		
Collection date					
Ordering physician					
Order date					

Comments

LIS message

Analyte	Result		Reference range	Critical range	Reportable range	Status
pH	7.794		7.350 - 7.450	5.500 - 9.000	6.500 - 8.000	High
pCO2	8.0	mmHg	35.0 - 48.0	4.0 - 251.0	5.0 - 250.0	Low
pO2	190.4	mmHg	83.0 - 108.0	4.0 - 751.0	5.0 - 750.0	High
Na+	139	mmol/L	138 - 146	84 - 181	85 - 180	
K+	3.8	mmol/L	3.5 - 4.5	0.5 - 13.0	1.5 - 12.0	
Ca++	1.01	mmol/L	1.15 - 1.33	0.00 - 5.00	0.25 - 4.00	Low
Glu	74	mg/dL	74 - 100	19 - 701	20 - 700	
Lac	2.42	mmol/L	0.56 - 1.39	0.00 - 21.00	0.30 - 20.00	High
cHCO3-	12.3	mmol/L	21.0 - 28.0	0.0 - 86.0	1.0 - 85.0	Low
cTCO2	12.5	mmol/L	22.0 - 29.0	0.0 - 86.0	1.0 - 85.0	Low
BE(ecf)	-6.2	mmol/L	-2.0 - 3.0	-31.0 - 31.0	-30.0 - 30.0	Low
cSO2	99.9	%	94.0 - 98.0	-1.0 - 101.0	0.0 - 100.0	High
pH(T)	7.761		7.350 - 7.450	5.500 - 9.000	6.500 - 8.000	High
pCO2(T)	8.7	mmHg	35.0 - 48.0	4.0 - 251.0	5.0 - 250.0	Low
pO2(T)	200.7	mmHg	83.0 - 108.0	4.0 - 751.0	5.0 - 750.0	High

11-Apr-2016 12:50　　　　　2.13　　　　　Page 1 of 1

EDM users can take advantage of a **Test Record Auto-Print** feature. When this feature is configured and enabled, test records received by the EDM will be automatically printed from the EDM using the pre-selected printer. The format of the printouts will be similar to the one used when manually printing records from the EDM. The test record auto-print feature can be configured on a per-department basis. Refer to 8.28 "Departments" below for details.

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8.11 Blood Tests: Exporting List of Tests to CSV File

EDM users can export Test Results to a CSV (Comma Separated Values) file. EDM offers this feature on **Blood Tests** page, through the **Save as CSV file** button. All Tests from the Main Tests Table are exported to a .csv file.

Users can open the file, inspect, and print it. The **Save** button opens a Windows File Save Dialog. The User may choose a desired location to save the file on the local hard drive.

The file is downloaded from the server to the local computer. The Browser notifies the user when download is complete.

8.12 QA Tests

The **QA tests** page displays Quality Assurance test records. From the Menu banner, select **QA tests** to view this page. Individual QA test details are displayed when the User selects a test from the Main Table. Single QA test details are displayed below the test table as shown in the following figure.

QA test records are arranged with tabs for: **Results, Equipment,** and **Test change log**. Test results are displayed under the **Results** tab.

*Note: If eVADs are used, test results will include a **Status** column indicating Pass or Fail results. The eVAD version will also be indicated. Refer to Appendix E "User Guide: Enhanced QA Features for the epoc System" in the end of this manual for details about obtaining and using eVADs.*

14-Jul-15 13:00:54	CV1:183-1-B525	Quality control	1111	Default	0059AAF	Rdr3610	iQC	Fail	Not sent
13-Jul-15 16:12:12	L3:179-3-B429	Calibration verification	1111	Julia	0059AAF	Rdr3610	OK	Pass	Not sent
13-Jul-15 15:58:25	L3:179-3-B429	Quality control	1111	Default	0059AAF	Rdr3610	OK	Pass	Not sent
13-Jul-15 15:16:55	CV1:183-1-B428	Calibration verification	1111	Default	0059AAF	Rdr3610	OK	Fail	Not sent

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Save as CSV file

Save changes | Cancel changes | Printable report | Send to LIS

Results | Equipment | Test change log

Test record details		**Test results**			
		Analyte	**Result**	**Reference range**	**Status**
Test date/time	13-Jul-15 16:12:12	pH	7.625	7.536 - 7.656	Pass
Lot ID	L3:179-3-B429	pCO2	20.7 mmHg	17.5 - 27.5	Pass
QA test type	Calibration verification	pO2	190.0 mmHg	154.5 - 209.1	Pass
Comments		Na+	163 mmol/L	158 - 172	Pass
		K+	6.1 mmol/L	5.6 - 6.8	Pass
		Ca++	0.63 mmol/L	0.58 - 0.72	Pass
Operator name		Glu	262 mg/dL	203 - 317	Pass
Operator ID	1111	Lac	6.62 mmol/L	4.73 - 7.47	Pass
Department	Julia	cHCO3-	21.5 mmol/L		
Test Status	OK	cTCO2	22.2 mmol/L		
Fluid lot	L3:179-3-B429	BE(ecf)	0.4 mmol/L		
Fluid ref	179.003.010	cSO2	99.8 %		
Fluid type	L3	A	124.4 mmHg		
Fluid expiry	31-Jul-15	A-a	-65.6 mmHg		
eVAD version	epoc15188.eVAD	a/A	1.5 %		
QA status	Pass				

8.13 Reports: Electronic QC

Electronic Quality Control is performed in each epoc Reader before each Test is performed. Access these Electronic QC Records from the **Top Menu** by selecting **Reports**, then **Electronic QC**.

Below is an example of Electronic QC data: these data can be printed by first generating a **Printable Report** or exported to CSV using the **Save as CSV file** button (same as printing or exporting Blood Test records).

Blood tests ▾ | QA tests ▾ | **Reports ◆** | Inventory ▾ | Settings ▾

Reports - Electronic QC (La[Electronic QC)
  Thermal QA
  Usage statistics

Selected Reader: All ⌄   From 05-Apr-16   To 11-Apr-16   Refresh

Reader SN	User ID	Date/Time	Sensor config	Host SW version	Reader firmware	Reader HW version	Ambient temperature	Ambient pressure	Battery	Result	Error Code
03610	1111	08-Apr-2016 14:51	26.2	3.22.4	2.2.10.3	17.0 16.10	78.14 F	746.46 mmHg	54.92	Pass	0

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Printable report | Save as CSV file

8.14 Reports: Thermal QA

Thermal Quality Assurance results include details of the thermal QA tests performed on epoc Readers. They may be accessed by selecting **Reports**, then **Thermal QA**.

8.15 Reports: Usage Statistics

The **Usage Statistics** page offers reports that can be viewed according to different system elements: epoc Reader, epoc Host, epoc Card Lot, and by the Operator. Access the Usage Statistics page from the Top Menu by selecting **Reports**, then **Usage Statistics**.

These reports include the following information:

1. The total number of Test Cards used.

2. Percentage of successful test runs.

3. Percentage of unsuccessful test runs due to iQC failures.

4. Percentage of unsuccessful test runs due to stopped or incomplete Tests.

5. Additional information such as date and time of most recent test run, date and time of the most recent epoc Reader EQC run and result, date and time of last epoc Host upload, and date and time of the last test performed by the operator.

Select the appropriate button at the bottom of the page to create views for different system elements.

Data may be filtered by **Date**, **Blood Tests** only, **QA Tests** only, and by **All Tests**. Reports may be generated by selecting the **Printable Report** or **Save as CSV file** button at the bottom of the page.

8.16 Reports: Patients List (ADT)

The option of viewing Patients Demographics is enabled via **EDM Settings** page.

When **Show patients list (ADT)** is checked, the menu item **Patients list (ADT)** becomes available under the **Reports** menu. This page contains all available patient demographics information obtained from an optional ADT feed.

Note: *Availability of patient demographics information in* **Patients list (ADT)** *requires a compatible ADT interface.*

8.17 Inventory: Hosts

Inventory contains information about the inventory of Hosts, Readers, card lots, and printers.

Hosts inventory allows users to review all epoc Host devices available in the EDM database.

For each individual epoc Host, the Host Inventory page is arranged with tabs for: **Details** and **Events**.

The **Details** tab contains hardware and software information for the selected epoc Host. Users can change the device name and assign the device to a department (also available from the **Departments** page) by entering changes in the bottom left section and clicking **Update**. Also, users can add comments by typing them in the white **Comments** box and clicking **Update**.

The **Events** tab contains historical logs of various activities associated with the selected epoc Host, such as configuration changes, software updates, changes to settings, etc. Both the list of devices and the history of each device can be saved as a PDF file by clicking **Printable Report,** or exported to **CSV**.

8.18 Inventory: Readers

Readers inventory is arranged with tabs for: **Details**, **QC status**†, **CV status**†, and **Events.** It allows users to review details of all epoc Readers available in EDM database, along with their history.

The **Details** tab contains hardware and software information for the selected epoc Reader. Also, the user can add comments by typing them in the white **Comments** box and clicking Update. **QC Expiry**† and **CV Expiry**† lines under the **Details** tab provide information about quality control and calibration verification results for the epoc Reader.

†Refer to Appendix E "User Guide: Enhanced QA Features for the epoc System" in the end of this manual for details.

The **QC status**† and **CV status**† tabs display the history of quality control and calibration verification performed on the epoc Reader based on the QA Schedule configuration.

† *Refer to Appendix E "User Guide: Enhanced QA Features for the epoc System" in the end of this manual for details.*

Reader name	Reader SN	Reader firmware	Reader HW version	Last EQC	EQC result	Last Thermal QA	Thermal QA result	QC expiry	CV expiry
Rdr3610	03610	2.2.10.1	17.0 16.10	08-Apr-2016 14:51	Pass	27-Jan-2016 10:38	Fail		
	00263	2.2.6.12	10.0 8.0			10-May-2015 12:46	Pass		
Rdr228	00228	2.2.9.3	10.0 8.7	02-Dec-2014 12:25	Pass				

Inventory - Readers (5/5) — Used within past 3 months

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[Printable report]   [Save as CSV file]

Details | QC status | CV status | Events

Reader name	Rdr3610
Reader SN	03610
Reader firmware	2.2.10.1
Reader HW version	17.0 16.10
Last EQC	08-Apr-2016 14:51
EQC result	Pass
Last Thermal QA	27-Jan-2016 10:38
Thermal QA result	Fail
QC expiry	
CV expiry	

Comments

[Update]

The **Events** tab contains historical logs of various activities associated with the selected epoc Reader, such as configuration changes, software updates, changes to settings, etc.

The list of epoc Readers and the history of each reader can be saved as a PDF file by clicking **Printable Report**, or exported to CSV.

8.19 Inventory: Card Lots

Card lots inventory allows users to review existing test card lots information. For users who wish to track when a lot was received and the remaining numbers of cards in each lot, user-editable fields are provided. To open the details window below the list, click on row with the card lot. The summary of card lot information, as displayed in the table, can be saved as a **PDF** or **CSV** file. Also, users can add comments by typing them in the white **Comments** box and clicking **Update**.

Note: *The provided comment field can be used to document Quality Assurance procedures performed on a lot of test cards.*

8.20 Inventory: Printers

Available mobile printers can be managed by accessing **Inventory**, then Printers. Users can add/modify printers, as well as assign individual printers to departments.

Note: *Printers can also be assigned to departments on the* **Departments** *page.*

For **Printer type**, three options are available from the dropdown menu: Zebra ZQ110, Martel LLP1880B-391, or Other. Select one depending on the printer model in use.

The summary of printer information, as displayed in the table, can be saved as a **PDF** or **CSV** file.

8.21 Users Page

The **Users** page allows making additions and modifications to user accounts for the epoc Host and EDM. The Users page can be accessed from the Top Menu by selecting **Settings,** then **User settings,** then **Users**.

The Users page:

To add a new user, check appropriate Group name(s) corresponding to the user's permissions for various tasks. Type the appropriate information for User ID, User name, Password, Confirm password, Account Status, and Account Expiry, and select **Allow QA tests**, **Allow user to upgrade Host?** for users that are members of the Host Operators group. More than one Group name may be checked.

Groups may be customized using the **User Settings**, **Groups** page (see next section).

The User ID and password will be used for Login for both the epoc Host and the EDM. When all information is entered, press the **Add** button. When the new user is created, they appear in the table on the left.

To modify a user account, select the user from the table on the left. The user's information will appear in the appropriate locations, the **Save** button becomes enabled, and the **Add** button becomes disabled.

After making changes, modify the user account by pressing **Save**.

Press **Cancel** to exit the modify mode and return to the add mode.

The table on the right displays the selected user's permissions.

The dropdown labeled **Group** allows for filtering by a selected group. The selected group (or All) may be exported to CSV format by pressing the **Save as CSV file** button.

The field labeled **User ID/Name** allows for searching for user accounts. Type in the user name or part thereof and press **Search**. The search results will include all matches found in all groups.

User ID	User name	Account status
1111		Enabled
1122	1122	Enabled

User ID/Name 11   Search   2/4

Account expiries for multiple users can be changed at the same time by highlighting multiple user, selecting new expiry and pressing **Save**.

A user account can also be deleted if, and only if, there are no test records associated with the User ID assigned to this user account.

8.22 Groups Page

The **Groups** page allows enabling of permissions for specific tasks and assigning them to a group. A user is assigned to a group to provide them with these group permissions.

Access the **Groups** page from the Top Menu. Select **Settings**, then **User settings,** and then **Groups**.
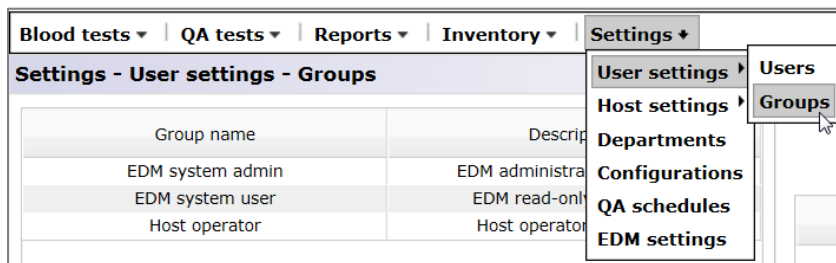
Groups page:

Type in the **Group Name** and **Description** to add a new group. Check applicable task names for the group. When finished, press the **Add** button. Once the group is created, the group name and description appear in the table on the left side of the page.

Select a group from the table to delete or modify the group. The group name and description will appear in the appropriate locations on the right side of the page, together with applicable task names checked. The **Delete** and **Save** buttons are now enabled. The **Add** button is now disabled. A group is deleted by pressing the **Delete** button. After making changes, press the **Save** button to keep changes.

Press the **Cancel** button to exit the **Delete or Modify** mode and return to the **Add** mode.

The following EDM tasks can be enabled to assign specific permissions:

Create, modify, delete user group	Edit critical handling fields	View analyte units
View groups	Save tests report (export)	Edit analyte units
Create, modify user account	View printable test record	View software upgrade files list
View accounts	Edit, resend accepted tests	Upload software upgrade files
Modify site settings	View QA tests	View Host configuration
View site settings	Edit QA lot ID	Edit Host configuration
View blood tests	Edit QA ID2	View EQC records
Edit Patient ID	Edit QA comments	Print, export EQC reports
Edit ID2	View analyte ranges	View statistics
Edit comments	Edit analyte ranges	Print, export usage statistics
View Thermal QA	View patients list	Print, export inventory reports
Print, export Thermal QA reports	View inventory	Edit inventory

8.23 Host Settings

Manage epoc Host configurations on the **Host settings** pages. There are separate pages for setting Units and Ranges and loading Software updates and eVADs†. Once configured, these settings are automatically sent to the epoc Host each time synchronization occurs.

†*Refer to Appendix E "User Guide: Enhanced QA Features for the epoc System" in the end of this manual for details about obtaining and using eVADs.*

The **Host Settings** pages are accessed from the Top Menu. Select **Settings**, then **Host settings**, and then **Units**, **Ranges**, **Software update**, or eVAD update.
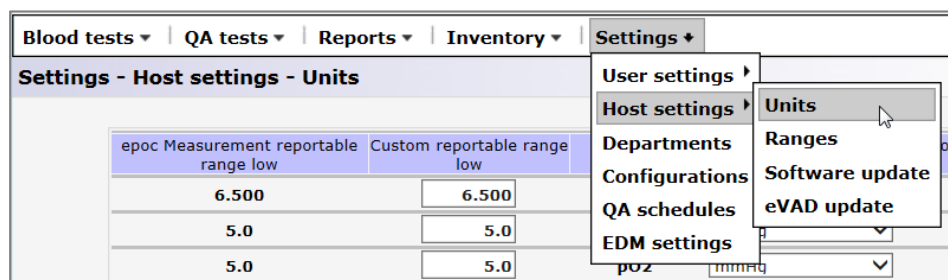
8.24 Host Settings: Units

To modify the units of measurement, select the required **Units** from the dropdown list and then press the **Save Changes** button. All the range values are now displayed using the new units.

Some health care institutions may need to customize reportable ranges. Custom reportable ranges may not be wider than epoc Measurement Ranges. The low and high values for custom reportable ranges are displayed next to each analyte.

Settings - Host settings - Units

epoc Measurement reportable range low	Custom reportable range low	Analyte	Unit	Custom reportable range high	epoc Measurement reportable range high
6.500	6.500	pH	None	8.000	8.000
5.0	6.0	pCO2	mmHg	250.0	250.0
5.0	4.0	pO2	mmHg	750.0	750.0
85	85	Na+	mmol/L	180	180
1.5	1.5	K+	mmol/L	12.0	12.0
65	65	Cl-	mmol/L	140	140
0.25	0.25	Ca++	mmol/L	4.00	4.00
20	20	Glu	mg/dL	700	700
0.30	0.30	Lac	mmol/L	20.00	20.00
0.30	0.30	Crea	mg/dL	15.00	15.00
10	10	Hct	%	75	75
3.3	3.3	cHgb	g/dL	25.0	25.0
1.0	1.0	cHCO3-	mmol/L	85.0	85.0
1.0	1.0	cTCO2	mmol/L	85.0	85.0
-30.0	-30.0	BE(ecf)	mmol/L	30.0	30.0
-30.0	-30.0	BE(b)	mmol/L	30.0	30.0
0.0	0.0	cSO2	%	100.0	100.0
-10	-10	AGapK	mmol/L	99	99
-14	-14	AGap	mmol/L	95	95
2	2	eGFR	mL/m/1.73m2	60	60
2	2	eGFR-a	mL/m/1.73m2	60	60
5.0	5.0	A	mmHg	800.0	800.0
1.0	1.0	A-a	mmHg	800.0	800.0
0.0	0.0	a/A	%	100.0	100.0

Please correct highlighted values.   Cancel   Save changes

Note: When a reportable range has been modified, it is shown in orange font color to quickly identify the change. If the modified reportable range is wider than the corresponding epoc Measurement Range, it is highlighted in red and changes are not saved.

8.25 Host Settings: Ranges

The **Ranges** page displays reference and critical ranges for all analytes, for selected test and sample type.

To change the **Range Values**, select your choices for **Test Type** and **Sample Type**. Enter new values into appropriate areas and press **Save Changes**. Changes may be applied to more than one sample type by checking desired sample types displayed on the right of the Main Range Values Table.

Rules for modifying the range values:

1. All values must be numerical;
2. Each value must be entered with expected precision (as displayed in the table);
3. The reference range values must not fall outside of the reportable range values.

Settings - Host settings - Ranges

Test type: Blood   Sample type: Unspecified

Reportable low	Ref. / Crt. low		Analyte	Unit	Ref. / Crt. high		Reportable high
6.500	Ref	7.350	pH	None	Ref	7.450	8.000
	Crt	5.500			Crt	4.000	
6.0	Ref	35.0	pCO2	mmHg	Ref	48.0	250.0
	Crt	4.0			Crt	251.0	
5.0	Ref	83.0	pO2	mmHg	Ref	108.0	750.0
	Crt	5.0			Crt	751.0	
85	Ref	138	Na+	mmol/L	Ref	146	180
	Crt	84			Crt	181	
1.5	Ref	3.5	K+	mmol/L	Ref	4.5	12.0
	Crt	0.5			Crt	13.0	
65	Ref	98	Cl–	mmol/L	Ref	107	140
	Crt	64			Crt	141	
0.25	Ref	1.15	Ca++	mmol/L	Ref	1.33	4.00
	Crt	0.00			Crt	5.00	
20	Ref	74	Glu	mg/dL	Ref	100	700
	Crt	19			Crt	701	
0.30	Ref	0.56	Lac	mmol/L	Ref	1.39	20.00
	Crt	0.00			Crt	21.00	
0.30	Ref	0.51	Crea	mg/dL	Ref	1.19	15.00
	Crt	0.00			Crt	16.00	
10	Ref	38	Hct	%	Ref	51	75
	Crt	9			Crt	76	
3.3	Ref	12.0	cHgb	g/dL	Ref	17.0	25.0
	Crt	2.3			Crt	26.0	
1.0	Ref	21.0	cHCO3–	mmol/L	Ref	28.0	85.0
	Crt	0.0			Crt	86.0	
1.0	Ref	22.0	cTCO2	mmol/L	Ref	29.0	85.0
	Crt	0.0			Crt	86.0	
-30.0	Ref	-2.0	BE(ecf)	mmol/L	Ref	3.0	30.0
	Crt	-31.0			Crt	31.0	
-30.0	Ref	-2.0	BE(b)	mmol/L	Ref	3.0	30.0
	Crt	-31.0			Crt	31.0	
0.0	Ref	94.0	cSO2	%	Ref	98.0	100.0
	Crt	-1.0			Crt	101.0	
-10	Ref	10	AGapK	mmol/L	Ref	20	99
	Crt	-11			Crt	100	
-14	Ref	7	AGap	mmol/L	Ref	16	95
	Crt	-15			Crt	96	
2	Ref	1	eGFR	mL/m/1.73m2	Ref	401	60
	Crt	1			Crt	401	
2	Ref	1	eGFR-a	mL/m/1.73m2	Ref	401	60
	Crt	1			Crt	401	

Please correct highlighted values.

Apply range values to the following sample types

- ☐ Blood:Arterial
- ☐ Blood:Capillary
- ☐ Blood:Cord
- ☐ Blood:Cord Arterial
- ☐ Blood:Cord Venous
- ☐ Blood:Mixed-venous
- ☐ Blood:Unknown
- ☑ Blood:Unspecified
- ☐ Blood:Venous
- ☐ QA:Default

Cancel   Save changes

Note: When a reportable range has been modified, it is shown in orange font color to quickly identify the change. If a reference range falls outside of the reportable range values, it is highlighted in red and changes are not saved.

8.26 Host Settings: Software Update

Use the **Software Update** page to upload software updates for the epoc Host and Reader.

1. Press the **Browse** button to select an upgrade file supplied by the Epocal representative. When the file is selected, the file path is displayed;

2. Press the **Verify** button to upload the file to the server. If the file contains a valid Software Update, the Host and Reader Update Versions are displayed below the **Verify** button;

3. Press the **Accept** button to accept File;

4. The new software update is now available to be uploaded to each epoc Host. See Section 7 "epoc Host Administration" in this manual for details about performing software upgrades on the epoc Host.

Software upgrades can be automatically downloaded to the epoc Host at the next synchronization by checking the applicable boxes on the right (see the illustration below). Departments can be configured individually for automatic upgrading.

The information about the software upgrade package includes compatible versions of epoc Host that can be upgraded to the version included in the selected update package.

Once epoc Host receives the upgrade, it will then be automatically upgraded after its next logout.

8.27 Host Settings: eVAD Update

Electronic Value Assignment Datasheets (eVAD) are available at alere-epoc.com, Customer Resource Center tab. After obtaining the eVAD file and verifying its version, use the **eVAD Update** page to upload eVADs to epoc Hosts. Refer to Appendix E "User Guide: Enhanced QA Features for the epoc System" in the end of this manual for details.

8.28 Departments

Configurations and epoc Hosts are assigned to departments to allow unique settings of a configuration to be used in a specific department. During synchronization, the configuration assigned to a particular department will be sent to each epoc Host assigned to that department. In addition, tests results and QA information received from epoc Hosts during synchronization can be sorted and filtered by the department to generate various reports.

Departments are accessed from the Top Menu. Select **Settings**, then **Departments.**

A new department may be added by pressing **Add** and then entering **Name** and **Description** (optional), assigning **Site**, **Configuration,** and **QA schedule**† (by selecting from the dropdown), setting the auto-print option with printer name, and then pressing **Save**.

† Refer to Appendix E "User Guide: Enhanced QA Features for the epoc System" in the end of this manual *for details*.

<u>Note</u>: *The sites must be previously established on the* **EDM Settings** *page, the configurations, on the* **Configurations** *page, and QA schedule, on* **QA schedules** *page.*

Mobile printers can be assigned to a department by checking the corresponding boxes. The printers can be removed in a similar way, by unchecking the corresponding boxes.

When a department is selected by clicking on the department's row in the Table under **Currently defined departments**, the fields to the right become editable. Press **Save** to retain changes.

Available Hosts and Hosts assigned to the selected department are displayed below under **All Hosts** and **Department Hosts**, respectively. A Host may be added to or removed from a department by pressing **Add→** or **←Remove**. An epoc Host that is not assigned to any Department specifically is automatically assigned to the Default Department.

Once selected, the Department may be deleted by pressing the **Delete** button only if no Hosts are assigned to it.

<u>Note</u>: *The* **Default Department** *can never be deleted or edited and is permanently assigned with the* **Default Configuration***.*

Detailed information about each department may be viewed by selecting the department and then clicking **Department details** bar. Scroll down to see **Department details**, **QA schedules, Configuration settings, Test selection, Enables sample types**, and **Barcode settings**.

▼ Department details

Department details	
Name	ICU
Description	Dpt #12
Site name	Default
Configuration	ICU
QA schedules	Default
Test record auto-print	No

QA schedules	
Quality control	Disabled
Calibration verification	Disabled
Electronic QC	Lock; Fixed; Every 8 Hours
Thermal QA	Disabled

Configuration settings	
Auth. to Login/Run tests	None
Auth. to View tests	None
Automatic log out after power off?	Yes
Automatic log out after inactivity?	Yes (5 min.)
Fixed length patient ID?	No
Temperature units	C
Apply hemodilution CF	Force selection
Require sample type selection?	No
Save raw data	On failure
Print ranges only if low/high?	Yes
Action when closing test	None
Enable background synchronization?	Yes
Close completed tests after 15 min?	Yes
Enforce critical handling?	Yes
Additional documentation?	Yes
Retain patient ID between tests?	Yes
Retain sample type between tests?	Yes
Allow user to reject test?	Yes
Allow data recall on incomplete test?	Yes

8.29 Configurations

There are a number of Host settings that may be configured uniquely and sent to specific Hosts assigned to specific departments. These Host settings are grouped together in **Configurations,** which can be then assigned as needed.

Configurations are accessed from the Top Menu. Select **Settings**, then **Configurations.**
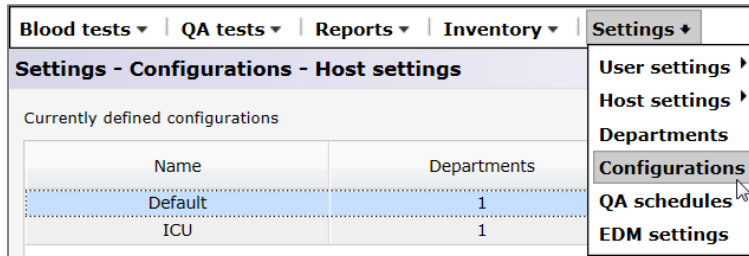
Below is the **Configurations** page:

A new **Configuration** may be created by clicking the **Add** button**.** Enter the new **Name** and **Description** (optional) under the **Add new configuration** option and press **Save**.

Configurations may then be edited by clicking on a configuration's row in the table under **Currently defined configurations**. The name and description can be modified in the editable fields to the right. Press **Update** to retain the changes. The current settings for the selected configuration are displayed under below, under **Configuration details** and can be modified.

Configuration details are arranged with tabs for: **Host settings, Test selection, Sample Types, 1D Barcodes,** and **2D Barcodes**. Open each tab to access editable fields. Press the **Save** button after finishing making changes.

Note: _Supported barcode types include 1D and 2D barcodes; however, 2D barcodes are available for Host^2 only._

8.30 QA Schedules

To configure QA schedules, go to **Settings**, then **QA Schedules**. Refer to Appendix E "User Guide: Enhanced QA Features for the epoc System" in the end of this manual for details on configuring QA schedules.

After a QA schedule is configured, it can be assigned to a department from the **Departments** page. Each department can have its own QA Schedule. It will apply to all Hosts assigned to this department.

Note: _All required QA testing must be completed before enabling QA Schedules._

8.31 EDM Settings

The epoc Enterprise data Manager settings are accessed from the Top Menu. Select **Settings**, then **EDM Settings.**

The **EDM settings** page is arranged with tabs for: **Hospital name, Sites, Language, Timeout, Unsaved test records, EDM interface settings,** and **About EDM** (read-only).

09 | Quality Assurance

9.1 Overview

This section describes Epocal's recommended quality control procedures used to verify the performance of epoc® System. It also describes additional quality control procedures that may be used. These recommended and additional procedures include internal quality control, liquid quality control, calibration verification, proficiency testing and whole blood quality control procedures. The rationale for epoc System quality control is described in the Theory of Operation section of this Manual.

9.2 Recommended Quality Control for epoc System

⚠ Follow federal, state and local requirements for quality control testing.

⚠ QA tests must be performed using the epoc System by Operators authorized to run them. Refer to epoc Host Administration or epoc Enterprise Data Manager Sections for setting up an Operator's Account to allow running of QA Tests.

See the epoc System Operation and epoc Host sections of the epoc System Manual for operating epoc System to run QA tests.

9.2.1 Verification of Newly Received Test Cards

A. Card Temperature Monitors During Shipping

Verify Test Card shipping temperatures are satisfactory using Temperature Monitors in the shipping carton. If temperature monitors indicate they were stored outside of the specified temperature range, place the card shipment on "Hold" and isolate from possible use. Contact Technical Services. Refer to the Test Cards section of the epoc System Manual for additional information.

B. Verification of Card Shipment

From each lot in each shipment of cards, analyze at least two (2) levels of fluid controls in duplicate using any verified Reader(s). (For proper fluid handling, see 9.4 Aqueous Fluid Handling below).

9.2.2 Verification of Reader Performance

A. Electronic Quality Control (Electronic QC)

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.

B. Verification of Thermal Control System (Thermal QA)

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

Verification of Thermal Control System (Thermal QA) should be performed twice a year for each Reader.

For best results, perform Thermal QA on a Reader after it has been resting in a location with no airflow (e.g. box or cabinet) and no change in temperature for at least two (2) hours.

To **verify Thermal Control System** for a Reader**:**

Turn the Reader "ON." Using an epoc Host, **discover**, then **press and hold the Reader Icon** for about one (1) second. Select **Run Thermal QA** from the dropdown menu. Measurements for Thermal QA are displayed, including "PASS" or "FAIL." Refer to the Troubleshooting and Error Messages section of this Manual if Thermal QA fails.

9.2.3 Control Fluids

Aqueous Blood Gas, Electrolyte, Metabolite and/or Hematocrit Control Fluids are commercially available for verifying integrity of newly received Test Card Lots. Recommended products are described in Table 9.1.

Various levels of Control Fluids are formulated at clinically relevant levels of Analytes.

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

Manufacturer	Description	Level	REF No.	Usage
Eurotrol Inc., Ede, The Netherlands	Eurotrol GAS-ISE-Metabolite QC	1	179.001.010	All but Hematocrit
Eurotrol Inc., Ede, The Netherlands	Eurotrol GAS-ISE-Metabolite QC	2	179.002.010	All but Hematocrit
Eurotrol Inc., Ede, The Netherlands	Eurotrol GAS-ISE-Metabolite QC	3	179.003.010	All but Hematocrit
Eurotrol Inc., Ede, The Netherlands	Eurotrol Hematocrit Control	A	195.002.010	Hematocrit
Eurotrol Inc., Ede, The Netherlands	Eurotrol Hematocrit Control	B	195.004.010	Hematocrit
Eurotrol Inc., Ede, The Netherlands	Eurotrol Hematocrit Control	C	195.003.010	Hematocrit

Table 9.1. QC Fluids Recommended for verification of epoc Test Cards.

Some Control Fluids may not be approved for sale in all Countries.

Also refer to 9.4 Aqueous Fluid Handling and 9.5 Value Assignment Datasheets below in this Section.

9.3 Optional Quality Control for epoc System

9.3.1 Calibration Verification

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

Commercially available five (5) Level Calibration Verification Sets can be used for verification of calibration of epoc Test Cards within reportable ranges. Recommended products are described in Table 9.2 below.

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

Manufacturer	Description	Level	REF No.	Usage
Eurotrol Inc., Ede, The Netherlands	Eurotrol Hematocrit Verification Fluids	1-5	190.000.005	Hematocrit Calibration Verification
Eurotrol Inc., Ede, The Netherlands	Eurotrol Calibration Verification Fluids	1-5	183.000.005	All but Hematocrit Calibration Verification

Table 9.2. Calibration Verification Fluids Recommended for verification of epoc Test Cards.

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

Also refer to 9.4 Aqueous Fluid Handling and 9.5 Value Assignment Datasheets below.

9.3.2 Proficiency Testing (External Quality Control)

Follow Proficiency Testing procedure to verify the Accuracy and Precision of epoc System Test Results over multiple laboratories and/or sites. Various laboratories can choose to register with different proficiency testing organizations.

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

Proficiency Testing samples are run as a QA Test when using epoc System (same as Control and Calibration Verification Fluids). Refer to 9.4 Aqueous Fluid Handling below.

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

CAP Linearity Studies:

CAP does not require mandatory use of the CAP Linearity Survey materials in order to satisfy the CAP accreditation program. Epocal recommends that the customers use the CAP AQ Survey, where an appropriate peer group already exists, instead of the CAP linearity study.

9.3.3 Quality Control Tests Run Using Whole Blood

When whole blood is used for epoc System Quality Control Tests, as it is in the case of Whole Blood Precision Tests, these samples should be run in the **Blood Test** mode. Always select the Blood Test (not QA Test) mode when testing blood samples.

9.4   Aqueous Fluid Handling

⚠ Always read the Manufacturer's Instructions provided with Control Fluids for product-specific information before following this procedure.

9.4.1 Storage

⚠ Always follow the Manufacturer's Storage Instructions.

9.4.2 Before Use

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

9.4.3 Ampoule Use for Blood Gas QC fluids

⚠ Handle Fluid carefully to avoid air contamination. Air contains less than 1 mmHg pCO$_2$ and about 150-180mmHg pO$_2$. Gas and pH levels may change when Fluid is exposed to air and/or transferred into plastic Syringe.

Quality Control Fluids contain dissolved gases, so they become very unstable soon after the ampoule is opened. Once the ampoule is opened, Fluid should be analyzed immediately. Multiple Test Cards can be tested using one (1) ampoule only if tested at same time on multiple Readers. Never use the last 0.5 mL of Control Fluid in the Syringe. Always use one (1) new ampoule for each Test Card tested when testing multiple Test Cards using a single epoc Reader.

9.4.4 Ampoule Use for Hematocrit QC fluids

One or multiple Test Cards can be tested using a single ampoule. Hematocrit Controls Fluids are not gas sensitive. Fluids do not require special handling to prevent air contamination.

9.4.5 Temperature Correction for Blood Gas QC Fluids

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.

It is well established that pCO_2 and pO_2 results are inversely affected by temperature[1,2]. Targets and ranges in Value Assignment Sheets can be adjusted to account for ambient temperature effects using Table 9.3 below.

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

Parameter	Level	15–17°C	18–20°C	21–23°C	24–26°C	27–28°C	29–30°C
pCO_2	~70mmHg	1.6	0.8	0.0	-0.8	-1.5	-2.0
pO_2	~55mmHg	4.0	2.0	0.0	-2.0	-3.6	-5.0
pO_2	~95mmHg	6.9	3.5	0.0	-3.5	-6.3	-8.6
pO_2	~145mmHg	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	~9.33kPa	0.22	0.11	0.00	-0.11	-0.20	-0.27
pO_2	~7.33kPa	0.53	0.26	0.00	-0.26	-0.48	-0.66
pO_2	~12.66kPa	0.92	0.46	0.00	-0.46	-0.84	-1.15
pO_2	~19.33kPa	1.27	0.63	0.00	-0.63	-1.16	-1.59

Table 9.3. Temperature correction for pCO_2 and pO_2 targets for Aqueous Control Fluids

9.4.6 Procedure

All Aqueous Control Fluids, including proficiency test samples, must be run as a QA Test when using epoc System (see the section "epoc System Operation" in the epoc System Manual for more information on selecting the QA Test).

The QA Test feature provides the following characteristics:

- The reportable range symbols ">" and "<" are not used to mark the test results outside of their reportable range, so the User can test levels at, or just outside of, reportable ranges. See the section on epoc Host Administration in this manual for more information about customizing reportable ranges;

- The Hematocrit result is reported as "uncorrected," i.e. this result does not take into account Sodium concentration in the sample. This allows for evaluating the Hematocrit Sensor independently from the Sodium Sensor (_Note: Sodium Sensor performance is verified separately._);

- Adjustments to calculations for fluid matrix;

- QA Test Results are stored separately from Blood Test Results in the epoc Enterprise Data Manager.

Immediately before use, shake the ampoule vigorously for at least fifteen seconds to re-equilibrate gases with the solution. When shaken, the ampoule should be held between the thumb and forefinger to avoid warming the solution.

Swirl the ampoule gently to return the solution to the bottom of the ampoule. Allow bubbles to rise between shaking and before opening the ampoule.

Protect the fingers with gauze, tissue, or gloves.

In order to preserve gases in the Fluid, immediately transfer the Fluid from the ampoule into a plain syringe by slowly aspirating it through a large-bore needle or blunt tip.

Without delay, deliver the Fluid into the Test Card.

9.4.7 Transfer with Syringe

To transfer Control Fluids from an ampoule to the Test Card, Epocal recommends plain 1-mL or 3-mL syringes and 16-20-gauge blunt needles. Carefully draw over 1mL of Fluid from the bottom of the ampoule.

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

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

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

Remove the blunt needle and apply the syringe luer in the Test Card's Sample Introduction Port as during a normal Blood Test procedure.

9.5   Value Assignment Datasheets

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

Value Assignment Datasheets contain Target Values and acceptable Ranges for Aqueous Control and Calibration Verification Fluids specific to the epoc System.

Printable Value Assignment Datasheets (VADs) and electronic Value Assignment Datasheets (eVAD) for the epoc System are available at alere-epoc.com, Customer Resource Center tab. Refer to Appendix E "User Guide: Enhanced QA Features for the epoc System" in the end of the epoc System Manual for more details on obtaining and using eVADs.

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

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

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

Each Value Assignment Datasheet is identified by the Fluid Name, Level, Lot Number, epoc System Sensor Configuration Version, and corresponding eVAD 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.

9.5.1 Target Values (Mean Values)

Target Values (Mean Values) are determined by factory-testing multiple ampoules of each level using multiple lots of epoc Test Cards with multiple Readers.

To establish Target Values, samples are analyzed after equilibration in the 21-23°C temperature range. $p\text{CO}_2$ and $p\text{O}_2$ values vary inversely proportional to temperature by about 1% per °C. Refer to 9.4.5 Temperature Correction for Blood Gas QC Fluids and for information on adjusting $p\text{O}_2$ and $p\text{CO}_2$ ranges outside the 21-23°C temperature range.

Also, to establish Target Values, samples are analyzed at approximately 760 mmHg atmospheric pressure. The $p\text{CO}_2$ readings will be insignificantly affected by the barometric pressure, BP. The $p\text{O}_2$ readings will decrease by (2mmHg + 6%) per 100mmHg barometric pressure under 760mmHg. Therefore, before comparing the gas readings with the published value assignments, the $p\text{O}_2$ readings need to be corrected as follows:

$$p\text{O}_2^{corrected} = p\text{O}_2^{reading} + (2\text{mmHg} + 6\% \cdot p\text{O}_2^{reading}) \cdot (760 \text{ mmHg-BP[mmHg]})/100\text{mmHg}$$

For example, if $p\text{O}_2$ reading is 150mmHg and BP = 630mmHg the corrected $p\text{O}_2$ reading for this altitude would be

$$p\text{O}_2^{\ corrected} = 150 + (2+ 6\% \cdot 150) \cdot (760 - 630)/100 = 150 + (2+9) \cdot 1.3 = 164.3 \text{ mmHg}$$

The above corrections were developed based on known effects of BP on gas partial pressure of aqueous solutions, as well as other factors specific to the epoc system.

Target Values are specific to the epoc System. Results obtained from Aqueous Fluids may differ when using other methods due to sample matrix effects.

9.5.2 Ranges

The ranges displayed represent the maximum deviations expected when Fluids and Test Cards are performing properly. If your results are outside the specified ranges, refer to the Troubleshooting and Error Messages section of this Manual.

Ranges for Control Fluids and Calibration Verification Fluids in Value Assignment Datasheets are determined for individual readings (n=1). Calibration Verification Ranges for the average of three readings (n=3) can be provided upon request.

9.5.3 References

1. Maas A.H.V, "Evaluation of ampouled tonometered buffer solutions as a quality control system for pH, pCO$_2$ and pO$_2$ measurements," Clin. Chem., 23(9), 1977, 1718-1725.

2. Battino R., Rettich T.R., Tominaga T., "The solubility of oxygen and ozone in liquids," J. of Phys. Chem. Ref. Data, 12(2), 1983, 163-178.

3. Burnett R. W. and Itano M., "An interlaboratory study of blood gas analysis: dependence of pO$_2$ and pCO$_2$ results on atmospheric pressure," Clin. Chem., 35(8), 1989, 1779-1781.

10   Care and Maintenance of epoc® System

10.1 General Information

Exercise safety precautions at all times when handling the epoc Reader, epoc Host and epoc Test Cards to prevent exposure to blood-borne pathogens.

Never attempt to clean or decontaminate the inside of the epoc Reader. If blood has entered the epoc Reader, turn the Reader "OFF" and place it in a plastic bag with a Biohazard Label on the bag. Contact your Epocal distributor to arrange for return of the Reader for repair.

Refer to the CLSI approved guidance "Protection of Laboratory Workers from Occupationally Acquired Infections" for information regarding good laboratory practices and protection from major infectious pathogens.

10.2 Care of the epoc System

The epoc Blood Analysis System requires a minimum of care and maintenance.

The following general practices are recommended:

1. Turn off the epoc Reader and epoc Host when not in use to conserve battery life.
2. Store the Reader and Host in a secure location when not in use.
3. Keep the Reader and Host in a dry location while in use and during storage.
4. Periodically check the condition of wires and cables of the AC adaptor to check for wear and to ensure integrity of electrical connections.
5. Keep this epoc System Manual available to both the Operator and Administrator.
6. Ensure that your epoc System Manual is complete and kept up to date.

10.3 Cleaning

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

Do not expose any electrical contacts to cleaning solutions.

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

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

Never attempt to:

1. Clean inside the Reader's card insertion slot.
2. Clean a Test Card.
3. Sterilize or autoclave any part of the epoc System.

General Cleaning Methods

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

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

- Mild detergent or non-abrasive cleaner;
- Alcohol;
- Soap and water;
- 10% household bleach solution.

Decontamination Method

Decontaminate the epoc Reader or epoc Host when blood is spilled on them to prevent exposure to any blood-borne pathogens.

Wear appropriate gloves to perform the following procedure:

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

10.4 Maintenance

The epoc Reader and the epoc Host require no maintenance or adjustment. In the event that a Reader or Host fails to operate, contact Epocal to arrange for repair.

The rechargeable Host battery can be replaced by a user. Refer to instructions for removing the Host battery in the Quick Start Guide for your epoc Host.

The rechargeable Reader battery and battery door can be replaced by a user. Refer to instructions below.

The Reader rubber feet can be replaced by a user. Refer to instructions below.

epoc Reader battery replacement

Battery door screw
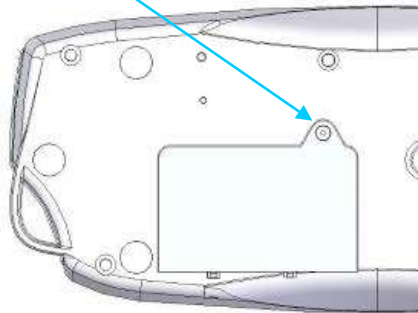
1) Remove the screw that connects the battery door to the Reader using a Philips #0 or 3/16" slotted screwdriver (depending on the screw type found in the Reader).

2) Lift the battery door from the Reader.

3) Carefully remove the battery from its compartment to allow access to its cable connection to the Reader.

Connector orientation tab

Pull connector out from here
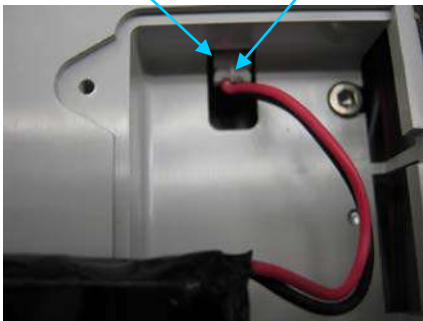
4) Gently unplug the battery from the Reader. Tweezers may be useful in order to pull the connector out.

5) Connect the new battery connector to the epoc Reader. The connector orientation tab should be visible as seen in the picture.

6) Place the new battery into its compartment. Place its wires in the location shown. Ensure that the battery is lying flat without wires underneath or on top.

Place wires in this slot

Ensure no wires are on top of battery

7) Install the battery door by inserting its hinge at an approximate 30° angle behind the battery. Pressure needs to be applied to the edge of the door in order for its hinges to snap into place. The battery door can then be closed into place.

8) Secure the door by fastening with the screw removed, using a Philips #0 or 3/16" slotted screwdriver. Do not over-tighten the screw to avoid damaging the plastic.

epoc Reader battery door replacement

Some steps of this procedure are very similar to those of battery replacement described above. Refer to the images above to find the screw that connects the battery door to the Reader and to see the angle at which the door hinge is inserted.

1) Remove the screw that connects the battery door to the reader using a Philips #0 or 3/16" screwdriver.

2) Lift the battery door from the reader.

3) Do not move the battery or wiring; it is installed in a way that facilitates easy battery door replacement.

4) Install the new battery door by inserting its hinge at an approximate 30° angle behind the battery. Pressure needs to be applied to the edge of the door in order for its hinges to snap into place. The battery door can then be closed into place.

5) Secure the door by fastening with the new screw provided with the replacement battery door, using a using a Philips #0 or 3/16" slotted screwdriver. Do not over-tighten the screw to avoid damaging the plastic.

epoc Reader rubber feet replacement

There are five locations where rubber feet are attached:

Replacement is only necessary if any of the feet fall off of the epoc Reader.

1) Remove any adhesive residue at the locations of the missing rubber feet using alcohol and a low-lint wipe. Apply alcohol to the wipe and squeeze out the excess liquid before touching the surface of the Reader.

2) Allow the alcohol to dry before attaching the new rubber feet.

3) Peel the new rubber foot away from its adhesive backing and press on to the cleaned location under the epoc Reader. It is recommended to wear gloves for this step in order to avoid contaminating the adhesive surfaces.

11   Theory of Operation

11.1 epoc® Host

The epoc Host is a Mobile Computer with epoc Host Application factory installed. The epoc Host is dedicated for use with the epoc Blood Analysis System. Other software applications are not permitted for use on the epoc Host.

The epoc Host communicates directly with the epoc Reader to acquire:

- Data to identify Test Card Type, Lot Number, and Use By Date
- Digitized raw electrical signals generated by Test Card Sensors
- Barometric Pressure Signal
- Three (3) Temperature Signals
- Digitized raw electrical signals from internal Electronic QC Test

The epoc Host:

- Sends instructions to epoc Reader
- Determines operational errors from raw QC signals
- Calculates concentrations of Analytes from raw digital data
- Displays Test Results with numerical values
- Maintains internal clock and calendar
- Stores all Test Records, including internal quality check data

11.2 epoc Reader

11.2.1 Sensor Interface

Electrical signals from Sensor Module in Test Card are received by Sensor Interface Circuit Board through internal connector in epoc Reader. Sensor Interface Circuit amplifies and multiplexes Raw Sensor Signals prior to digitization.

11.2.2 Mechanical System

epoc Reader's Card Insertion Slot includes two (2) mating surfaces that clamp the Test Card after insertion into epoc Reader.

Upon insertion of Test Card into Card Slot:

- Barcode on Test Card is read by Barcode Scanner in Reader
- Connector array in epoc Reader contacts module containing Sensors
- Two (2) Heater Blocks in epoc Reader contact Test Card Sensor region, above and below Test Card, to maintain 37°C Temperature during test.

After insertion, Test Card engagement process activates Motor that:

- displaces Valve Plug in Test Card to open sealed Calibrator Reservoir in Test Card
- displaces Calibration Fluid from Calibrator Reservoir to Measurement Region, which is Fluidic Channel above Sensor Module in Test Card

11.2.3 Multiplexing and Analog-to-Digital Conversion

The analog-to-digital Converter converts analog signals into digital form and then to wireless transmittable Bluetooth format.

The following signals are transmitted by epoc Reader to epoc Host:

- Potentiometric, amperometric, and conductometric Signals from Sensor Interface Circuit
- Battery voltage and internal temperature of Reader
- Heater power Signals and temperature sensor Signals from each Heater Block to maintain temperature at 37°C during test
- Barcode data acquired from Test Card
- Environmental Barometric Pressure as measured by Pressure Transducer

11.2.4 Analog Control Signals

epoc Reader applies two (2) types of Signals to the Sensors:

1. a digital-to-analog converter generates a voltage which is applied to Amperometric Sensors
2. AC conductivity circuit generates AC (Alternating Current) excitation voltage which is applied between conductivity sensor and Ground (GND).

11.2.5 Operator Interface

Once epoc Host measurement process begins, User can operate epoc Reader without referring to epoc Host, using series of Audio and Visual cues from epoc Reader.

11.3 epoc Test Card

epoc Test Card includes following major components:

- **Moulded Plastic Housing [1]** with fluid channels, reservoirs, and a recess where **Sensor Module [2]** is mounted so module's outer contact surface is flush with card surface and module's inner sensor surface is facing the card's fluid channels.
- **Sensor Module [2]** is an epoxy foil supporting array of foil electrode contacts on outer side and array of sensor membranes on inner side. Sensor membranes electrically contact electrode contacts through holes in epoxy foil. Sensor Module is assembled into card and sealed with UV sensitive adhesive.
- Calibration Fluid Reservoir recessed in card body contains about 150 μL of aqueous calibration fluid. Reservoir is covered by two (2) layers of **Polyethylene Coated Aluminum Foil [6, 7]**. Calibration fluid is sealed within card during manufacture by thermally sealing foil layers.
- **Valve Plug [5]** is sealed within upper and lower foil layers at calibration fluid reservoir effluent channel. Motor drive is activated upon insertion of Test Card into Reader so Valve Plug punctures seal at effluent channel.

- Plastic **Upper Label [3]** is laminated and sealed to card during manufacture to form cover over fluidic channels already moulded as troughs in card.
- One fluidic channel in moulded card connects Calibration Fluid Reservoir to Sensor Module and then to Waste Chamber.
- Second fluidic channel connects Sample Entry Port to Sensor Module and then to Waste Chamber. Sample Entry Port includes silicone-based **Sample Port Seal [4]** to seal Syringe tip during sample introduction.
- **Lower Label [8]**,white and made from plastic, includes printed Test Card information.
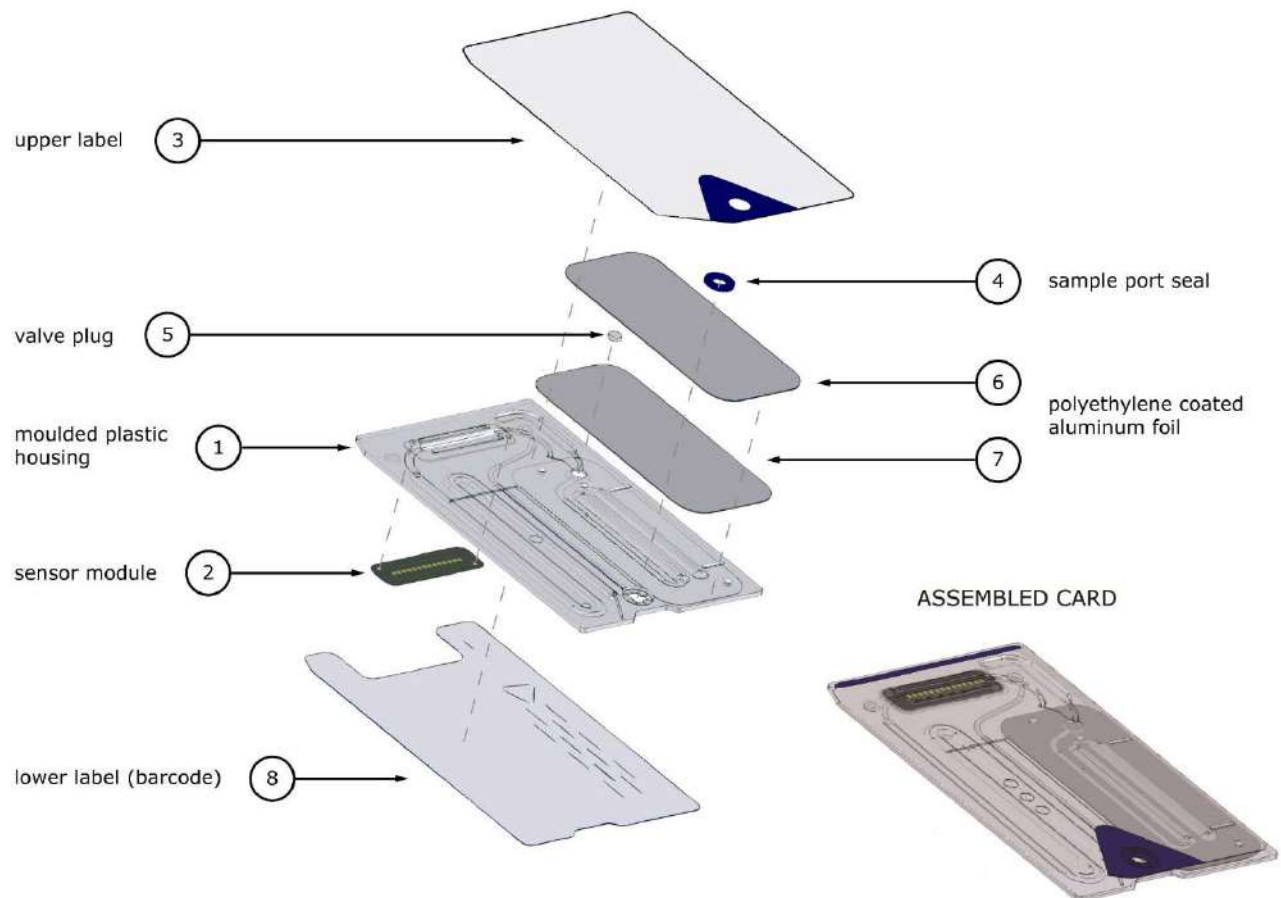
11.4 Sensor Module

Sensor Module:

- Is a smart-card module adapted for use
- Includes lamination of epoxy foil on one side
- Has gold coated copper foil on other side
- Array of electrodes and contacts are formed by gold copper foil
- A hole through epoxy is located over each electrode location

ELECTRODE CONTACT SURFACE OF THE MODULE

epoxy foil

14 gold contacts

14 leads connecting electrodes to contacts

14 gold electrodes

multiple gold contacts to the thermal block in the reader
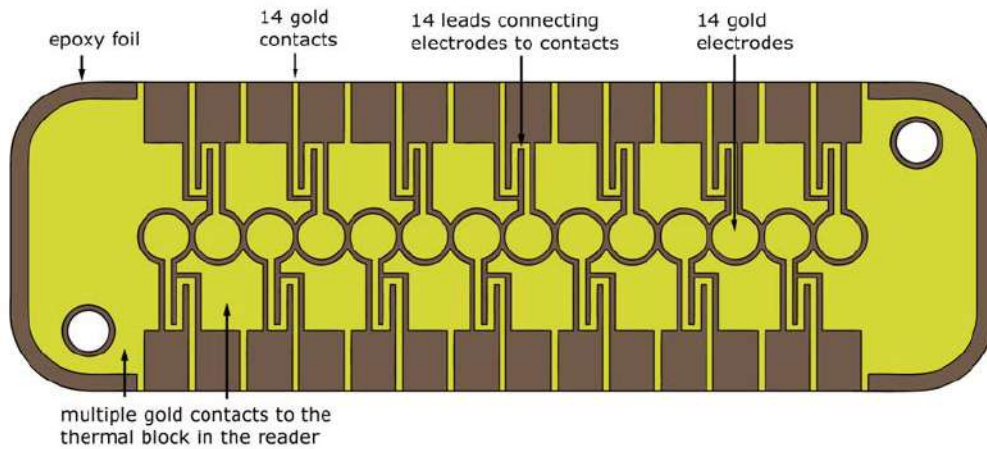
SENSOR SURFACE OF THE MODULE

epoxy foil

14 holes located over each of 14 gold electrodes on the contact side of the epoxy

2 alignment holes for assembly of the module to the card
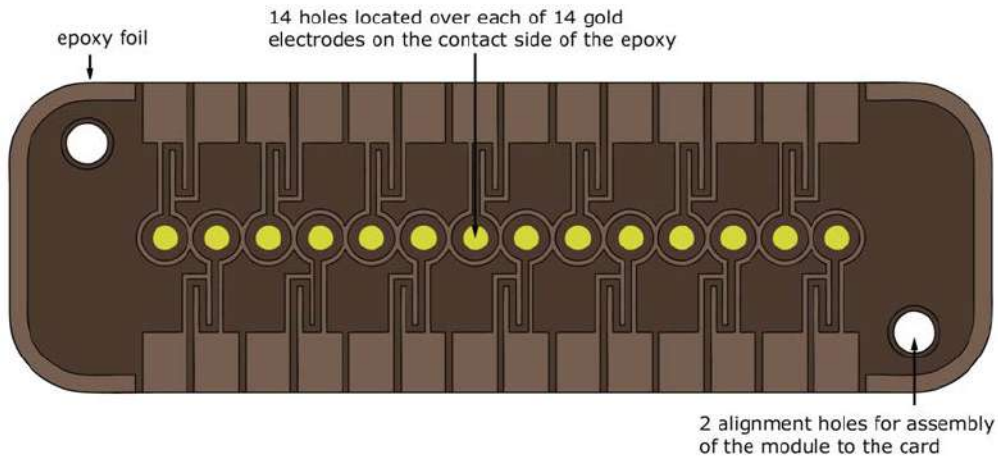
- 14 electrode locations in Sensor Module.
- Each electrode located under a hole through epoxy foil
- Perimeter of epoxy isolates electrodes from each other
- Electrochemically active sensor membranes are deposited into cavity formed by hole at each electrode location

VIEW ALONG MODULE SENSOR CHANNEL *BEFORE* MEMBRANE PRINTING

epoxy   14 holes

14 gold electrodes
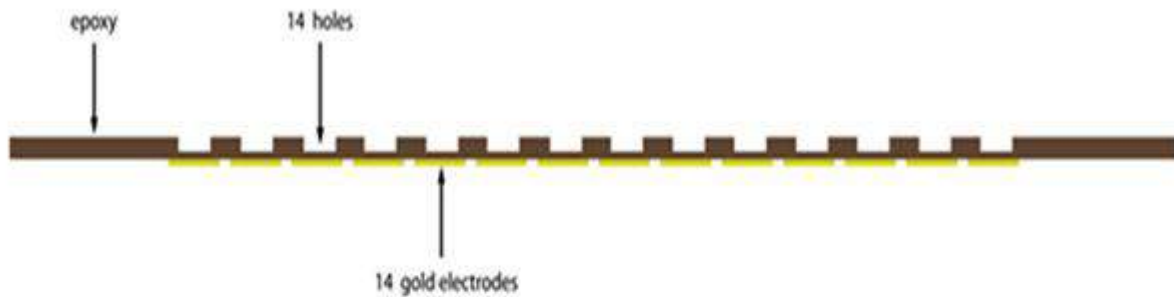
VIEW ALONG MODULE SENSOR CHANNEL *AFTER* MEMBRANE PRINTING

conductivity · unused · membrane · membrane · membrane · membrane · membrane · membrane · membrane · ground · membrane · membrane · membrane · membrane
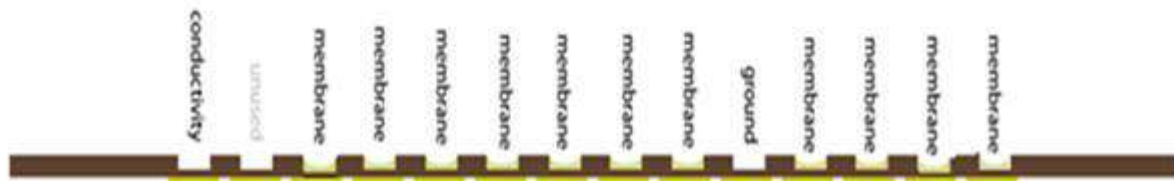
11.5 Sensor Electrodes

11.5.1 Measurement Method

Measurements are performed on undiluted specimens. Undiluted methods are also called direct methods, whereas methods that dilute the sample are called indirect methods.

For electrolytes, indirect methods measure the concentration of analyte per unit volume of plasma. Direct methods, which measure the free ion concentration of analyte per unit volume of plasma water, can read up to 7% higher than indirect methods because there is an excluded volume occupied by plasma protein and lipids that is not considered in indirect measurements. However, the result typically runs only 3-5% higher because some of the analyte is bound to protein. When there is disagreement between the methods, such as when the patient has abnormal total protein or lipid levels, it is recognized by industry as interference on the indirect method, the direct method giving the clinically correct result for electrolytes[1]. At normal levels of protein and lipids the systematic offset between methods is generally corrected for in commercial direct measuring instruments so that the reference ranges for all instruments are in agreement. In the factory epoc sensors are calibrated so that reference ranges are in agreement with indirect reference methods at normal levels of total protein and lipids.

Direct measurement of hematocrit by the conductometric technique gives a result related to the non-conducting excluded volume fraction of the sample fluid. Red blood cell volume is the predominant component of the non conducting volume, but proteins, lipids, and white blood

cells also contribute. Elevated hematocrit readings are expected at abnormally elevated levels of these components. Decreased hematocrit readings are expected at abnormally low levels of protein, such as found in diluted samples taken from patients on cardiopulmonary bypass. Osmotic imbalance causes a discrepancy between direct (conductometric, spun) and indirect (Coulter) measurements because of variation in the mean cell volume.

There are three (3) types of sensor measurements used in epoc Test Card – potentiometric, amperometric and conductometric.

In potentiometry[2,4], (for sodium, potassium, chloride, ionized calcium, pH and pCO_2) the open circuit potential of a membrane coated sensor electrode (which is responsive to the concentration of the analyte) is measured versus a reference electrode (which is approximately non-responsive). The measurement is performed by a high input impedance operational amplifier in the epoc Reader connected to each of the electrode pairs comprising sensor electrode and reference electrode.

The potential difference, V, between the electrode pair follows the modified Nernst equation (Nicolsky equation) which is

$$V = V_0 + sLOG(C + \alpha)$$

where C is the concentration of the analyte being measured and s, the slope of the electrode response, is about 60mV per decade concentration change for a univalent analyte (pH, K, Na, pCO_2) and about 30mV per decade for divalent (iCa). V_0 is a constant. The term $\alpha = \Sigma K_i C_i$ models the combined effects of interferents of type i at concentration C_i, with K_i being the interference coefficient. When the measurement includes a calibration, the electrodes first being immersed in a calibration fluid with concentration, C_{cal}, then in the sample fluid with unknown concentration, C_{smpl}, the calibrated sensor signal is the difference, ΔV, between the potential difference in sample and the calibrator given by

$$\Delta V = +sLOG\frac{C_{smpl} + \alpha}{C_{cal} + \alpha}$$

An improvement in the above equation incorporates highly reproducible and well characterized mV offsets

$$\Delta V_{corr} = \Delta V_{raw} + \beta$$

In amperometry[2] (for pO_2, glucose, lactate, and creatinine) the current, i, flowing through a membrane-coated amperometric indicator electrode to the ground electrode is measured, when the indicator electrode is poised at a fixed potential versus the reference electrode. In the amperometric measurement of dissolved oxygen, the electrode selectively reduces the analyte species that diffuses through the membrane covering the electrode. In the amperometric measurement of glucose, lactate, and creatinine, the analyte diffuses through the top membrane and is enzymatically transformed into hydrogen peroxide, that is further reduced at a small negative potential using a red-ox mediated horseradish peroxidase, HRP, catalyzed reaction. The governing equation for an ideal, linearly responding sensor (membrane diffusion-limited current) is given by:

$$c = \frac{i}{r}$$

where r now is the electrode's responsivity (amps per unit concentration, in the case of the glucose, lactate, and creatinine sensors or amps per unit partial pressure in the case of the oxygen sensor). When the measurement includes a calibration, the calibrated sensor signal, D, is the ratio of sensor currents in the sample and the calibrator.

$$D = \frac{i_{smpl}}{i_{cal}}$$

Therefore the equation of the ideal sensor is

$$c_{smpl} = c_{cal} D$$

Where c_{cal} is the concentration of the analyte in the calibration fluid and/or the partial pressure of oxygen in the calibrator, which is the value in air saturated aqueous fluid (corrected to atmospheric pressure at sea level -- 101.32kPa, via the measurement of the actual atmospheric pressure by a pressure sensor in the card Reader). In the real case the sensor deviates somewhat from ideality. Because there is a small sensor zero current, the calibrated sensor signal does not pass through zero at zero concentration and/or oxygen partial pressure. This is modeled by an intercept, a and sensitivity factor, s, giving the modified sensor equation

$$c_{smpl} = c_{cal} \frac{s(D - a)}{(1 - a)}$$

The calibrated sensor signal D, is slightly non-linear at very high concentrations or partial pressures, which is modeled as a power series with terms up to i^3. The modified calibrated sensor signal is now given by

$$D = \frac{i_{smpl} + y_1 i_{smpl}^2 + y_2 i_{smpl}^3}{i_{cal} + y_1 i_{cal}^2 + y_2 i_{cal}^3}$$

An improvement in the above equation incorporates highly reproducible and well characterized effects

$$D_{corr} = D_{raw}(1 + \delta)$$

Hematocrit is measured by AC conductimetry[2]. A pair of spaced-apart electrodes in the flow channel is used (to minimize contact impedance and blood cell settling errors). The down-stream conductivity-high electrode also serves as the detector for adequate sample volume delivery. The measurement employs a 8kHz voltage source with 320mV peak-to-peak. The normalized sensor signal, D, is the ratio of the resistance of blood to the resistance of calibrator fluid

$$D = \frac{R_{bld}}{R_{cal}} = \frac{\rho_{bld}(l/A)}{\rho_{cal}(l/A)}$$

D is thus also equal to the resistivity ratio, because the geometric cell constants (effective area A and path length l) are the same in the sample measurement as in the calibrator.

The basis of the conductometric hematocrit measurement is the fact that red blood cells are surrounded by a non-conducting membrane and the blood resistivity is therefore related to the volume occupied by non-conducting red cells. This is described by the modified Maxwell-Fricke equation[3], in which the resistivity of blood ρ_{bld} is related to the resistivity of plasma ρ_{plsm} according to,

$$\rho_{bld} = \rho_{plsm} \frac{1+bH}{1-aH}$$

where a and b are constants and H is the hematocrit (fractional packed cell volume).

The resistivity of plasma can be estimated from the calibrator fluid's resistivity and the sodium concentration value measured in the sample $C_{Na.smpl}$, relative to the known sodium value in the calibrator fluid $C_{Na.cal}$, according to the equation

$$\rho_{plsm} = c\rho_{cal}$$

where c is a function of sodium and total protein (volume fraction) concentration in normal blood. Therefore,

$$D = \frac{\rho_{bld}}{\rho_{cal}} = \frac{c(1+bH)}{1-aH}$$

11.5.2 Electrode Components

1. pH Electrode

The pH sensor is comprised of a plasticized PVC membrane ion selective electrode[4] containing the pH selective ionophore tridodecylamine.

2. pCO$_2$ Electrode

The pCO$_2$ sensor is a modified Severinghaus electrode[2,5] comprising a gold electrode surface coated with an internal layer containing quinhydrone, sodium bicarbonate and carbonic anhydrase catalyst, and an outer, heterogeneous carbon dioxide permeable membrane.

3. pO$_2$ Electrode

The pO$_2$ sensor is a modified Clarke electrode[2.5] comprising a gold cathode surface coated with a heterogeneous oxygen permeable membrane.

4. Sodium Electrode

The sodium sensor is comprised of a plasticized PVC membrane ion selective electrode[4] containing the sodium selective salt sodium methylmonensin.

5. Potassium Electrode

The potassium sensor is comprised of a plasticized PVC membrane ion selective electrode[4] containing the potassium selective ionophore valinomycin.

6. Ionized Calcium Electrode

The ionized calcium sensor is comprised of a plasticized PVC membrane ion selective electrode[4] containing the ionized calcium selective salt calcium tetra methyl butyl phenyl phosphate.

7. Chloride Electrode

The chloride sensor is comprised of a plasticized PVB membrane ion selective electrode[4] containing the chloride selective ionophore tridodecyl methyl ammonium chloride.

8. Glucose Electrode

The Glucose sensor is a hydrogen peroxide electrode comprising a gold cathode surface coated with an internal layer containing glucose oxidase[2], peroxidase (HRP) and a redox mediator (ABTS, i.e. 2,2'-azino-bis(3-ethylbenzothiazoline-6-sulfonic acid) diammonium salt) and an outer, heterogeneous oxygen permeable membrane.

9. Lactate Electrode

The Lactate sensor is a hydrogen peroxide electrode comprising a gold cathode surface coated with an internal layer containing lactate oxidase, peroxidase (HRP) and a redox mediator (ABTS, i.e. 2,2'-azino-bis(3-ethylbenzothiazoline-6-sulfonic acid) diammonium salt) and an outer, heterogeneous oxygen permeable membrane.

10. Creatinine Electrode

The Creatinine sensor is a hydrogen peroxide electrode comprising a gold cathode surface coated with an internal layer containing the enzymes creatinine amidohyrdolase, creatine amidinohydrolase and sarcosine oxidase, peroxidase (HRP) and a redox mediator, a middle creatine-screening layer containing the enzymes creatine amidinohydrolase, sarcosine oxidase and catalase and an outer, heterogeneous oxygen permeable membrane.

11. Hematocrit Electrodes

Two gold electrodes.

12. Reference Electrode

The reference electrode is a salt bridge type structure[4] with a redox couple at the electrode surface coated by a heterogeneous water vapor permeable salt bridge electrolyte containing membrane.

11.6 Quality Control and epoc System

11.6.1 Introduction

There are two (2) types of quality control procedures in routine use in today's clinical analyzers which are accepted under CLIA guidelines: traditional QC (specified in the original CLIA 1988 regulation[6]) and equivalent QC (now described in the CLIA update of 2003[7]).

⚠ Equivalent QC is not a substitute for external Quality Controls. Follow federal, state and local requirements for quality control testing.

Traditional QC uses fluid (pseudo-sample) controls run on an analyzer intermittently (but at least two (2) levels once per day according to CLIA 88) in between patient samples. Traditional analyzer designs employ reusable components for the test procedure (reagents, sensors, fluidic channels and measurement chambers). Because these components are reusable they can be prone to degradation or contamination during normal use. Failure modes of this type include chemical contamination introduced by a sample which carries over into multiple sequential runs, clogging of fluidic conduits or measurement chambers causing multiple fluidic problems including sample bubbling, fibrin formation over sensing elements, ageing and loss of response-slope of sensors and the like. Because these problems persist they can cause errors in multiple subsequent assays until the condition is detected by a QC pseudo-sample and it is corrected by the operator. It is precisely that the errors persist that they can be detected by pseudo-sample QC. Sporadic errors, those that occur on a single sample run, are not effectively detected by traditional pseudo-sample QC.

The epoc System uses QC procedures that have been specifically developed for use in devices employing single use test cards. These QC procedures are now well accepted by the industry, and have been accepted as valid by CLIA and entitled Equivalent QC. The principle behind this approach is that in a point-of-care application or in a stat lab deployment, where test results are enacted upon immediately, it is important to detect an error <u>when</u> it occurs. It is also not effective to use as the <u>primary</u> error detector methodology a pseudo-sample QC that relies on an error's persistence for error detection.

Since the epoc System employs single use test cards it does not comprise those components of traditional multi-use analyzers that are most prone to persistent error. Dominant error modes in unit-use devices like the epoc System are sporadic in nature, only affecting the instant card being run. Accordingly, the approach used in equivalent QC by the epoc System employs a battery of internal quality control tests that are performed by the system each time a test is run, suppressing results when an error condition is detected. Each test begins with fresh sensors and a fresh calibrator fluid. The conforming response of the sensors' signals to the fresh calibrator fluid is well characterized from a large database of tests run in the Epocal factory. If the sensor signal is uncharacteristic due to mis-manufacture, mis-handling or mis-storage, the system's software will suppress the result.

Far less common are persistent error modes that arise from components of the test system that share a common history over more than one test. These include epoc Reader contaminations which may affect a series of results if uncorrected, or the malfunction of an entire batch of unit-use cards. These error conditions are also effectively detected in the battery of tests performed on the card in use. For example in-line QC measurements also include epoc Reader electronic QC tests, which are performed upon connection with an epoc

Host and before each card is run, will detect contamination of the epoc Reader which might result in erroneous operation. As further assurance batch acceptance and monitoring procedures are recommended for the confirmation of persistent error modes in test cards which might be defective because of non-conforming manufacture, shipment or storage.

11.6.2 Overview of epoc System Internal QC (iQC).

Each time a Test Card is run there are multiple monitoring tests taking place in the background that are used to control the quality of the test procedure and flag non-conforming tests.

There are three (3) phases of QC tests performed by the epoc System:

1. **Initialization**: An initial battery of tests covering 2 different levels over the dynamic range is performed by the epoc Reader (epoc Reader electronic QC test) every time the Reader connects with an epoc Host. In addition, QC tests are performed by the epoc Reader on the card and on the operator process after card insertion during initialization.

2. **In-calibration**: QC tests performed to assess the card and sensors' conformance during the calibration interval before sample is introduced.

3. **During sample measurement**: QC tests performed to monitor the operator procedure and sample integrity during and after sample introduction.

	Initialization	In-Calibration	Sample
epoc Reader	√	√	√
Cards and test	√	√	√
User procedures	√		√
Sample integrity			√

Together these tests provide a broad spectrum protection against erroneous operation of the epoc Blood Analysis System.

epoc System Limitations: The epoc System does not detect and flag pre-analytical sample handling problems. i.e. it measures the sample it receives. Pre-analytical errors include sample hemolysis, sample degradation through ageing and improper anticoagulation, degassing or gassing up of non-anaerobically handled specimens, contamination with interfering chemicals arising from improper sample collection. These sample handling errors are not detected, and require proper User training for their control and minimization.

The approach to error detection in the epoc iQC system is statistically based, and essentially the same regardless of the iQC measurement category. From the large database of test results obtained in the factory:

1. The histogram of conforming values for the iQC measurement is established.

2. The distribution of iQC measurement values associated with a non-conformance leading to an analytical error is established.

3. The thresholds or limits for the iQC measurement value which are the basis for the decision to accept or reject the test run are established. When an iQC measurement falls within the acceptable limits, the test run proceeds to report an analytical value. When a measurement falls outside of the acceptable limits, the analytical result is not reported, either for an individual test or for the entire card depending on the measurement type and error category.

11.6.3 Detailed Description of epoc iQC System

The table below shows the scope of the epoc System's error detection activity in detail.

Total Measurements	On what	Measurement type	Measurement	When	Checks for	Looks for
1	card's barcode	optical scan		At initialization	card type & integrity	card from expired lot
10	each sensor channel	Reader's channel isolation	i	At initialization	Reader integrity	Reader contamination: persistent error requires corrective action
10	each sensor channel	card's channel isolation	i	At initialization after card introduction	Reader integrity, card integrity	card contamination / manufacturing
10	each sensor	sensor raw signal	v, i or σ	At sensor calibration	card integrity	manufacturing / shipment / storage integrity
10	each sensor	sensor raw signal	$dv(i,\sigma)/dt$	At sensor calibration	card integrity	manufacturing / shipment / storage integrity
10	each sensor	sensor raw signal	rms (v, i, σ)	At sensor calibration	card integrity	manufacturing / shipment / storage integrity
2	both heaters	thermal transient	T	At sensor calibration	card integrity	abnormal contact of card to heater
2	both heaters	power transient	W	At sensor calibration		
1	fluidic sensor	fluidic integrity	σ	At sensor calibration	operator procedure	conforming calibrator delivery and conductivity
10	each sensor	sensor raw signal	$+dv(i,\sigma)/dt$	At sample introduction	sample integrity	sensor rise time abnormality
10	each sensor	sensor raw signal	$d^2v(i,\sigma)/dt^2$	At sample introduction	sample integrity	interference
2	both heaters	thermal transient	T	At sample introduction	operator procedure	out of spec cold sample
2	both heaters	power transient	W	At sample introduction	operator procedure	
1	fluidic sensor	air segment conductivity level	σ	At sample introduction	sample integrity	air segment in sample
1	fluidic sensor	air segment width (low)	t	At sample introduction	operator procedure	too fast sample injection causing fluid segmentation
1	fluidic sensor	air segment width (high)	σ	At sample introduction	operator procedure	too slow or discontinuous sample injection
10	each sensor	sensor raw signal	$dv(i,\sigma)/dt$	In sample	sample integrity	sample abnormality
10	each sensor	sensor raw signal	rms(v,i,σ)	In sample	sample integrity	sample abnormality
2	both heaters	power level	W	In sample		

1. Initialization Tests

Initialization tests are performed upon connection and at the start of the test run before sensor calibration.

2. In-Calibration Tests

In-calibration iQC tests are performed after the calibrator is delivered to the sensor array. During the calibration interval (extending for 150 to 175 seconds, depending on environmental thermal conditions) the sensors are heated to 37°C and they wet-up from the dry storage state within the first minute or so, achieving wet up within 60 – 100 seconds.

Within the card, the function of the calibration fluid is not the same as an external quality control fluid with an assigned mean, SD and set pass/fail concentrations. Instead, it is used as a single point calibration in every test. The iQC process applied during calibration is described in detail in this section.

3. During Sample Measurement Tests

A. Operator Procedures

The epoc System has been designed to operate robustly in the hands of individuals not trained in laboratory science, i.e. health care professionals at the point of care. Quality control is fully automated and invisible to the user. Laboratory training is not required to obtain reliable results. The system detects erroneous operator procedures when they occur.

For example the system will flag the following conditions and not deliver a test result when:

- Using an expired card
- Rerunning an already used test card
- Putting in too little sample
- Introducing the sample too rapidly
- Introducing the sample too slowly
- Introducing the sample at the wrong time

B. Sample Integrity Tests

The system also detects abnormalities in the introduced sample including:

- Samples with air bubbles
- Samples with some interferents

11.6.4 Validating Performance of epoc System Including iQC

Until recently, regulations and laboratory accreditation standards specified use of traditional quality control regimens, including daily use of liquid "control" materials.

As new technologies such as the epoc System become available, the community has recognized the limitations of relying upon traditional regimens, prompting various regulatory and accreditation organizations to modify their standards accordingly.

Many of the newly drafted regulations and accreditation standards recognize the danger of denoting specific methods of achieving an effective Quality Control regimen. Additionally, specific methods cannot anticipate future technological changes, so many of the regulatory and accreditation organizations are changing their standards to place the responsibility of establishing and validating the quality system a laboratory employs on the laboratory director.

Quality control regimens should be established using information from the manufacturer and scientific literature.

It is important to validate the performance of the epoc System and the recommended quality control regimen to develop personal confidence in our approach to the challenges of putting a diagnostic device in the hands of individuals untrained in laboratory science.

It is recommended to use appropriate commercially available quality control materials to comply with federal, state and local regulatory authorities overseeing your institution.

11.7 References

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2. P. D'Orazio, M.E. Meyerhoff, "Electrochemistry and Chemical Sensors", Chapter 4 in Tietz Textbook of Clinical Chemistry and Molecular Diagnostics-Fourth Edition, C.A. Burtis, E.R. Ashwood, and D.E. Burns eds., Elsevier Saunders, St.Louis, 2006.

3. H. Fricke, A Mathematical Treatment of the Electric Conductivity and Capacity of Disperse Systems, Physic. Rev., 24, pp. 575-587, 1925.

4. See, for example, W.E. Morf, The Principles of Ion-Selective Electrodes and of Membrane Transport, Studies in Analytical Chemistry 2, Elsevier Publishing Co., Netherlands, 1981.

5. See, for example, O. Siggard-Andersen, The Acid-Base Status of Blood, 4th Edition, Williams and Wilkins, Baltimore 1974.

6. Clinical Laboratory Improvement Amendments of 1988; Final Rule. Federal Register. Feb 28, 1992.

7. Clinical Laboratory Improvement Amendments of 1988; Final Rule. Federal Register. Jan. 24, 2003.

12 BGEM Test Card Specifications

12.1 General BGEM Test Card Specifications

12.1.1 Indications for Use – epoc® System

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

The **Blood Gas Electrolyte and Metabolite (BGEM) Test Card** panel configuration includes sensors for pH, pCO_2, pO_2, Sodium, Potassium, Ionized Calcium, Chloride, Glucose, Lactate, Creatinine, and Hematocrit.

pH, pCO_2, pO_2 (blood gases) measurements from the epoc Blood Analysis System are used in the diagnosis and treatment of life-threatening acid-base disturbances.

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

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

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

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

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

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

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

12.2   Test Card Configuration and Use

The epoc Blood Gas Electrolyte and Metabolytes (BGEM) Test Cards include the following measured and calculated Test Results.

Note: The CT-1006-00-00 epoc BGEM Test Card is identical to its predecessor, the CT-1004-00-00 epoc BGEM Test Card, except for that the CT-1006-00-00 epoc BGEM Test Card features Creatinine and Chloride sensors printed into previously empty sensor wells.

epoc BGEM CT-1004-00-00	epoc BGEM CT-1006-00-00
pH	pH
pCO$_2$	pCO$_2$
pO$_2$	pO$_2$
Sodium Na+	Sodium Na+
Potassium K+	Potassium K+
Ionized Calcium Ca++	Ionized Calcium Ca++
Glucose Glu	Chloride Cl-
Lactate Lac	Glucose Glu
Hematocrit Hct	Lactate Lac
*Bicarbonate cHCO$_3$-	Creatinine Crea
*Total carbon dioxide cTCO$_2$	Hematocrit Hct
*Base excess BE	*Bicarbonate cHCO$_3$-
*Oxygen saturation cSO$_2$	*Total carbon dioxide cTCO$_2$
*Alveolar Oxygen A	*Base excess BE
*Arterial Alveolar Oxygen Tension Gradient A-a	*Oxygen saturation cSO$_2$
*Arterial Alveolar Oxygen Tension Ratio a/A	*Alveolar Oxygen A
*Hemoglobin cHgb	*Arterial Alveolar Oxygen Tension Gradient A-a
	*Arterial Alveolar Oxygen Tension Ratio a/A
	*Anion Gap AGap, AGapK
	*Estimated Glomerular Filtration Rate eGFR, eGFR-a
	*Hemoglobin cHgb
* *calculated values*	* calculated values

Note: Some tests are not available in all markets.

12.2.1   Storage Stability

⚠️ Test Cards must be stored in their Card Pouch at Room Temperature, 15 to 30°C (59 to 86°F), at all times. Never fridge store or allow Test Cards to freeze.

12.2.2   Additional Information

Refer to Section 3 "epoc System Operation" in this manual for detailed sample collection and system operating instructions for conducting a blood test.

Refer to Section 9 "Quality Assurance" in this manual for quality control requirements.

12.2.3   Test Timing

The initiation of a test starts with establishing a communications link between the Host and Reader. Test Card is removed from Card Pouch. Card should be inserted immediately into Reader. During 165 second (approximate) calibration period User acquires blood sample for test. After calibration is complete Reader Indicator and epoc Host inform User that Card is ready to receive blood sample. Card is now ready for sample introduction, and sample can be introduced at any time thereafter for up to 450 seconds (7.5 minutes), after which the sample introduction period times-out, and can no longer accept sample. Approximately 30 seconds after sample introduction, Host displays analytical Test Results and card can be removed from Reader and discarded in biohazard waste.

12.2.4   Sample Type

Fresh whole blood from arterial, venous, or capillary sources, is introduced to the card using a Syringe or epoc Care-Fill™ Blood Collection Tube. See "Sample Collection Details" below for the time periods when the blood is considered fresh and thus suitable for testing.

12.2.5   Sample Volume

At least 92 microliters.

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

12.2.6   Sample Collection

The epoc System is designed for point-of-care blood analysis. Test samples immediately after drawing a sample to obtain results that represent patient status with greatest accuracy.

Please note that all epoc System tests are categorized as having moderate complexity (non-waived status) under CLIA.

Always use ISO594-1 compliant Syringe for sample introduction.

The epoc System is intended to be used with fresh whole blood samples only. Do not use clotted samples.

Always wear protective gloves when handling blood samples.

The specimen used to fill a Test Card must be collected and handled properly to ensure that the results represent Patient's current status.

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

When anticoagulants are needed, use exclusively heparin for the anticoagulant.

See table below for additional options for specific tests and sample collection methods.

Test	Sample Collection Details *(see also References at the end of the present subsection)*		
	Syringes • **1 or 3 mL plastic** • **Without anticoagulant must be run within 3-5 min** • **With Li or Na heparin** • **With balanced heparin**	**Evacuated Tubes** • **With Li or Na heparin** • **Without anticoagulant must be run immediately Note that clot activators may be present in some collection devices**	**Capillary Tubes** • **epoc Care-Fill Capillary Tubes only**
pO_2	• Non-iced syringes [1,2] • Test in less than 30 min[1,2]	• Not recommended[1]	• Test in less than 5 min recommended
pH/pCO_2*	• Test in less than 30 min[1,2]	• Test in less than 30 min[1,2]	• Test in less than 5 min recommended
Ionized Calcium	• With Li or Na heparin only if <10 IU/mL[3] • With balanced heparin only if <70 IU/mL[3] • Test in less than 30 min to avoid artifacts of metabolic activity[1,2,3]	• With Li or Na heparin only if <10 IU/mL[3] • Test in less than 30 min to avoid artifacts of metabolic activity[1,2,3]	• Care-Fill capillary tubes contain 65 IU/mL of calcium balanced lithium heparin • Test in less than 5 min recommended
Glucose	• Test in less than 30 min to avoid effects of glycolysis[11,12]	• With Li or Na heparin only (do not use NaF) • Test in less than 30 min to avoid effects of glycolysis[11,12]	• Test in less than 5 min recommended
Lactate	• Test in less than 5 min to avoid effects of glycolysis[13]	• With Li or Na heparin only (do not use NaF) • Test in less than 5 min to avoid effects of glycolysis[13]	• Test in less than 5 min recommended
Hematocrit	• Immediate testing is recommended in order to avoid RBC settling. (*Note: Re-suspension of RBC requires an air bubble of significant volume[4]*)	• With Li or Na heparin only (do not use EDTA) • Test in less than 1 h to avoid effects of glycolysis and electrolyte shifts[14]	• Immediate testing is recommended in order to avoid RBC settling
All other tests	• Test in less than 1 h to avoid effects of glycolysis and electrolyte shifts[14]	• With Li or Na heparin** • Test in less than 1 h to avoid effects of glycolysis and electrolyte shifts[14]	• Test in less than 5 min recommended

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

** Use of evacuated collection tubes containing Na heparin may cause a positive error on the sodium results.[15] See also Section 12.6.7 D.

12.2.7   Analysis Time

Approximately 35 seconds after sample introduction for Blood Test mode.

Approximately 44 seconds after sample introduction for QA Test mode.

See Section 6 "epoc Host" in this manual for details.

12.2.8   Interpretation of Results

If Patient Test Results are inconsistent with clinical assessment, a fresh Patient sample should be collected and tested on another card.

Look further in this section for information on factors affecting results of various sensors. Certain substances, such as drugs, may affect the Test Results[5-7].

12.2.9   Measurement ranges (some values may be rounded)

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

Measured Parameters				
Test Name	Acronym	Units of Measure	Measurement Range	Reference Range[8-10]
pH	pH	pH units	6.5 – 8.0	7.35 – 7.45 arterial
				7.32 – 7.43 venous
Carbon Dioxide, Partial Pressure	pCO_2	mm Hg	5 – 250	35 – 48 arterial
				41 – 51 venous
		kPa	0.7 – 33.3	4.7 – 6.4 arterial
				5.4 – 6.8 venous
Oxygen, Partial Pressure	pO_2	mm Hg	5 – 750	83 – 108 arterial**
		kPa	0.7 - 100	11.1 – 14.4 arterial**
Sodium	Na+	mmol/L	85 – 180	138 – 146
		mEq/L		
Potassium	K+	mmol/L	1.5 – 12.0	3.5 – 4.5
		mEq/L		
Ionized Calcium	Ca++	mmol/L	0.25 – 4.00	1.15 – 1.33
		mg/dL	1.0 – 16.0	4.6 – 5.3
		mEq/L	0.5 – 8.0	2.3 – 2.7
Chloride	Cl-	mmol/L	65 – 140	98 – 107
		mEq/L		
Glucose*	Glu	mmol/L	1.1 – 38.5	4.1 – 5.5
		mg/dL	20 – 700	74 – 100
		g/L	0.20 – 7.00	0.74 – 1.00
Lactate	Lac	mmol/L	0.30 – 20.00	0.56 – 1.39 venous
		mg/dL	2.7 – 180.2	5.0 – 12.5 venous
		g/L	0.03 – 1.80	0.05 – 0.12 venous
Creatinine	Crea	mg/dL	0.30 – 15.00	0.51 – 1.19
		μmol/L	27 – 1326	45 – 105
Hematocrit	Hct	% PCV	10 – 75	38 – 51
		L/L	0.10 – 0.75	0.38 – 0.51

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

** As per CLSI C46-A2[1], arterial blood samples are preferred for blood gas analysis. Therefore, reference ranges for arterial blood gases may not be directly applied to venous and capillary blood gases. Note that there are conflicting reports[16-21] regarding the validity of pO_2 analysis performed on arterialized capillary blood samples, compared to arterial pO_2. Variability in both capillary collection process and in capillary blood itself may affect test results for pH, pO_2, pCO_2, and calculated sO_2 of capillary samples.

Calculated Parameters				
Test Name	**Acronym**	**Units of Measure**	**Measurement Range**	**Reference Range[8-10,22]**
Actual Bicarbonate	cHCO$_3$-	mmol/L	1 – 85	21 – 28 arterial
				22 – 29 venous
		mEq/L	1 – 85	21 – 28 arterial
				22 – 29 venous
Total Carbon Dioxide	cTCO$_2$	mmol/L	1 – 85	22 – 29 arterial
				23 – 30 venous
		mEq/L	1 – 85	22 – 29 arterial
				23 – 30 venous
Base Excess of Extra Cellular Fluid	BE(ecf)	mmol/L	-30 – +30	-2 – +3
		mEq/L		
Base Excess of Blood	BE(b)	mmol/L	-30 – +30	-2 – +3
		mEq/L		
Oxygen Saturation	cSO$_2$	%	0 – 100	94 – 98 arterial
Alveolar Oxygen	A	mmHg	5-800	†
		kPa	0.67-106.64	†
Arterial Alveolar Oxygen Tension Gradient	A–a	mmHg	1-800	†
		kPa	0.13-106.64	†
Arterial Alveolar Oxygen Tension Ratio	a/A	%	0-100	†
		fraction	0-1	†
Anion Gap	AGap	mmol/L	-14 – +95	7 – 16
		mEq/L		
Anion Gap, K+	AGapK	mmol/L	-10 – +99	10 – 20
		mEq/L		
Estimated Glomerular Filtration Rate	eGFR	mL/min/1.73m^2	2 – 60 or >60*	†
Estimated Glomerular Filtration Rate, if African American	eGFR-a	mL/min/1.73m^2	2 – 60 or >60*	†
Hemoglobin	cHgb	g/dL	3.3 – 25	12 – 17
		mmol/L	2.0 – 15.5	7.4 – 10.6
		g/L	33 – 250	120 – 170

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

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

12.2.10 References

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12.3   pH

pH is measured by potentiometry using a pH selective membrane electrode. The concentration of hydrogen ions is obtained from the measured potential using the Nernst equation.

12.3.1   Indications for Use

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

Measurement of pH, pCO_2, pO_2 (blood gases) is used in the diagnosis and treatment of life-threatening acid-base disturbances.

12.3.2   Contents

Each Test Card incorporating a pH test contains a hydrogen ion sensing electrode with a hydrogen ion selective membrane, a reference electrode and a calibrator fluid containing a known concentration of pH buffer salts.

12.3.3   Traceability

Values of pH assigned to controls and calibrator fluids are traceable to NIST standards.

12.3.4   Sample Collection

Refer to 12.2.6 Sample Collection.

12.3.5   Additional Information

Refer to Section 3 "epoc System Operation" in this manual for detailed sample collection and system operating instructions for conducting a blood test.

Refer to Section 9 "Quality Assurance" in this manual for quality control requirements.

12.3.6   Measurement Range

	Measurement Range	Reference Range[1]	
		Arterial	**Venous**
pH	6.5 – 8.0	7.35 – 7.45	7.32 – 7.43

12.3.7   Temperature Correction

pH is a temperature dependent quantity, measured at 37°C on the epoc System. The pH value can be corrected to the Patient's temperature. Patient temperature is entered on the Test Information Page of the Reader Tab on the epoc Host (see Section 3 "epoc System Operation" in this manual).

The pH at the Patient's temperature (T, °C) is calculated as follows[2]:

pH (T) = pH − 0.0147(T - 37) + 0.0065(7.4 − pH) (T − 37)

12.3.8   Performance Data

Typical performance data summarized below were obtained in-house as well as in healthcare facilities by healthcare professionals trained in the use of the epoc System. Experimental designs conformed to applicable CLSI guidelines.

Applicable standards include: CLSI EP09-A2[3] for method comparison studies, CLSI EP07-A2[4] for interference studies and CLSI EP05-A2[10] for precision studies.

A. Precision Data

Twenty replicates of each of two levels of commercial controls were analyzed at each of 20 different sites. The precision study at each site employed from two (2) to eight (8) epoc Readers, and multiple lots of epoc Test cards were included across all of the sites. The pooled SD and averaged means are presented below:

Aqueous Control	Units	Mean	SD	%CV
High Level	pH units	7.641	0.008	0.1
Low Level	pH units	7.045	0.010	0.1

Because the SDs presented here are the pooled averages from multiple customer performance verifications, it is expected that, occasionally, SDs from an individual precision study to be higher or lower than these averages. Each site must establish whether the results of their precision studies are clinically acceptable. Alternatively, an f-test can be used to determine whether their precision is statistically equivalent to typical precision values summarized above.

B. Linearity Data

This study was performed in-house on multiple whole blood samples with pH values spanning the reportable range. Linearity is reported versus an in-house standard pH electrode method with traceability to NIST standards.

	Test Range	Units	Slope	Intercept	R
pH	6.4 – 7.9	pH units	1.021	-0.15	0.999

C. Clinical Sites Method Comparison Data

Linear regression analysis was performed on the method comparison data in accordance with CLSI EP09-A2[3]. In the method comparison statistics table, N is the number of Patient specimens in the data set, Sxx and Syy are the pooled pair-wise imprecision of the comparative and epoc test methods respectively, Syx is the standard error and R is the correlation coefficient.

Clinical Site Method Comparison 1: In one hospital study, the epoc System was compared with the i-STAT 300[6] in the lab (two test occasions), and then at three point-of-care sites.

Method Comparison Summary Statistics: whole blood

X: i-STAT 300 test

Y: epoc test

pH	Lab 1	Lab 2	POC 1	POC 2	POC 3	All	All*
N	34	24	35	27	22	142	149
Sxx	0.016	0.012	0.010	0.010	0.015	0.013	0.014
Syy	0.005	0.006	0.006	0.006	0.008	0.006	0.007
Intercept	0.152	0.006	0.448	-0.772	-0.367	0.029	0.251
Slope	0.978	0.999	0.938	1.104	1.050	0.995	0.966
Syx	0.019	0.021	0.013	0.015	0.024	0.018	0.020
Xmin	6.991	7.085	7.243	7.223	7.174	6.991	6.770
Xmax	7.592	7.557	7.507	7.522	7.557	7.592	7.982
R	0.993	0.985	0.961	0.981	0.985	0.987	0.991
Mean Bias (pH units)							-0.007

*This data set includes Patient samples spiked with NaOH for extended data range.

Clinical Site Method Comparison 2: In another hospital study, the epoc System was compared with the Radiometer ABL 735[7] in the lab.

Method Comparison Summary Statistics: whole blood

X: Radiometer ABL 735

Y: epoc test

pH	N	Sxx	Syy	Intercept	Slope	Syx	Xmin	Xmax	R	Mean Bias (pH units)
Lab	77	0.011	0.010	0.366	0.952	0.017	7.175	7.542	0.975	0.011

D. Limitations and Interferences

Exposure of the sample to air will affect pH, pCO_2, pO_2 and ionized calcium results due to the sample equilibration with the gas levels in the air, with pH affected by the pCO_2 change[9] and ionized calcium affected by the pH change[8]. Air contains less than 1 mmHg pCO_2 and about 150-180 mmHg pO_2. Do not introduce air bubbles into a collection device. If present, air bubbles should be removed immediately after collection.

Whole blood specimens should not be over-diluted with liquid anti-coagulants or other solutions used in therapies as this may alter results. Refer to 12.2.6 Sample Collection.

Interference testing[4] was performed in-house on the epoc pH sensor. In each of these tests a whole blood specimen was aliquoted into two samples. The test sample was spiked by addition of interferent, while the control sample was spiked by the addition of the solvent of the interferent. The pH bias between the mean of six replicates on both the control

sample and the test sample with added interferent was calculated.

Clinically significant interfering substances are itemized below:

- Samples contaminated with benzalkonium salts used as coatings for in-dwelling lines may cause lower pH results[2]. For proper line-flushing procedures refer to CLSI H11-A4[5].

The following levels of exogenous interferences were tested and found to be clinically insignificant: 447 mg/dL ethanol, 1 mmol/L sodium pentothal, 4.3 mmol/L acetyl salicylate, 0.4 mmol/L ascorbate, 4.3 mmol/L salicylate, 1 mmol/L iodide, 2.2 mmol/L ibuprofen, 1.66 mmol/L acetaminophen, 2 mmol/L ammonium, 4 mmol/L lithium, 35 mmol/L bromide, 2.64 mmol/L propofol, 0.7 mmol/L cefotaxime, 0.16 mmol/L ampicillin, 1 mmol/L sodium perchlorate, 4.8 µM Zofran™, 2.5 mM N-acetylcysteine.

The following levels of endogenous interferences were tested and found to be clinically insignificant: 20 mmol/L NaCl, 8 mmol/L KCl, 3 mmol/L $CaCl_2$, 10 to 120 mmHg $p\text{CO}_2$, pH 6.9 to 7.7, +20 mmol/L bicarbonate, 10 mmol/L lactate, +20% PCV Hct, 3% to 11% total protein, 0.8g/dL lipids, 9.1 mmol/L cholesterol, 20 mmol/L β-hydroxybutyrate, 2mmol/L (24mg/dL) L-cysteine, 0.26 mmol/L bilirubin, +2 mmol/L phosphate.

E. References

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12.4 pCO_2

pCO_2 is measured by potentiometry using a membrane covered pH sensing electrode[9,10]. The electrode voltage is proportional to the dissolved carbon dioxide concentration through the Nernst equation.

12.4.1   Indications for Use

The pCO_2 test, as part of the epoc Blood Analysis System, is intended for use by trained medical professionals as an in vitro diagnostic device for the quantitative testing of samples of heparinized or un-anticoagulated arterial, venous or capillary whole blood in the laboratory or at the point of care.

Measurement of pH, pCO_2, pO_2 (blood gases) is used in the diagnosis and treatment of life-threatening acid-base disturbances.

12.4.2   Contents

Each Test Card incorporating a pCO_2 test contains a pH sensing electrode overlaid with a bicarbonate containing membrane, a carbon dioxide permeable membrane, a reference electrode and a calibrator fluid containing a known concentration of dissolved carbon dioxide.

12.4.3   Traceability

Dissolved carbon dioxide concentration values assigned to controls and calibrator fluids are traceable to NIST standards via commercially available certified gas standards.

12.4.4   Sample Collection

Refer to 12.2.6 Sample Collection.

12.4.5   Additional Information

Refer to Section 3 "epoc System Operation" in this manual for detailed sample collection and system operating instructions for conducting a blood test.

Refer to Section 9 "Quality Assurance" in this manual for quality control requirements.

12.4.6   Measurement Range

	Measurement Range	Reference Range[2]	
		Arterial	Venous
pCO₂	5 – 250 mmHg	35 – 48 mmHg	41 – 51 mmHg
	0.7 – 33.3 kPa	4.7 – 6.4 kPa	5.4 – 6.8 kPa

12.4.7 Temperature Correction

pCO_2 is a temperature dependent quantity, measured at 37°C on the epoc System. The pCO_2 value can be corrected to the Patient's temperature. Patient temperature is entered on the Test Information Page of the Reader Tab on the epoc Host (see Section 3 "epoc System Operation" in this manual).

The pCO_2 at the Patient's temperature (T, °C) is calculated as follows[1]

$$pCO_2 (T) = pCO_2 \times 10^{0.019(T - 37)}$$

12.4.8 Performance Data

Typical performance data summarized below were obtained in-house as well as in healthcare facilities by healthcare professionals trained in the use of the epoc System. Experimental designs conformed to applicable CLSI guidelines.

Applicable standards include: CLSI EP09-A2[4] for method comparison studies, CLSI EP07-A2[7] for interference studies and CLSI EP05-A2[11] for precision studies.

A. Precision Data

Twenty replicates of each of two levels of commercial controls were analyzed at each of 20 different sites. The precision study at each site employed from two (2) to eight (8) epoc Readers, and multiple lots of epoc Test cards were included across all of the sites. The pooled SD and averaged means are presented below:

Aqueous Control	Units	Mean	SD	%CV
High Level	mmHg	67.9	2.5	3.7
Low Level	mmHg	20.8	0.7	3.4

Because the SDs presented here are the pooled averages from multiple customer performance verifications, it is expected that, occasionally, SDs from an individual precision study to be higher or lower than these averages. Each site must establish whether the results of their precision studies are clinically acceptable. Alternatively, an f-test can be used to determine whether their precision is statistically equivalent to typical precision values summarized above.

B. Linearity Data

This study was performed in-house on multiple whole blood samples with pCO_2 values spanning the reportable range. Linearity is reported versus an in-house standard blood gas method with traceability to NIST standards.

	Test Range	Units	Slope	Intercept	R
pCO_2	10-230	mmHg	1.058	-3.6	0.999

C. Clinical Sites Method Comparison Data

Linear regression analysis was performed on the method comparison data in accordance with CLSI EP09-A2[4]. In the method comparison statistics table, N is the number of Patient specimens in the data set, Sxx and Syy are the pooled pair-wise imprecision of the comparative and epoc test methods respectively, Syx is the standard error and R is the correlation coefficient.

Clinical Site Method Comparison 1: In one hospital study, the epoc System was compared with the i-STAT 300[5] in the lab (two test occasions), and then at three (3) point-of-care sites.

Method Comparison Summary Statistics: whole blood

X: i-STAT 300 test

Y: epoc test

pCO_2	Lab 1	Lab 2	POC 1	POC 2	POC 3	All
N	34	24	35	28	22	143
Sxx	1.4	2.1	0.6	1.5	1.7	1.5
Syy	1.3	1.3	0.6	1.1	1.2	1.1
Intercept	-2.0	-1.2	-6.1	5.0	1.0	-0.9
Slope	1.048	1.055	1.167	0.911	0.983	1.041
Syx	3.1	2.3	1.6	2.3	2.4	2.4
Xmin	19.7	26.7	35.6	29.1	23.6	19.7
Xmax	112.2	92.5	54.4	55.6	63.0	112.2
R	0.993	0.991	0.967	0.949	0.978	0.990
Mean Bias (mmHg)						0.8

Clinical Site Method Comparison 2: In another hospital study, the epoc System was compared with the Radiometer ABL 735[6] in the lab.

Method Comparison Summary Statistics: whole blood

X: Radiometer ABL 735

Y: epoc test

pCO_2	N	Sxx	Syy	Intercept	Slope	Syx	Xmin	Xmax	R	Mean Bias (mmHg)
Lab	77	1.5	0.8	1.6	0.924	1.97	27.6	101.5	0.987	-1.445

D. Limitations and Interferences

Exposure of the sample to air will affect pH, pCO_2, pO_2 and ionized calcium results due to the sample equilibration with the gas levels in the air, with pH affected by the pCO_2 change[3] and ionized calcium affected by the pH change[8]. Air contains less than 1 mmHg pCO_2 and about 150-180 mmHg pO_2. Do not introduce air bubbles into a collection device. If present, air bubbles should be removed immediately after collection.

Whole blood specimens should not be over-diluted with liquid anti-coagulants or other solutions used in therapies as this may alter results. Refer to 12.2.6 Sample Collection.

Interference testing[7] was performed in-house on the epoc pCO_2 sensor. In each of these tests a whole blood specimen was aliquoted into two samples. The test sample was spiked by addition of interferent, while the control sample was spiked by the addition of the solvent of the interferent. The pCO_2 bias between the mean of six replicates on both the control sample and the test sample with added interferent was calculated.

Clinically significant interfering substances are itemized below:

- Bromide will increase the pCO_2 by 0.19 mmHg/mM bromide

The following levels of exogenous interferences were tested and found to be clinically insignificant: 447 mg/dL ethanol, 1 mmol/L sodium pentothal, 4.3 mmol/L acetyl salicylate, 0.4 mmol/L ascorbate, 4.3 mmol/L salicylate, 2.2 mmol/L ibuprofen, 1.66 mmol/L acetaminophen, 2 mmol/L ammonium, 4 mmol/L lithium, 0.4 mmol/L iodide, 2.64 mmol/L propofol, 0.7 mmol/L cefotaxime, 0.16 mmol/L ampicillin, 1 mmol/L sodium perchlorate, 4.8 µM Zofran™, 2.5 mM N-acetylcysteine, 0.7 mM metronidazole.

The following levels of endogenous interferences were tested and found to be clinically insignificant: 20 mmol/L NaCl, 8 mmol/L KCl, 3 mmol/L $CaCl_2$, pH 6.9 to 7.7, +20 mmol/L bicarbonate, 10 mmol/L lactate, +20% PCV Hct, 3% to 11% total protein, 0.8g/dL lipids, 9.1 mmol/L cholesterol, 20 mmol/L β-hydroxybutyrate, 2mmol/L (24mg/dL) L-cysteine, 0.26 mmol/L bilirubin, +2 mmol/L phosphate.

E. References

1. CLSI. Blood Gas and pH Analysis and Related Measurements; Approved Guideline, CLSI C46-A2, Vol. 29, No. 8, Blood gas and pH analysis and related measurements-Approved Guideline, second edition, Wayne, Pennsylvania, USA, 2009.

2. Reference Ranges Table 56-1 in Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, fourth edition, C.A. Burtis, E.R. Ashwood, and D.E. Bruns eds., Elsevier Saunders, St. Louis, 2006.

3. M.G. Scott, V.A. LeGrys and J.S. Klutts, Chapter 27 of Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, fourth edition, C.A. Burtis, E.R. Ashwood, and D.E. Bruns eds., Elsevier Saunders, St. Louis, 2006.

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5. i-STAT 300, Abbott Point of Care Inc., 104 Windsor Center Drive, East Windsor, NJ 08520, "i-STAT" is a registered trademark of Abbott Laboratories.

6. Radiometer ABL 735, Radiometer Medical ApS, Åkandevej 21, DK-2700 Brønshøj, Denmark, "Radiometer" and "ABL" are registered trademarks of Radiometer Medical ApS.

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12.5 $p\text{O}_2$

$p\text{O}_2$ is measured by amperometry using a membrane covered oxygen sensing cathode electrode. The oxygen reduction current is proportional to the dissolved oxygen concentration[9].

12.5.1 Indications for Use

The $p\text{O}_2$ test, as part of the epoc Blood Analysis System, is intended for use by trained medical professionals as an in vitro diagnostic device for the quantitative testing of samples of heparinized or un-anticoagulated arterial, venous or capillary whole blood in the laboratory or at the point of care.

Measurement of pH, $p\text{CO}_2$, $p\text{O}_2$ (blood gases) is used in the diagnosis and treatment of life-threatening acid-base disturbances.

12.5.2 Contents

Each Test Card incorporating a $p\text{O}_2$ test contains a sensing electrode with a oxygen permeable membrane, a reference electrode, a counter electrode and a calibrator fluid containing a known concentration of dissolved oxygen.

12.5.3 Traceability

Dissolved oxygen concentration values assigned to controls and calibrator fluids are traceable to NIST standards via commercially available certified gas standards.

12.5.4 Sample Collection

Refer to 12.2.6 Sample Collection.

12.5.5 Additional Information

Refer to Section 3 "epoc System Operation" in this manual for detailed sample collection and system operating instructions for conducting a blood test.

Refer to Section 9 "Quality Assurance" in this manual for quality control requirements.

12.5.6 Measurement Range

	Measurement Range	Reference Range[3], Arterial
$p\text{O}_2$	5 – 750 mmHg	83 – 108 mmHg
	0.7 – 100 kPa	11.1 – 14.4 kPa

Refer to Sections 5.2.2, 5.2.3, and 5.2.4 of CLSI C46-A2[1] for more information on sample types.

12.5.7   Temperature Correction

pO_2 is a temperature dependent quantity, measured at 37°C on the epoc System. The pO_2 value can be corrected to the Patient's temperature. Patient temperature is entered on the Test Information Page of the Reader Tab on the epoc Host (see Section 3 "epoc System Operation" in this manual).

The pO_2 at the Patient's temperature (T, °C) is calculated as follows[1]

$$pO_2\ (T) = pO_2 \times 10^{\frac{5.49x10^{-11}\,pO_2{}^{3.88}+0.071}{9.71x10^{-9}\,pO_2{}^{3.88}+2.30}(T-37)}$$

12.5.8   Performance Data

Typical performance data summarized below were obtained in-house as well as in healthcare facilities by healthcare professionals trained in the use of the epoc System. Experimental designs conformed to applicable CLSI guidelines.

Applicable standards include: CLSI EP09-A2[4] for method comparison studies, CLSI EP07-A2[7] for interference studies and CLSI EP05-A2[10] for precision studies.

A. Precision Data

Twenty replicates of each of two levels of commercial controls were analyzed at each of 20 different sites. The precision study at each site employed from two (2) to eight (8) epoc Readers, and multiple lots of epoc Test cards were included across all of the sites. The pooled SD and averaged means are presented below:

Aqueous Control	Units	Mean	SD	%CV
High Level	mmHg	181.7	6.2	3.4
Low Level	mmHg	63.8	4.1	6.4

Because the SDs presented here are the pooled averages from multiple customer performance verifications, it is expected that, occasionally, SDs from an individual precision study to be higher or lower than these averages. Each site must establish whether the results of their precision studies are clinically acceptable. Alternatively, an f-test can be used to determine whether their precision is statistically equivalent to typical precision values summarized above.

B. Linearity Data

This study was performed in-house on multiple whole blood samples with pO_2 values spanning the reportable range. Linearity is reported versus an in-house standard blood gas method with traceability to NIST standards.

	Test Range	Units	Slope	Intercept	R
pO_2	10 – 750	mmHg	1.022	-3.9	0.9995

C. Clinical Sites Method Comparison Data

Linear regression analysis was performed on the method comparison data in accordance with CLSI EP09-A2[4]. In the method comparison statistics table, N is the number of Patient specimens in the data set, Sxx and Syy are the pooled pair-wise imprecision of the comparative and epoc test methods respectively, Syx is the standard error and R is the correlation coefficient.

Clinical Site Method Comparison 1: In one hospital study, the epoc System was compared with the i-STAT 300[5] in the lab (two test occasions), and then at three point-of-care sites.

Method Comparison Summary Statistics: whole blood

X: i-STAT 300 test

Y: epoc test

pO_2	Lab 1	Lab 2	POC 1	POC 2	POC 3	All
N	34	23	35	28	22	142
Sxx	2.6	4.3	3.2	6.2	2.7	4.6
Syy	1.7	3.5	3.0	2.9	2.6	2.7
Intercept	-6.5	-3.1	-1.3	0.3	-3.9	-1.7
Slope	1.142	1.006	1.083	1.041	1.090	1.053
Syx	8.5	4.5	4.5	4.9	4.2	6.6
Xmin	26.0	35.0	43.5	36.0	35.5	26.0
Xmax	174.5	226.5	185.0	187.5	166.0	226.5
R	0.977	0.995	0.995	0.990	0.994	0.978
Mean Bias (mmHg)						1.2

Clinical Site Method Comparison 2: In another hospital study, the epoc System was compared with the Radiometer ABL 735[6] in the lab.

Method Comparison Summary Statistics: whole blood

X: Radiometer ABL 735

Y: epoc test

pO_2	N	Sxx	Syy	Intercept	Slope	Syx	Xmin	Xmax	R	Mean Bias (mmHg)
Lab	77	3.4	3.7	-0.8	1.117	5.1	10.2	278.5	0.997	5.0

D. Limitations and Interferences

Exposure of the sample to air will affect pH, pCO_2, pO_2 and ionized calcium results due to the sample equilibration with the gas levels in the air, with pH affected by the pCO_2 change[1] and ionized calcium affected by the pH change[8]. Air contains less than 1 mmHg pCO_2 and about 150-180 mmHg pO_2. Do not introduce air bubbles into a collection device. If present, air bubbles should be removed immediately after collection.

Whole blood specimens should not be over-diluted with liquid anti-coagulants or other solutions used in therapies as this may alter results. Refer to 12.2.6 Sample Collection.

Interference testing[7] was performed in-house on the epoc pO_2 sensor. In each of these tests a whole blood specimen was aliquoted into two samples. The test sample was spiked by addition of interferent, while the control sample was spiked by the addition of the solvent of the interferent. The pO_2 bias between the mean of six replicates on both the control sample and the test sample with added interferent was calculated.

Clinically significant interfering substances are itemized below:

- Metronidazole will cause an average bias of +4 mmHg/100µM metronidazole. Note that as per CLSI EP07-A2[7], therapeutic levels of metronidazole range between 35 and 234µM.

The following levels of exogenous interferences were tested and found to be clinically insignificant: 447 mg/dL ethanol, 1 mmol/L sodium pentothal, 4.3 mmol/L acetyl salicylate, 0.4 mmol/L ascorbate, 4.3 mmol/L salicylate, 1 mmol/L iodide, 2.2 mmol/L ibuprofen, 1.66 mmol/L acetaminophen, 2 mmol/L ammonium, 4 mmol/L lithium, 37.5 mmol/L bromide, 2.7% halothane, 2.64 mmol/L propofol, 0.7 mmol/L cefotaxime, 0.16 mmol/L ampicillin, 1 mmol/L sodium perchlorate, 4.8 µM Zofran™, 2.5 mM N-acetylcysteine.

The following levels of endogenous interferences were tested and found to be clinically insignificant: 20 mmol/L NaCl, 8 mmol/L KCl, 3 mmol/L $CaCl_2$, 10 to 120 mmHg pCO_2, pH 6.9 to 7.7, +20 mmol/L bicarbonate, 10 mmol/L lactate, +20% PCV Hct, 3% to 11% total protein, 0.8g/dL lipids, 9.1 mmol/L cholesterol, 20 mmol/L β-hydroxybutyrate, 1 mmol/L L-cysteine, 0.26 mmol/L bilirubin, +2 mmol/L phosphate.

E. References

1. CLSI. Blood Gas and pH Analysis and Related Measurements; Approved Guideline, CLSI C46-A2, Vol. 29, No. 8, Blood gas and pH analysis and related measurements- Approved Guideline, second edition, Wayne, Pennsylvania, USA, 2009.
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3. Reference Ranges Table 56-1 in Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, fourth edition, C.A. Burtis, E.R. Ashwood, and D.E. Bruns eds., Elsevier Saunders, St. Louis, 2006.
4. CLSI. Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline, second edition, CLSI document EP09-A2 (ISBN 1-56238-472-4), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2002.
5. i-STAT 300, Abbott Point of Care Inc., 104 Windsor Center Drive, East Windsor, NJ 08520, "i-STAT" is a registered trademark of Abbott Laboratories.
6. Radiometer ABL 735, Radiometer Medical ApS, Åkandevej 21, DK-2700 Brønshøj, Denmark, "Radiometer" and "ABL" are registered trademarks of Radiometer Medical ApS.
7. CLSI. Interference Testing in Clinical Chemistry; Approved Guideline, CLSI document EP07-A2 (ISBN 1-56238-480-5), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2002.
8. D.B. Endres and R.K. Rude, Chapter 49 (p. 1901) of Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, fourth edition, C.A. Burtis, E.R. Ashwood, and D.E. Bruns eds., Elsevier Saunders, St. Louis, 2006.
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10. CLSI. Evaluation of Precision in Clinical Chemistry Devices; Approved Guideline, second edition, CLSI document EP05-A2 (ISBN 1-56238-542-9), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004.

12.6   Sodium (Na+)

Sodium is measured by potentiometry using an ion selective membrane electrode. The concentration of sodium ions is obtained from the measured potential using the Nernst equation. The epoc sodium measurement is an undiluted (direct) method. Values may differ from those obtained by dilutional (indirect) methods.[1]

12.6.1   Indications for Use

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

Measurement of sodium is used in diagnosis and treatment of diseases involving electrolyte imbalance.

12.6.2   Contents

Each Test Card incorporating a sodium test contains a sodium sensing electrode with a sodium selective membrane, a reference electrode and a calibrator fluid containing a known concentration of sodium salts.

12.6.3   Traceability

Values of sodium ion concentration assigned to controls and calibrator fluids are traceable to NIST standards.

12.6.4   Sample Collection

Refer to 12.2.6 Sample Collection.

12.6.5   Additional Information

Refer to Section 3 "epoc System Operation" in this manual for detailed sample collection and system operating instructions for conducting a blood test.

Refer to Section 9 "Quality Assurance" in this manual for quality control requirements.

12.6.6   Measurement Range

	Measurement Range	Reference Range[2,3]
Na+	85 – 180 mmol/L	138 – 146 mmol/L
	85 – 180 mEq/L	138 – 146 mEq/L

12.6.7   Performance Data

Typical performance data summarized below were obtained in-house as well as in healthcare facilities by healthcare professionals trained in the use of the epoc System. Experimental designs conformed to applicable CLSI guidelines.

Applicable standards include: CLSI EP09-A2[4] for method comparison studies, CLSI EP07-A2[5] for interference studies and CLSI EP05-A2[12] for precision studies.

A. Precision Data

Twenty replicates of each of two levels of commercial controls were analyzed at each of 20 different sites. The precision study at each site employed from two (2) to eight (8) epoc Readers, and multiple lots of epoc Test cards were included across all of the sites. The pooled SD and averaged means are presented below:

Aqueous Control	Units	Mean	SD	%CV
High Level	mmol/L	164.3	0.98	0.6
Low Level	mmol/L	112.5	0.76	0.7

Because the SDs presented here are the pooled averages from multiple customer performance verifications, it is expected that, occasionally, SDs from an individual precision study to be higher or lower than these averages. Each site must establish whether the results of their precision studies are clinically acceptable. Alternatively, an f-test can be used to determine whether their precision is statistically equivalent to typical precision values summarized above.

B. Linearity Data

This study was performed in-house on multiple whole blood samples with sodium concentration spanning the reportable range. Linearity is reported versus an in-house standard ion selective electrode method with traceability to NIST standards.

	Test Range	Units	Slope	Intercept	R
Na+	80-190	mmol/L	0.973	3.8	0.9995

C. Clinical Sites Method Comparison Data

Linear regression analysis was performed on the method comparison data in accordance with CLSI EP09-A2[4]. In the method comparison statistics table, N is the number of Patient specimens in the data set, Sxx and Syy are the pooled pair-wise imprecision of the comparative and epoc test methods respectively, Syx is the standard error and R is the correlation coefficient.

Clinical Site Method Comparison 1: In one (1) hospital study, the epoc System was compared with the i-STAT 300[6] in the lab (2 test occasions) then at three (3) point-of-care sites:

Method Comparison Summary Statistics: whole blood

X: i-STAT 300 test

Y: epoc test

Na+	Lab 1	Lab 2	POC 1	POC 2	POC 3	All	All*
N	34	24	35	27	22	142	156
Sxx	0.79	0.61	0.48	0.62	0.45	0.61	0.62
Syy	0.77	0.82	0.84	0.89	0.66	0.80	0.88
Intercept	22.2	8.4	5.3	27.9	28.9	8.8	-9.6
Slope	0.839	0.944	0.963	0.812	0.803	0.941	1.077
Syx	2.18	2.07	1.67	1.38	2.46	2.05	2.22
Xmin	125	123	130	135	130	123	123
Xmax	143	145	143	146	146	146	179
R	0.822	0.914	0.888	0.847	0.813	0.880	0.953
Mean Bias (mM)							0.77

*This data set includes Patient samples spiked with NaCl for extended data range.

Clinical Site Method Comparison 2: In another hospital study, the epoc System was compared with the Radiometer ABL 735[7] in the lab.

Method Comparison Summary Statistics: whole blood

X: Radiometer ABL 735

Y: epoc test

Na+	N	Sxx	Syy	Intercept	Slope	Syx	Xmin	Xmax	R	Mean Bias (mM)
Lab	77	0.78	0.79	19.1	0.881	1.81	131	160	0.924	2.67

D. Limitations and Interferences

Similar to other dry reagent methods, a decrease (increase) of total protein will increase (decrease) Na+ by 1.3 mM/(g/dL) versus a direct method. The epoc Na+ result tracks the reading of an indirect (dilutional) method[1,8,9].

Concordant with direct methods, hyperlipidemia does not affect the Na+ measurement[8,9]. The effect of Intralipid was tested up to 5% (lipid vol)/(plasma vol) and was found to be clinically insignificant.

Whole blood specimens should not be over-diluted with liquid anti-coagulants or other solutions used in therapies as this may alter results. Refer to 12.2.6 Sample Collection.

Interference testing[5] was performed in-house on the epoc sodium sensor. In each of these tests a whole blood specimen was aliquoted into two (2) samples. The test sample was spiked by addition of an interferent, while the control sample was spiked by the addition of the solvent of the interferent. The sodium bias between the mean of six (6) replicates on both the control sample and the test sample with added interferent was calculated.

Clinically significant interfering substances are itemized below:

- Use of evacuated collection tubes containing Na heparin may give erroneously high sodium results. The effect from the sodium heparin in these tubes is to increase the sodium result by approximately 1-2 mmol/L[13]
- 20 mmol/L β-hydroxybutyrate will decrease Na+ by 3 mmol/L
- 16 mmol/L bromide will increase sodium by 5 mmol/L
- Samples contaminated with benzalkonium salts used as coatings for in-dwelling lines may cause significant elevation of sodium results[10]. For proper line-flushing procedures refer to CLSI H11[11].

Systematic errors in sodium readings may occur with over 20% hemodilution of plasma using solutions that are not consistent with the ionic characteristics of plasma, such as Normal Saline, Ringer's (Baxter Healthcare Corporation), and 10% Dextrose (Baxter Healthcare Corporation).

Hemodilution is associated with priming cardiopulmonary bypass pumps, plasma volume expansion, or other fluid administration therapies.

Such errors are prevented when physiologically balanced multi-electrolyte intravenous solutions containing low mobility anions that match the ionic characteristics of plasma, such as Plasma-Lyte™-A (Baxter Healthcare Corporation), Lactated Ringer's (Baxter Healthcare Corporation), Lactated Ringer's + 5% Dextrose injection (Baxter Healthcare Corporation), Plasbumin™-5 (Telacris Biotherapeutics), Pentaspan™ (Bristol-Myers Squibb), and Voluven™ (Fresenius Kabi) are used.

The following levels of exogenous interferences were tested and found to be clinically insignificant: 447 mg/dL ethanol, 1 mmol/L sodium pentothal, 4.3 mmol/L acetyl salicylate, 0.4 mmol/L ascorbate, 4.3 mmol/L salicylate, 0.7 mmol/L iodide, 2.2 mmol/L ibuprofen, 1.66 mmol/L acetaminophen, 2 mmol/L ammonium, 4 mmol/L lithium, 3 µmol/L dobutamine , 2.5 mmol/L tolbutamide, 2.64 mmol/L propofol, 0.7 mmol/L cefotaxime, 0.16 mmol/L ampicillin, 1 mmol/L sodium perchlorate, 4.8 µM Zofran™, 2.5 mM N-acetylcysteine, 0.7 mM metronidazole.

The following levels of endogenous interferences were tested and found to be clinically insignificant: 8 mmol/L KCl, 3 mmol/L $CaCl_2$, 10 to 120 mmHg pCO$_2$, pH 6.9 to 7.7, +20 mmol/L bicarbonate, +20% PCV Hct, 9.1 mmol/L cholesterol, 2mmol/L (24mg/dL) L-cysteine, 0.26 mmol/L bilirubin, +2 mmol/L phosphate.

E. References

1. M.G. Scott, V.A. LeGrys and J.S. Klutts, Chapter 27 of Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, fourth edition, C.A. Burtis, E.R. Ashwood, and D.E. Bruns eds., Elsevier Saunders, St. Louis, 2006.

2. Reference Ranges Table 56-1 in Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, fourth edition, C.A. Burtis, E.R. Ashwood, and D.E. Bruns eds., Elsevier Saunders, St. Louis, 2006.

3. B.E. Statland, Clinical Decision Levels for Lab Tests, Medical Economic Books, Oradell, NJ, 1987.

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6. i-STAT 300, Abbott Point of Care Inc., 104 Windsor Center Drive, East Windsor, NJ 08520, "i-STAT" is a registered trademark of Abbott Laboratories.

7. Radiometer ABL 735, Radiometer Medical ApS, Åkandevej 21, DK-2700 Brønshøj, Denmark, "Radiometer" and "ABL" are registered trademarks of Radiometer Medical ApS.

8. G. Dimeski, R. J. Barnett, "Effects of Total Plasma Protein Concentration on Plasma Sodium, Potassium and Chloride Measurements by an Indirect Ion Selective Electrode Measurement System", Critical Care and Resuscitation, 7, 12-15, 2005.

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12.7 Potassium (K+)

Potassium is measured by potentiometry using an ion selective membrane electrode. The concentration of potassium ions is obtained from the measured potential using the Nernst equation. The epoc potassium measurement is an undiluted (direct) method. Values may differ from those obtained by dilutional (indirect) methods.[1]

12.7.1 Indications for Use

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

Measurement of potassium is used in diagnosis and treatment of diseases involving electrolyte imbalance.

12.7.2 Contents

Each Test Card incorporating a potassium test contains a potassium sensing electrode with a potassium selective membrane, a reference electrode, and calibrator fluid containing a known concentration of potassium salts.

12.7.3 Traceability

Values of potassium ion concentration assigned to controls and calibrator fluids are traceable to NIST standards

12.7.4 Sample Collection

Refer to 12.2.6 Sample Collection.

12.7.5 Additional Information

Refer to Section 3 "epoc System Operation" in this manual for detailed sample collection and system operating instructions for conducting a blood test.

Refer to Section 9 "Quality Assurance" in this manual for quality control requirements.

12.7.6 Measurement Range

	Measurement Range	Reference Range[2]
K+	1.5 – 12.0 mmol/L	3.5 – 4.5 mmol/L
	1.5 – 12.0 mEq/L	3.5 – 4.5 mEq/L

If a K result is higher than as per clinical status, the blood sample should be spun down and evaluated for hemolysis either visually or on a lab analyzer.

12.7.7 Performance Data

Typical performance data summarized below were obtained in-house as well as in healthcare facilities by healthcare professionals trained in the use of the epoc System. Experimental designs conformed to applicable CLSI guidelines.

Applicable standards include: CLSI EP09-A2[3] for method comparison studies, CLSI EP07-A2[4] for interference studies and CLSI EP05-A2[9] for precision studies.

A. Precision Data

Twenty replicates of each of two levels of commercial controls were analyzed at each of 20 different sites. The precision study at each site employed from two (2) to eight (8) epoc Readers, and multiple lots of epoc Test cards were included across all of the sites. The pooled SD and averaged means are presented below:

Aqueous Control	Units	Mean	SD	%CV
High Level	mmol/L	6.09	0.06	1.0
Low Level	mmol/L	2.1	0.04	1.9

Because the SDs presented here are the pooled averages from multiple customer performance verifications, it is expected that, occasionally, SDs from an individual precision study to be higher or lower than these averages. Each site must establish whether the results of their precision studies are clinically acceptable. Alternatively, an f-test can be used to determine whether their precision is statistically equivalent to typical precision values summarized above.

B. Linearity Data

This study was performed in-house on multiple whole blood samples with potassium concentration spanning the reportable range. Linearity is reported versus an in-house standard ion selective electrode method with traceability to NIST standards.

	Test Range	Units	Slope	Intercept	R
K+	1.5-12	mmol/L	1.006	0.03	0.9995

C. Clinical Sites Method Comparison Data

Linear regression analysis was performed on the method comparison data in accordance with CLSI EP09-A2[3]. In the method comparison statistics table, N is the number of Patient specimens in the data set, Sxx and Syy are the pooled pair-wise imprecision of the comparative and epoc test methods respectively, Syx is the standard error and R is the correlation coefficient.

Clinical Site Method Comparison 1: In one hospital study, the epoc System was compared with the i-STAT 300[5] in the lab (two test occasions), and then at three (3) point-of-care sites.

Method Comparison Summary Statistics: whole blood

X: i-STAT 300 test

Y: epoc test

K+	Lab 1	Lab 2	POC 1	POC 2	POC 3	All	All*
N	34	24	35	27	22	142	146
Sxx	0.040	0.061	0.040	0.061	0.030	0.047	0.048
Syy	0.043	0.052	0.045	0.045	0.045	0.046	0.049
Intercept	-0.164	-0.144	-0.171	-0.134	0.134	-0.044	-0.018
Slope	1.056	1.042	1.051	1.057	0.971	1.021	1.013
Syx	0.088	0.114	0.057	0.077	0.114	0.094	0.094
Xmin	2.5	3.0	2.6	2.9	3.3	2.5	2.5
Xmax	6.1	4.8	5.1	4.9	6.7	6.7	7.8
R	0.991	0.979	0.993	0.993	0.988	0.989	0.993
Mean Bias (mM)							0.04

*This data set includes Patient samples spiked with KCl for extended data range.

Clinical Site Method Comparison 2: In another hospital study, the epoc System was compared with the Radiometer ABL 735[6] in the lab.

Method Comparison Summary Statistics: whole blood

X: Radiometer ABL 735

Y: epoc test

K+	N	Sxx	Syy	Intercept	Slope	Syx	Xmin	Xmax	R	Mean Bias (mM)
Lab	77	0.057	0.044	-0.073	1.026	0.090	2.4	7.1	0.996	0.05

D. Limitations and Interferences

Sample hemolysis will cause elevated potassium values. Improper sample collection technique may cause variation in potassium values due to hemolysis[1].

Whole blood specimens should not be over-diluted with liquid anti-coagulants or other solutions used in therapies as this may alter results. Refer to 12.2.6 Sample Collection.

Interference testing[4] was performed in-house on the epoc potassium sensor. In each of these tests a whole blood specimen was aliquoted into two samples. The test sample was spiked by addition of an interferent, while the control sample was spiked by the addition of the solvent of the interferent. The potassium bias between the mean of six (6) replicates on both the control sample and the test sample with added interferent was calculated.

Clinically significant interfering substances are itemized below:

- Samples contaminated with benzalkonium salts used as coatings for in-dwelling lines may cause significant elevation of potassium results[7]. For proper line-flushing procedures refer to CLSI H11-A4[8].

The following levels of exogenous interferences were tested and found to be clinically insignificant: 447 mg/dL ethanol, 1 mmol/L sodium pentothal, 4.3 mmol/L acetyl salicylate, 0.4 mmol/L ascorbate, 4.3 mmol/L salicylate, 0.7 mmol/L iodide, 2.2 mmol/L ibuprofen, 1.66 mmol/L acetaminophen, 2 mmol/L ammonium, 4 mmol/L lithium, 38 mmol/L bromide, 3 μmol/L dobutamine , 2.5 mmol/L tolbutamide, 2.64 mmol/L propofol, 0.7 mmol/L

cefotaxime, 0.16 mmol/L ampicillin, 1 mmol/L sodium perchlorate, 4.8 µM Zofran™, 2.5 mM N-acetylcysteine, 0.7 mM metronidazole.

The following levels of endogenous interferences were tested and found to be clinically insignificant: 20 mmol/L NaCl, 3 mmol/L $CaCl_2$, 10 to 120 mmHg pCO_2, pH 6.9 to 7.7, +20 mmol/L bicarbonate, 10 mmol/L lactate, +20% PCV Hct, 3% to 11% total protein, 0.8g/dL lipids, 9.1 mmol/L cholesterol, 20 mmol/L β-hydroxybutyrate, 2mmol/L (24mg/dL) L-cysteine, 0.26 mmol/L bilirubin, +2 mmol/L phosphate.

E. References

1. M.G. Scott, V.A. LeGrys and J.S. Klutts, Chapter 27 of Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, fourth edition, C.A. Burtis, E.R. Ashwood, and D.E. Bruns eds., Elsevier Saunders, St. Louis, 2006.

2. Reference Ranges Table 56-1 in Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, fourth edition, C.A. Burtis, E.R. Ashwood, and D.E. Bruns eds., Elsevier Saunders, St. Louis, 2006.

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12.8 Ionized Calcium (Ca++)

Note: **Ca++** and **iCa** *are equivalent analyte acronyms that stand for ionized calcium.*

Ionized calcium is measured by potentiometry using an ion selective membrane electrode. The concentration of calcium ions is obtained from the measured potential using the Nernst equation.

12.8.1 Indications for Use

The ionized calcium test, as part of the epoc Blood Analysis System, is intended for use by trained medical professionals as an in vitro diagnostic device for the quantitative testing of samples of heparinized or un-anticoagulated arterial, venous or capillary whole blood in the laboratory or at the point of care.

Measurement of ionized calcium is used in diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany.

12.8.2 Contents

Each Test Card incorporating an ionized calcium test contains a calcium ion sensing electrode with a calcium selective membrane, a reference electrode and a calibrator fluid containing a known concentration of calcium salts.

12.8.3 Traceability

Values of calcium ion concentration assigned to controls and calibrator fluids are traceable to NIST standards

12.8.4 Sample Collection

Refer to 12.2.6 Sample Collection.

12.8.5 Additional Information

Refer to Section 3 "epoc System Operation" in this manual for detailed sample collection and system operating instructions for conducting a blood test.

Refer to Section 9 "Quality Assurance" in this manual for quality control requirements.

12.8.6 Measurement Range

	Measurement Range	**Reference Range[1]**
Ca++	0.25 – 4.00 mmol/L	1.15 – 1.33 mmol/L
	1.0 – 16.0 mg/dL	4.6 – 5.3 mg/dL
	0.5 – 8.0 mEq/L	2.3 – 2.7 mEq/L

12.8.7 Performance Data

Typical performance data summarized below were obtained in-house as well as in healthcare facilities by healthcare professionals trained in the use of the epoc System. Experimental designs conformed to applicable CLSI guidelines.

Applicable standards include: CLSI EP09-A2[2] for method comparison studies, CLSI EP07-A2[3] for interference studies and CLSI EP05-A2[11] for precision studies.

A. Precision Data

Twenty replicates of each of two levels of commercial controls were analyzed at each of 20 different sites. The precision study at each site employed from two (2) to eight (8) epoc Readers, and multiple lots of epoc Test cards were included across all of the sites. The pooled SD and averaged means are presented below:

Aqueous Control	Units	Mean	SD	%CV
High Level	mmol/L	1.56	0.018	1.2
Low Level	mmol/L	0.66	0.011	1.7

Because the SDs presented here are the pooled averages from multiple customer performance verifications, it is expected that, occasionally, SDs from an individual precision study to be higher or lower than these averages. Each site must establish whether the results of their precision studies are clinically acceptable. Alternatively, an f-test can be used to determine whether their precision is statistically equivalent to typical precision values summarized above.

B. Linearity Data

This study was performed in-house on multiple whole blood samples with ionized calcium concentration spanning the reportable range. Linearity is reported versus an in-house standard ion selective electrode method with traceability to NIST standards.

	Test Range	Units	Slope	Intercept	R
Ca++	0.6-3.7	mmol/L	1.017	-0.01	0.999

C. Clinical Sites Method Comparison Data

Linear regression analysis was performed on the method comparison data in accordance with CLSI EP09-A2[2]. In the method comparison statistics table, N is the number of Patient specimens in the data set, Sxx and Syy are the pooled pair-wise imprecision of the comparative and epoc test methods respectively, Syx is the standard error and R is the correlation coefficient.

Clinical Site Method Comparison 1: In one hospital study, the epoc System was compared with the i-STAT 300[4] in the lab (two test occasions), and then at three point-of-care sites.

Method Comparison Summary Statistics: whole blood

X: i-STAT 300 test

Y: epoc test

Ca++	Lab 1	Lab 2	POC 1	POC 2	POC 3	All	All*
N	34	24	35	28	22	143	156
Sxx	0.016	0.019	0.014	0.017	0.015	0.016	0.016
Syy	0.011	0.014	0.017	0.014	0.015	0.014	0.015
Intercept	0.003	0.050	0.157	0.106	0.103	0.102	-0.026
Slope	0.980	0.953	0.851	0.925	0.923	0.908	1.021
Syx	0.025	0.033	0.020	0.016	0.024	0.029	0.031
Xmin	0.8	0.9	1.1	1.0	1.0	0.8	0.80
Xmax	1.4	1.6	1.3	1.3	1.3	1.6	2.20
R	0.974	0.961	0.891	0.978	0.939	0.943	0.985
Mean Bias (mM)							0.014

*This data set includes Patient samples spiked with $CaCl_2$ for extended data range.

Clinical Site Method Comparison 2: In another hospital study the epoc System was compared with the Radiometer ABL 735[5] in the lab.

Method Comparison Summary Statistics: whole blood

X: Radiometer ABL 735

Y: epoc test

Ca++	N	Sxx	Syy	Intercept	Slope	Syx	Xmin	Xmax	R	Mean Bias (mM)
Lab	77	0.023	0.016	-0.045	1.025	0.040	0.34	1.52	0.981	-0.013

D. Limitations and Interferences

Specimen choice, collection technique, anti-coagulant type and level as well as sample handling will affect the concentration of ionized calcium[6].

Exposure of the sample to air will affect pH, pCO_2, pO_2 and ionized calcium results due to the sample equilibration with the gas levels in the air, with pH affected by the pCO_2 change[7] and ionized calcium affected by the pH change[8]. Air contains less than 1 mmHg pCO_2 and about 150-180 mmHg pO_2. Do not introduce air bubbles into a collection device. If present, air bubbles should be removed immediately after collection.

Whole blood specimens should not be over-diluted with liquid anti-coagulants or other solutions used in therapies as this may alter results. Refer to 12.2.6 Sample Collection.

Interference testing[3] was performed in-house on the ionized calcium sensor. In each of these tests a whole blood specimen was aliquoted into two samples. The test sample was spiked by addition of interferent, while the control sample was spiked by the addition of the solvent of the interferent. The ionized calcium bias between the mean of six replicates on both the control sample and the test sample with added interferent was calculated.

Clinically significant interfering substances are itemized below:

- 20 mmol/L β-hydroxybutyrate will decrease Ca++ by 0.038 mmol/L;
- 4.3 mmol/L salicylate or acetyl salicylate will decrease Ca++ by 0.06 mmol/L. Therapeutic range for salicylate is 0.1mM to 2 mM (1.4 mg/dL to 27.4 mg/dL)[13];
- 10 mmol/L bromide will increase Ca++ by 0.05 mmol/L;
- 1 mmol/L sodium perchlorate will decrease Ca++ by 0.23 mmol/L.

The therapeutic level for perchlorate is in the range of 100–1000 mg/dL. No effect has been observed in persons exposed at 0.5 mg/dL or below[12].

Samples contaminated with benzalkonium salts used as coatings for in-dwelling lines may cause significant elevation of ionized calcium results[9]. For proper line-flushing procedures refer to CLSI H11[10].

Highly heparinized samples will decrease the iCa[6]; balanced heparin or low heparin collection tubes/syringes are recommended.

Systematic errors in ionized calcium readings may occur with over 20% hemodilution of plasma using solutions that are not consistent with the ionic characteristics of plasma, such as Normal Saline, Ringer's (Baxter Healthcare Corporation), and 10% Dextrose (Baxter Healthcare Corporation).

Hemodilution is associated with priming cardiopulmonary bypass pumps, plasma volume expansion, or other fluid administration therapies.

Such errors are prevented when physiologically balanced multi-electrolyte intravenous solutions containing low mobility anions that match the ionic characteristics of plasma, such as Plasma-Lyte™-A (Baxter Healthcare Corporation), Lactated Ringer's (Baxter Healthcare Corporation), Lactated Ringer's + 5% Dextrose injection (Baxter Healthcare Corporation), Plasbumin™-5 (Telacris Biotherapeutics), Pentaspan™ (Bristol-Myers Squibb), and Voluven™ (Fresenius Kabi) are used.

The following levels of exogenous interferences were tested and found to be clinically insignificant: 447 mg/dL ethanol, 1 mmol/L sodium pentothal, 0.4 mmol/L ascorbate, 1 mmol/L iodide, 2.2 mmol/L ibuprofen, 1.66 mmol/L acetaminophen, 2 mmol/L ammonium, 4 mmol/L lithium, 3 µmol/L dobutamine, 2.5 mmol/L tolbutamide, 1.34 mmol/L propofol, 0.7 mmol/L cefotaxime, 0.16 mmol/L ampicillin, 4.8 µM Zofran™, 2.5 mM N-acetylcysteine, 0.7 mM metronidazole.

The following levels of endogenous interferences were tested and found to be clinically insignificant: 20 mmol/L NaCl, 8 mmol/L KCl, 10 to 120 mmHg pCO$_2$, pH 6.9 to 7.7, +20 mmol/L bicarbonate, +20% PCV Hct, 0.8g/dL lipids, 9.1 mmol/L cholesterol, 2mmol/L (24mg/dL) L-cysteine, 0.26 mmol/L bilirubin, +2 mmol/L phosphate.

E. References

1. Reference Ranges Table 56-1 in Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, fourth edition, C.A. Burtis, E.R. Ashwood, and D.E. Bruns eds., Elsevier Saunders, St. Louis, 2006.

2. CLSI. Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline, second edition, CLSI document EP09-A2 (ISBN 1-56238-472-4), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2002.

3. CLSI. Interference Testing in Clinical Chemistry; Approved Guideline, CLSI document EP07-A2 (ISBN 1-56238-480-5), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2002.

4. i-STAT 300, Abbott Point of Care Inc., 104 Windsor Center Drive, East Windsor, NJ 08520, "i-STAT" is a registered trademark of Abbott Laboratories.

5. Radiometer ABL 735, Radiometer Medical ApS, Åkandevej 21, DK-2700 Brønshøj, Denmark, "Radiometer" and "ABL" are registered trademarks of Radiometer Medical ApS.

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12. C. Goebel, M.B. Kruse, A. Engel, S.H. Lamm, "On the use of human data in assessing effects on human health: the case of perchlorate." Annals of Epidemiology, volume 14, issue 8, p. 607, September 2004.

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12.9   Chloride (Cl-)

Chloride is measured by potentiometry using an ion selective membrane electrode. The concentration of chloride ions is obtained from the measured potential using the Nernst equation.

12.9.1   Indications for Use

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

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

12.9.2   Contents

Each Test Card incorporating a chloride test contains a chloride ion sensing electrode with a chloride selective membrane, a reference electrode and a calibrator fluid containing a known concentration of chloride salts.

12.9.3   Traceability

Values of chloride ion concentration assigned to controls and calibrator fluids are traceable to NIST standards

12.9.4   Sample Collection

Refer to 12.2.6 Sample Collection.

12.9.5   Additional Information

Refer to Section 3 "epoc System Operation" in this manual for detailed sample collection and system operating instructions for conducting a blood test.

Refer to Section 9 "Quality Assurance" in this manual for quality control requirements.

12.9.6   Measurement Range

	Measurement Range	Reference Range[1]
Cl-	65 – 140 mmol/L	98 – 107 mmol/L
	65 – 140 mEq/L	98 – 107 mEq/L

12.9.7   Performance Data

Typical performance data summarized below were obtained in-house as well as in healthcare facilities by healthcare professionals trained in the use of the epoc System. Experimental designs conformed to applicable CLSI guidelines.

Applicable standards include: CLSI EP09-A2[2] for method comparison studies, CLSI EP07-A2[3] for interference studies, CLSI EP05-A2[4] for precision studies, and CLSI EP06-A[8] for linearity studies.

A. Precision Data

Precision (CLSI EP05-A2[4]): Three card lots using at least 25 epoc Readers with replicate measurements were run in-house twice a day for twenty days for each fluid. In the precision data tables below, SD_{WD} denotes within-day standard deviation, SD_{DD} denotes day-to-day standard deviation and SD_T denotes total standard deviation.

Aqueous Control	Units	N	Mean	SD_{WD}	SD_{DD}	SD_T	WD%CV	Total %CV
High level	mM	240	125.0	0.61	0.61	0.86	0.5%	0.7%
Low level	mM	240	76.9	0.35	0.18	0.39	0.5%	0.5%

Pooled Whole Blood Precision Data: One hundred forty five patient samples were run in duplicate with approximately equal numbers of venous, arterial and capillary samples. Pooled pair-wise precision was estimated over three concentration ranges.

Range	<90	90 - 112	≥112
N	20	98	27
Average Reading, mM	78	105	123
Pair Precision (SD), mM	0.4	0.7	1.2
%CV	0.5%	0.6%	1.0%

B. Linearity Data

Whole Blood Linearity Study (CLSI EP06-A[8]): This study was performed in-house on multiple whole blood samples with *Chloride* values spanning the reportable range. Linearity is reported versus theoretical chloride values based on gravimetric mixtures of high and low chloride samples (as measured using an in-house standard method). Six card lots were used in this study.

Test Range	Slope	Intercept	R
65-144mM	0.968	3.08	0.9995

C. Clinical Sites Method Comparison Data

Linear regression analysis was performed on the method comparison data in accordance with CLSI EP09-A2[2]. In the method comparison statistics table, N is the number of patient specimens in the data set, Sxx and Syy are the pooled pair-wise imprecision of the comparative and epoc test methods respectively, Syx is the standard error and R is the correlation coefficient.

Method comparison studies were performed at two hospitals. Venous samples were compared with 2 non-point-of-care systems (2 serum methods). Venous, arterial and capillary patient samples were compared with a whole blood point-of-care system.

Cl-	Non-POC Systems*	i-STAT 300†
N	95	155
Sxx	0.6	0.9
Syy	0.7	0.8
Slope	0.90	0.99
Intercept	9.62	0.07
Syx	2.2	1.9
Xmin	71	69
Xmax	142	139
R	0.97	0.99
Mean Bias at 112 mM	-1.4	-1.0

* Pooled venous sample data. Approximate equal number vs. Roche Cobas 6000[6], Siemens Advia[7]

† Patient samples approximately equal numbers of venous, arterial and capillary samples versus i-STAT 300[5]

D. Limitations and Interferences

Interference testing[3] was performed in-house on the epoc chloride sensor. In each of these tests a pooled human serum specimen was aliquoted into two (2) samples. The test sample was spiked by addition of interferent, while the control sample was spiked by the addition of the solvent of the interferent. The chloride bias between the mean of six (6) replicates on both the control sample and the test sample with added interferent was calculated.

Unacceptable interference bias was defined as producing a significant error more than 5% of the time. The concentration of interfering substance considered as causing no clinically significant interference is defined as a bias (difference between the test and the control sample) of ≤ 3.5% for chloride concentrations ≤125 mM and ≤5.9% for chloride concentrations >125 mM..

Clinically significant interfering substances are itemized below:

- ß-Hydroxybutyrate will have no significant effect up to 8.27 mM (85.2 mg/dL) after which it will increase the chloride reading by up to 0.37 mM/mM β-hydroxybutyrate.
- Bromide will have no significant effect up to 1.63 mM (13.1 mg/dL) after which it will increase the chloride reading by up to 2.75 mM/mM bromide.
- Citrate will have no significant effect up to 2.79 mM (52.7 mg/dL) after which it will increase the chloride reading by up to 1.13 mM/mM citrate.
- N-acetylcysteine will have no significant effect up to 5.55 mM (90.5 mg/dL) after which it will decrease the chloride reading by up to 0.79 mM/mM N-acetylcysteine. It has been reported that 1 mM N-acetyl cysteine is therapeutically unattainable in plasma[9]. The therapeutic level for N-acetyl cysteine is 0.3 mM[10].
- Salicylic acid will have no significant effect up to 1.67 mM (22.9 mg/dL) after which it will increase the chloride reading by up to 2.94 mM/mM salicylic acid. Therapeutic range for salicylate is 0.1mM to 2 mM (1.4 mg/dL to 27.4 mg/dL)[11]
- Thiocyanate will have no significant effect up to 0.89 mM (5.2 mg/dL) after which it will increase the chloride reading by up to 5.62 mM/mM thiocyanate.

The following levels of exogenous interferences were tested and found to be clinically insignificant: 1.324 mmol/L (20 mg/dL) acetaminophen, 3.62 mmol/L (65.2 mg/dL)

acetylsalicylic acid, 342 µmol/L (6.8 mg/dL) Na ascorbate, 3.4 µmol/L (0.1 mg/dL) EDTA, 71 µmol/L (1.7 mg/dL) methyldopa, 2.55 mmol/L (156 mg/dL) oxidized glutathione, 2.55 mmol/L (78 mg/dL) reduced glutathione, 920 µmol/L (6.96 mg/dL) hydroxyurea, 282 µmol/L (4 mg/dL) isoniazid (nydrazid), 0.8% (800 mg/dL) intralipid, 3 µmol/L (0.1 mg/dL) dobutamine, 5.87 µmol/L (0.1 mg/dL) dopamine, 86.8 mmol/L (400 mg/dL) ethanol, 105 µmol/L (0.44 mg/dL) fluoride, 133 µmol/L (0.4 mg/dL) formaldehyde, 55 mmol/L (990 mg/dL) glucose, 0.4 mmol/L (5 mg/dL) guaiacol, 3000 U/L heparin, 2.43 mmol/L (50 mg/dL) ibuprofen, 0.1 mmol/L (2.0 mg/dL) L-Dopa, 51.2 µmol/L (1.2 mg/dL) lidocaine, 248 µmol/L (6 mg/dL) thiopental, 2.37 mmol/L (64 mg/dL) tolbutamide, 2.99 mmol/L (38 mg/dL) iodide, 2.643 mmol/L (120 mg/dL) cefazolin, 1.46 mmol/L (81 mg/dL) ceftriaxone.

The following levels of endogenous interferences were tested and found to be clinically insignificant: +342 µmol/L (+20.1mg/dL) bilirubin unconjugated, +342 µmol/L (+28.8 mg/dL) bilirubin conjugate, +382 µmol/L (+5.0 mg/dL) creatine, 109 mmHg CO_2, 15 mmHg CO_2, +40 mmol/L (+244 mg/dL) bicarbonate, pH > 8.0, pH < 6.8, +20% hematocrit, -20% hematocrit, <6% protein,>9% protein, 1.4 mmol/L (23.5 mg/dL) uric acid. 6.6 mmol/L (74 mg/dL) lactate, 131 mmHg O_2, 22 mmHg O_2, 0.25 mmol/L (2.9 mg/dL) proline, 1 µmol/L (0.01 mg/dL) sarcosine, 42.9 mmol/L (258 mg/dL) urea.

E. References

1. Reference Ranges Table 56-1 in Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, fourth edition, C.A. Burtis, E.R. Ashwood, and D.E. Bruns eds., Elsevier Saunders, St. Louis, 2006.

2. CLSI. Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline, second edition, CLSI document EP09-A2 (ISBN 1-56238-472-4), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2002.

3. CLSI. Interference Testing in Clinical Chemistry; Approved Guideline, CLSI document EP07-A2 (ISBN 1-56238-480-5), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2002.

4. CLSI. Evaluation of Precision in Clinical Chemistry Devices; Approved Guideline, second edition, CLSI document EP05-A2 (ISBN 1-56238-542-9), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004.

5. i-STAT 300, Abbott Point of Care Inc., 104 Windsor Center Drive, East Windsor, NJ 08520, "i-STAT" is a registered trademark of Abbott Laboratories.

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12.10   Glucose (Glu)

Glucose is measured by amperometry[1]. The sensor comprises an immobilized enzyme first layer coated onto a gold electrode of the electrode module, with a diffusion barrier second layer. The glucose oxidase enzyme is employed to convert glucose to hydrogen peroxide,

<div align="center">Glucose Oxidase</div>

$$\beta\text{-D-glucose} + O_2 + H_2O \quad \rightarrow \quad \text{D-gluconic acid} + H_2O_2 \quad (1)$$

and then uses an amperometric sensor to detect the enzymatically produced hydrogen peroxide. Peroxide detection is by redox mediated (ABTS (2,2'-azino-bis(3-ethylbenzothiazoline-6-sulfonic acid) diammonium salt), horseradish peroxidase (HRP) catalyzed, reduction on a gold electrode.

$$H_2O_2 + HRP^{red} \rightarrow HRP^{ox} \qquad\qquad (2)$$

$$HRP^{ox} + Red \rightarrow Ox + HRP^{red} \qquad (3)$$

$$Ox + e^- \rightarrow Red \qquad\qquad (4)$$
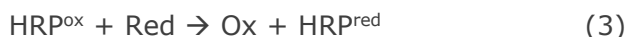
The reduction current is proportional to the concentration of glucose in the test fluid.

The epoc Glucose result is reported as **plasma equivalent[2]** glucose concentration**.**

12.10.1 Indications for Use

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

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

12.10.2 Contents

Each Test Card incorporating a Glucose test contains a sensing electrode with a redox mediated enzymatic membrane covered with an oxygen permeable diffusion layer, a reference electrode, a counter electrode and a calibrator fluid containing a known concentration of glucose.

12.10.3 Traceability

Glucose concentration values assigned to controls and calibrator fluids are traceable to NIST standards.

12.10.4 Sample Collection

Refer to 12.2.6 Sample Collection.

As per Tietz[13], capillary blood samples exhibit higher glucose than venous blood samples, by 2-5mg/dL in fasting patients and by 20% to 25% after a glucose load.

After the sample collection, glucose decreases in blood as a result of glycolysis by about 6% per hour[13], and by as much as 13% per hour[14]

Always test immediately using Li or Na heparin as the anticoagulant or using no anticoagulant.

Do not use NaF or potassium oxalate as preservative.

12.10.5 Additional Information

Refer to Section 3 "epoc System Operation" in this manual for detailed sample collection and system operating instructions for conducting a blood test.

Refer to Section 9 "Quality Assurance" in this manual for quality control requirements.

12.10.6 Measurement Range

	Measurement Range	Reference Range[3]
Glucose	1.1 – 38.5 mmol/L	4.1 – 5.5 mmol/L
	20 - 700 mg/dL	74 – 100 mg/dL
	0.20 -7.00 g/L	0.74 – 1.00 g/L

12.10.7 Performance Data

Typical performance data summarized below were obtained in-house as well as in healthcare facilities by healthcare professionals trained in the use of the epoc System. Experimental designs conformed to applicable CLSI guidelines.

Applicable standards include: CLSI EP09-A2[4] for method comparison studies, CLSI EP07-A2[5] for interference studies and CLSI EP05-A2[6] for precision studies.

A. Precision Data

Twenty replicates of each of two levels of commercial controls were analyzed at each of 20 different sites. The precision study at each site employed from two (2) to eight (8) epoc Readers, and multiple lots of epoc Test cards were included across all of the sites. The pooled SD and averaged means are presented below:

Aqueous Control	Units	Mean	SD	%CV
High Level	mg/dL	263.9	7.5	2.8
Low Level	mg/dL	44.2	1.5	3.4

Because the SDs presented here are the pooled averages from multiple customer performance verifications, it is expected that, occasionally, SDs from an individual precision study to be higher or lower than these averages. Each site must establish whether the results of their precision studies are clinically acceptable. Alternatively, an f-test can be used to determine whether their precision is statistically equivalent to typical precision values summarized above.

B. Linearity Data

This study was performed in-house on multiple whole blood samples with *Glucose* values spanning the reportable range. Three types of samples were considered, i.e. normal hematocrit-normal venous blood pO_2, normal hematocrit– hypoxic blood sample and elevated hematocrit-normal venous blood pO_2. Linearity is reported versus two in-house standard whole blood glucose method with traceability to NIST standards.

Type of Blood Sample	Test Range	Units	Slope	Intercept	R
43% Hct, 30 mmHg pO_2	20 – 700	mg/dL	1.022	-3.32	0.9999
62% Hct, 30 mmHg pO_2	20 – 700	mg/dL	1.018	-4.04	0.9998
43% Hct, <20 mmHg pO_2	20 – 700	mg/dL	0.955	+0.33	0.9998

C. Clinical Sites Method Comparison Data

Linear regression analysis was performed on the method comparison data in accordance with CLSI EP09-A2[4]. In the method comparison statistics table, N is the number of Patient specimens in the data set, Sxx and Syy are the pooled pair-wise imprecision of the comparative and epoc test methods respectively, Syx is the standard error and R is the correlation coefficient.

Clinical Site Method Comparison 1: In one hospital study, the epoc System was compared with the i-STAT 300[7] in the lab and at one point-of-care site.

Method Comparison Summary Statistics: whole blood

X: i-STAT 300 CG8 cartridges test

Y: epoc test

Glu	N	Sxx	Syy	Intercept	Slope	Syx	Xmin	Xmax	R
All	80	0.93	3.4	-2.2	1.031	5.6	20.0	605.5	0.9995

The precision in whole blood was assessed from the pooling of within method pairs from the method comparison data. This is shown in the table below.

Glucose [mg/dL]			
Range	20 – 70	70 – 200	200 – 700
N	10	59	11
Average Reading	44.8	116.4	383.8
Pair Precision (SD)	0.80	2.44	7.08
%CV	1.8%	2.1%	1.8%

Clinical Site Method Comparison 2: In another hospital study, the epoc System was compared simultaneously with the Roche-Hitachi[8] instrument in the lab and with i-STAT 300[7]. The summaries are presented in the tables below.

Method Comparison Summary Statistics: whole blood

X: Roche-Hitachi P800-D2400 test

Y: epoc test

Glu	N	Sxx	Syy	Intercept	Slope	Syx	Xmin	Xmax	R	Mean Bias (%)
All	73	-	3.6	-0.2	0.971	3.0	23.0	546.0	0.998	-3.14

Method Comparison Summary Statistics: whole blood

X: i-STAT 300 G cartridges test

Y: epoc test

Glu	N	Sxx	Syy	Intercept	Slope	Syx	Xmin	Xmax	R	Mean Bias (%)
All	80	3.25	4.25	-1.33	1.003	4.45	22.5	517.5	0.999	-2.23%

The precision in whole blood was assessed from the pooling of within method pairs from the method comparison data. This is shown in the table below.

Glucose [mg/dL]			
Range	20 – 70	70 – 200	200 – 700
N	16	53	11
Average Reading	53.5	113.4	299.0
Pair Precision (SD)	1.32	3.18	8.73
%CV	2.47%	2.81%	2.92%

D. Consolidated Method Comparison Study Focusing on Low End Glucose Range

We evaluated the performance of the epoc glucose sensor in the low end range of glucose concentrations on Patient samples in clinical settings including at the point of care at several different hospitals. The results shown below include method comparison data against i-STAT[7] (whole blood method), ABL 800 Flex[9] (whole blood method), Roche-Hitachi[8] (plasma method), and J&J[12] (plasma method). We supplemented the above mentioned clinical results with an in-house full duplicate method comparison[4] against i-STAT[7] and ABL705[9]. In this study high hematocrit blood samples were prepared by removing half of the plasma volume from a venous sample that was allowed to glycolyse. The hematocrit of these specimens was tested by micro-centrifugation method[11] and found to be ~62%, i.e. characteristic to the upper range of the neonatal blood[10]. After the glucose reached ~20 mg/dL, it was spiked to cover uniformly the low range glucose, i.e. 20-80 mg/dL specific to neonatal population[10]. One sample was treated with Hexokinase, NADH-β and ATP in order to obtain a zero glucose concentration.

The data was processed as per CLSI EP09-A2 recommendations[4]. The correlation plot and bias plot are presented in the figures below. The test results versus the various reference instruments (X) are color coded.

epoc Low End Study	All points	Lab (plasma)	i-STAT	ABL	Roche	J&J
N	78	11	40	27	9	2
Sxx	1.0		0.6	1.6		
Syy	1.1	1.4	1.1	1.0	1.5	0.7
Intercept	-0.2	1.1	1.0	-2.2	0.8	
Slope	0.984	0.936	0.992	0.990	0.942	
Syx	2.9	2.1	2.55	2.16	2.21	
Xmin	1.5	23.0	20	1.5	23	25
Xmax	63.0	63.0	60	53	63	25
R	0.973	0.980	0.974	0.985	0.973	
Decision Level	40	40	40	40	40	
Bias	-0.8	-1.4	0.7	-2.6	-1.52	
Bias 95% Conf. Hi	-0.3	-0.5	1.3	-1.9	-0.18	
Bias 95% Conf. Lo	-1.3	-2.3	0.1	-3.3	-2.86	

Method Comparison Summary Statistics: whole blood

X (blue circles):   i-Stat 300 G cartridges (whole blood) test

X (green squares):   Roche Hitachi Lab (plasma) test

X (red diamonds):   ABL 705 (whole blood) test

X (yellow triangles): J&J Lab (plasma) test

Y: epoc test
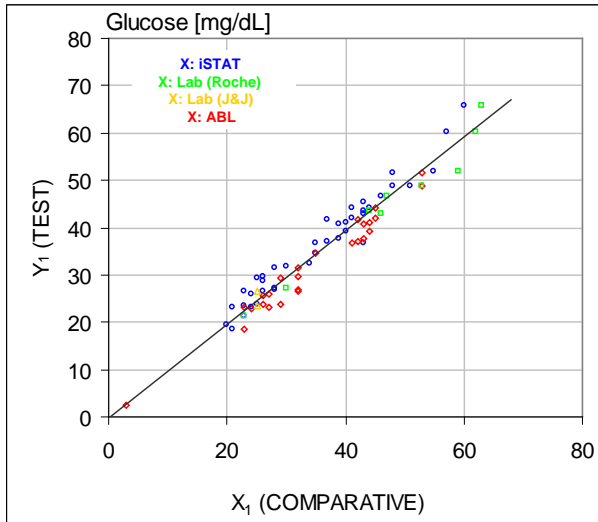
Low end glucose range, correlation plot versus various comparative instruments

Low end glucose range, bias plot versus various comparative instruments
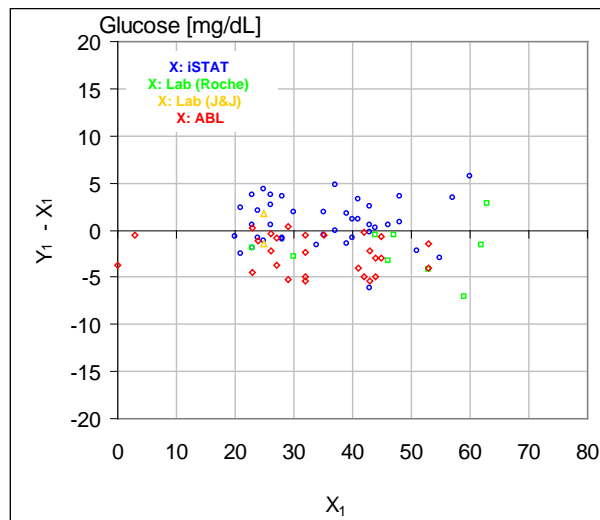
E. Method Comparison Study Focusing on Capillary Blood Specimens

We evaluated the performance of the epoc tests on authentic capillary blood specimens in clinical settings at the point of care. The comparative method used i-STAT 300[7] analyzers with CG8 cartridges and Radiometer CLINITUBE capillaries. Comparison testing was performed at four (4) locations: NICU, Well-baby Nursery, and two (2) different outpatient drawing areas. There were a total of 48 samples collected, of which 24 in full duplicate. Of the 48 samples, 12 were adult blood specimens and 36 were neonatal blood specimens.

The data was processed as per CLSI EP09-A2 recommendations[4]. The correlation plot and bias plot are presented in the figures below. The test results versus the patient age are color coded.

Method Comparison Summary Statistics: capillary blood

X: i-STAT 300 test

Y: epoc test

Glu	N	Sxx	Syy	Intercept	Slope	Syx	Xmin	Xmax	R
All	48	1.13	1.80	5.1	0.935	2.42	42.5	147	0.9942
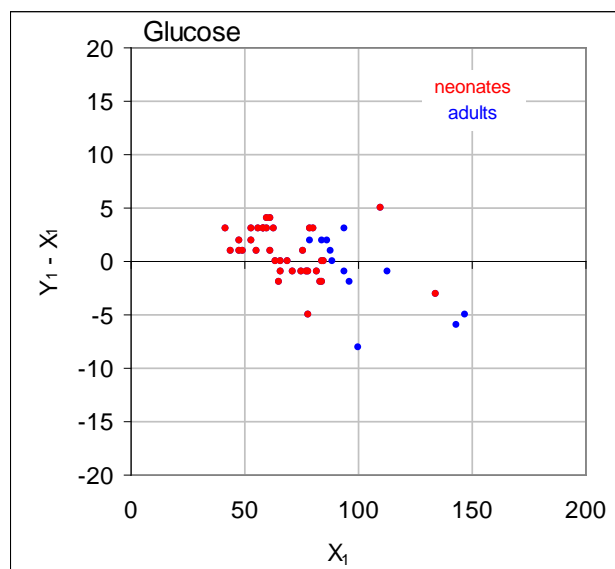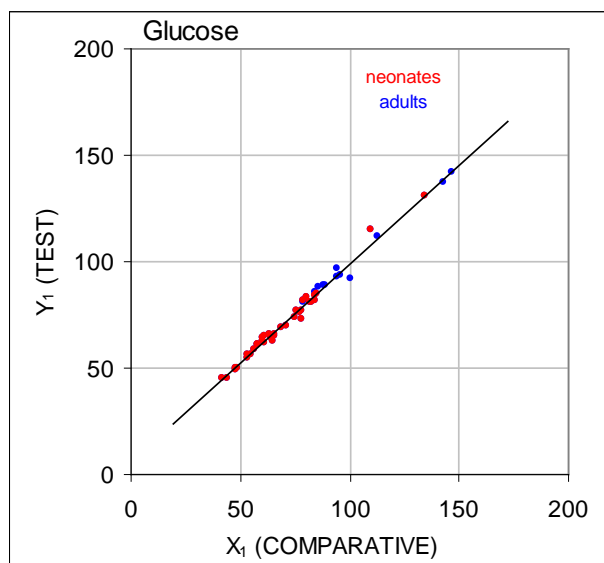
F. Limitations and Interferences

As per Tietz[13], capillary blood samples exhibit higher glucose than venous blood samples, by 2 to 5 mg/dL in fasting patients and by 20% to 25% after a glucose load.

After the sample collection, glucose decreases in blood as a result of glycolysis by about 6% per hour[13], and by as much as 13% per hour[14].

Always test immediately using Li or Na heparin as the anticoagulant or using no anticoagulant.

Do not use NaF or potassium oxalate as preservative.

Interference testing[5] was performed in-house on the epoc *glucose* sensor. In each of these tests a whole blood specimen was aliquoted into two samples. The test sample was spiked by addition of interferent, while the control sample was spiked by the addition of the solvent of the interferent. The *glucose* bias between the mean of six replicates on both the control sample and the test sample with added interferent was calculated.

Clinically significant interfering substances are itemized below:

- Iodide will have no significant effect up to 28 μM (0.47 mg/dL KI), after which it will decrease glucose reading by as much as (-0.16 mg/dL)/ μM I-, i.e. (-9.5 mg/dL)/(mg/dL KI).

- Bromide will have no significant effect up to 28 mM (224 mg/dL NaBr), after which it will decrease glucose reading by (-0.23 mg/dL)/mM Br, i.e. (-0.029 mg/dL)/(mg/dL NaBr).

- N-acetylcysteine will have no significant effect up to 500 μM (8.2 mg/dL) N-acetylcysteine, after which it will decrease the glucose reading by (-7.2mg/dL)/mM N-acetylcysteine, i.e. (-0.44mg/dL)/(mg/dL N-acetylcysteine). It has been reported that 1 mM N-acetylcysteine is therapeutically unattainable in plasma[15]. The therapeutical level for N-acetylcysteine is 0.3 mM[16].

- Flaxedil™ (gallamine triethiodide) will have no significant effect up to 11 μM (1 mg/dL), after which it will decrease the glucose reading by (−0.27 mg/dL)/ μM gallamine triethiodide, i.e. (−3 mg/dL)/(mg/dL gallamine triethiodide).

- Thiocyanate will have no significant effect up to 1 mM (5.9 mg/dL KSCN), after which it will decrease the glucose reading with -1.7%/mM SCN, i.e. (−0.29 mg/dL)/(mg/dL KSCN).

- Uric acid will have no significant effect up to 700μM (11.8 mg/dL), after which it will decrease the glucose reading by (-3.5 mg/dL)/mM uric acid, i.e. (−0.21 mg/dL)/(mg/dL uric acid).

- Mannose will have no significant effect up to 2 mM (36 mg/dL), after which it will increase the glucose reading by 2.12 mg/dL / (mM mannose), i.e. 0.059 mg/dL / (mg/dL mannose).

- Xylose will have no significant effect up to 3 mM (45 mg/dL), after which it will increase the glucose reading by 0.96 mg/dL / (mM xylose), i.e. 0.064mg/dL /(mg/dL xylose).

- Metamizole (dipyrone) will have no significant effect up to 0.194 mM, after which it will decrease the glucose reading by up to 3% / 0.1mM metamizole.

The following levels of exogenous interferences were tested and found to be clinically insignificant: 1.66 mM (25 mg/dL) acetaminophen, 0.09 mmol/L (10 mg/dL) anidulafungin, 3.3 mmol/L (60 mg/dL) acetyl salicylate, 630 µmol/L (12.5 mg/dL) Na ascorbate, 89.2 µmol/L (4.5 mg/dL) clindamycin hydrochloride, 0.1 mmol/L (0.65 mg/dL) K cyanide, 6.15nmol/L (507 ng/dL) digoxin, 66 µmol/L (2.2 mg/dL) dobutamine, 100 µmol/L (1.9 mg/dL) dopamine HCl, 50 µmol/L (~1 mg/dL) L-dopa, 9 mmol/L (263 mg/dL) EDTA, 12 µmol/L (0.2 mg/dL) ephedrine, 87 mM (400 mg/dL) ethanol, 4.84 mmol/L (30 mg/dL) ethylene glycol, 1.78 µmol/L (60 µg/dL) famotidine, 1 mmol/L (18 mg/dL) fructose, 181 µmol/L (6 mg/dL) furosemide, 3.3 mmol/L (59 mg/dL) galactose, 238 µmol/L (10 mg/dL) gentamicin, 4.5 µmol/L (200 µg/dL) glipizide, 1.1 mmol/L (28.5 mg/dL) glucosamine, 2.55 mmol/L RBC oxidized glutathione, 2.55 mmol/L RBC reduced glutathione, 400 µmol/L (5 mg/dL) guaiacol, 80U/mL heparin, 0.4 mmol/L (14.5 mg/dL) hydrocortisone, 2.5 mmol/L (19 mg/dL) hydroxyurea, 292 µmol/L (4 mg/dL) Nydrazid™ (isoniazide), 48.6 µmol/L (1.76 mg/dL) levofloxacin, 1 mmol/L (34 mg/dL) linezolid, 13.3 mmol/L (479 mg/dL) maltose, 937.5 µmol/L (1500 mg/dL) icodextrin, 71 µmol/L (1.7 mg/dL) methyldopa, 77.4 µmol/L (2.9 mg/dL) 6α-methyl prednisolone, 0.7 mM (12 mg/dL) metronidazole, 17.4 µM (0.6 mg/dL) omeprazole, 102 µmol/L (2.4 mg/dL) procainamide, 4.22 µmol/L (0.12 mg/dL) promethazine hydrochloride, 37 µmol/L (1.2 mg/dL) quinidine, 1.67 µmol/L (40 µg/dL) salbutamol (albuterol), 4.34 mmol/L (60 mg/dL) salicylic acid, 1.96 µmol/L (60 µg/dL) sertraline, 413 µmol/L (10 mg/dL) sodium pentothal, 1 mmol/L (31 mg/dL) Tolinase™ (tolazamide), 2.37 mmol/L (64 mg/dL) tolbutamide, 69 µmol/L (10 mg/dL) vancomycin, 21.3 µmol/L (1 mg/dL) vitamin K1, 2.64 mmol/L (47 mg/dL) propofol, 0.7 mmol/L (334.2 mg/dL) cefotaxime, 0.16 mmol/L (59.4 mg/dL) ampicillin, 1 mmol/L (122.4 mg/dL) sodium perchlorate, 4.8 µM (1.75 mg/dL) Zofran™.

The following levels of endogenous interferences were tested and found to be clinically insignificant: +20 mmol/L (168 mg/dL) Na bicarbonate, +86 µmol/L (+7.3 mg/dL) bilirubin conjugated, +510 µmol/L (+30 mg/dL) bilirubin unconjugated, 13mM (503.1 mg/dL) cholesterol, 15 to 140 mmHg pCO$_2$, 2mmol/L (24mg/dL) L-cysteine, +20 mmol/L (+256 mg/dL) Na β-hydroxybutyrate, +20 mmol/L (+180 mg/dL) Na L-lactate, +0.8g/dL lipids, +59.2 µmol/L (+1.9 mg/dL) norepinephrine, pH 6.7 to 7.7, +20% PCV Hct, 3.4% to 10.4% total protein, 11.2mM (991 mg/dL) triglycerides.

G. References

1. P. D'Orazio, M.E. Meyerhoff, "Electrochemistry and Chemical Sensors", Chapter 4 in Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, fourth edition, C.A. Burtis, E.R. Ashwood, and D.E. Bruns eds., Elsevier Saunders, St. Louis, 2006.
2. P. D'Orazio et al, Approved IFCC recommendation on reporting results for blood glucose (abbreviated), Clin Chem 2005 51: 1573-1576
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5. CLSI. Interference Testing in Clinical Chemistry; Approved Guideline, CLSI document EP07-A2 (ISBN 1-56238-480-5), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2002.
6. CLSI. Evaluation of Precision in Clinical Chemistry Devices; Approved Guideline, second edition, CLSI document EP05-A2 (ISBN 1-56238-542-9), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2004.

7. i-STAT 300, Abbott Point of Care Inc., 104 Windsor Center Drive, East Windsor, NJ 08520, "i-STAT" is a registered trademark of Abbott Laboratories.

8. Roche-Hitachi are registered trademarks of F. Hoffman-La Roche Ltd., 4070 Basel, Switzerland.

9. Radiometer ABL 705 and ABL 800Flex, Radiometer Medical ApS, Åkandevej 21, DK-2700 Brønshøj, Denmark, "Radiometer" and "ABL" are registered trademarks of Radiometer Medical ApS.

10. C. Rooks, "Points to consider for portable blood glucose monitoring devices intended for bedside use in the neonate nursery", Guidance to FDA publication No. 87-4224, 1996.

11. CLSI. Procedure for determining Packed Cell Volume by the Microhematocrit method; Approved Standard, third edition, CLSI document H07-A3 (ISBN 1-56238-413-9), CLSI, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2000.

12. J&J VITROS DTII is a registered trademark of Ortho-Clinical Diagnostics, a Johnson&Johnson company, Raritan, NJ 08869, United States.

13. D.B. Sacks, Chapter 25 (p. 837) of Tietz Textbook of Clinical Chemistry and Molecular Diagnostics, fourth edition, C.A. Burtis, E.R. Ashwood, and D.E. Bruns eds., Elsevier Saunders, St. Louis, 2006.

14. Chapter 141, Blood Glucose of J. Michael McMillin, Walker HK, Hall WD, Hurst JW, editors. Clinical Methods: The History, Physical, and Laboratory Examinations, third edition. Boston: Butterworths; 1990.

15. S. Whillier, J.E. Raftos, B. Chapman, P.W. Kuchel, "Role of N-acetylcysteine and cysteine in glutathione synthesis in human erythrocytes." Redox Report: Communications In Free Radical Research, 2009, vol. 14, issue 3, p 115.

16. P. Ventura, R. Panini, M. C. Pasini, G. Scarpetta, G. Salvioli, "N-Acetyl-Cysteine Reduces Homocysteine Plasma Levels After Single Intravenous Administration by Increasing Thiols Urinary Excretion." Pharmacological Research. Volume 40, Issue 4, October 1999, P. 345-350.

12.11   Lactate (Lac)

Lactate is measured by amperometry[1]. The sensor comprises an immobilized enzyme first layer coated onto a gold electrode of the electrode module, with a diffusion barrier second layer. The lactate oxidase enzyme is employed to convert lactate to hydrogen peroxide,

$$\text{Lactate Oxidase}$$

$$\text{L-lactate} + O_2 + H_2O \quad \rightarrow \quad \text{Pyruvic acid} + H_2O_2 \quad (1)$$

and then uses an amperometric sensor to detect the enzymatically produced hydrogen peroxide. Peroxide detection is by redox mediated (ABTS (2,2'-azino-bis(3-ethylbenzothiazoline-6-sulfonic acid) diammonium salt), horseradish peroxidase (HRP) catalyzed, reduction on a gold electrode.

$$H_2O_2 + HRP^{red} \rightarrow HRP^{ox} \qquad\qquad (2)$$

$$HRP^{ox} + Red \rightarrow Ox + HRP^{red} \qquad (3)$$

$$Ox + e^- \rightarrow Red \qquad\qquad\qquad (4)$$
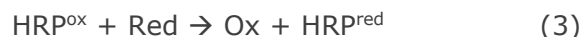
The reduction current is proportional to the concentration of lactate in the test fluid.

12.11.1 Indications for Use

The *Lactate* test, as part of the epoc Blood Analysis System, is intended for use by trained medical professionals as an in vitro diagnostic device for the quantitative testing of samples of heparinized or un-anticoagulated arterial, venous or capillary whole blood in the laboratory or at the point of care.

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

12.11.2 Contents

Each test card incorporating a *Lactate* test contains a sensing electrode with a redox mediated enzymatic membrane covered with an oxygen permeable diffusion layer, a reference electrode, a counter electrode and a calibrator fluid containing a known concentration of lactate.

12.11.3 Traceability

Certified standard reference material for lactate is not available at present. Lactate values assigned to controls and calibration verification materials are traceable to a working calibrator prepared from Sodium L-Lactate from Sigma-Aldrich Co., Item Number 71718, >99% purity.

12.11.4 Sample Collection

Refer to 12.2.6 Sample Collection.

Collection of a satisfactory specimen for Lactate analysis requires special procedures to prevent changes in lactate both during and after blood is drawn[11].

As per Tietz[11], for venous samples, do not use a tourniquet or immediately remove the tourniquet before the draw. During exercise, Lactate may increase significantly within 10 seconds. Therefore, for relevant Lactate readings, the patients should be fasting and at rest for at least 2 hours. After sample collection, lactate rapidly increases in blood as a result of glycolysis by as much as 20% in 3 min and 70% in 30 min at 25°C.

Always test immediately using Li or Na heparin as the anticoagulant or using no anticoagulant. Do not use NaF or potassium oxalate as preservative.

12.11.5 Additional Information

Refer to Section 3 "epoc System Operation" in this manual for detailed sample collection and system operating instructions for conducting a blood test.

Refer to Section 9 "Quality Assurance" in this manual for quality control requirements.

12.11.6 Measurement Range

	Measurement Range	Reference Range[2,] Venous
Lactate	0.30 – 20.00 mmol/L	0.56 – 1.39 mmol/L
	2.7 – 180.2 mg/dL	5.0 – 12.5 mg/dL
	0.03 – 1.80 g/L	0.05 – 0.12 g/L

12.11.7 Performance Data

Typical performance data summarized below were obtained in-house as well as in healthcare facilities by healthcare professionals trained in the use of the epoc System. Experimental designs conformed to applicable CLSI guidelines.

Applicable standards include: CLSI EP09-A2[3] for method comparison studies, CLSI EP07-A2[4] for interference studies, CLSI EP06-A[7] for linearity studies, and CLSI EP05-A2[5] for precision studies.

A. Precision Data

Twenty replicates of each of two levels of commercial controls were analyzed at each of 20 different sites. The precision study at each site employed from two (2) to eight (8) epoc Readers, and multiple lots of epoc Test cards were included across all of the sites. The pooled SD and averaged means are presented below:

Aqueous Control	Units	Mean	SD	%CV
High Level	mmol/L	6.11	0.21	3.4
Low Level	mmol/L	0.95	0.06	6.3

Because the SDs presented here are the pooled averages from multiple customer performance verifications, it is expected that, occasionally, SDs from an individual precision study to be higher or lower than these averages. Each site must establish whether the results of their precision studies are clinically acceptable. Alternatively, an f-test can be used to determine whether their precision is statistically equivalent to typical precision values summarized above.

B. Linearity Data

Whole Blood Linearity Study (CLSI EP06-A[7]): This study was performed in-house on multiple whole blood samples with *Lactate* values spanning the reportable range. Linearity is reported versus theoretical lactate values based on gravimetric mixtures of high and low lactate samples. Four (4) card lots were used in this study.

Test Range	Slope	Intercept	R
0.3-20.1 mM	1.001	0.271	0.9995

C. Clinical Sites Method Comparison Data

Linear regression analysis was performed on the method comparison data in accordance with CLSI EP09-A2[3]. In the method comparison statistics table, N is the number of Patient specimens in the data set, Sxx and Syy are the pooled pair-wise imprecision of the comparative and epoc test methods respectively, Syx is the standard error and R is the correlation coefficient.

Method comparison studies were performed at two (2) hospitals. At one hospital, 99 venous samples were tested. At another hospital, both 43 arterial and 44 capillary samples were tested. Sample lactate concentrations on the comparison device varied from 0.57 to 14.57 mmol/L.

In these studies, the epoc System was compared with the i-STAT 300 analyzer[6].

Method Comparison Summary Statistics: whole blood—venous, arterial, capillary

X: i-STAT CG4+ cartridges

Y: epoc test

Lac	epoc	N	Sxx	Syy	Intercept	Slope	Syx	Xmin	Xmax	R	Mean Bias (%)
	i-STAT	373	0.215	0.530	0.132	0.967	0.948	0.48	19.95	0.985	2.75

D. Limitations and Interferences

Collection of satisfactory specimen for Lactate analysis requires special procedures to prevent changes in Lactate both during and after blood is drawn[11].

As per Tietz[11], for venous samples, do not use a tourniquet or immediately remove the tourniquet before the draw. During exercise, Lactate may increase significantly within 10 seconds. Therefore, for relevant Lactate readings, the patients should be fasting and at rest for at least 2 hours.

After the sample collection, lactate rapidly increases in blood as a result of glycolysis by as much as 20% in 3 min and 70% in 30 min at 25°C.

Always test immediately using Li or Na heparin as the anticoagulant or using no anticoagulant.

Do not use NaF or potassium oxalate as preservative.

Interference testing[4] was performed in-house on the epoc lactate sensor. In each of these tests a pooled human serum specimen was aliquoted into two (2) samples. The test sample was spiked by addition of interferent, while the control sample was spiked by the addition of the solvent of the interferent. The lactate bias between the mean of six (6) replicates on both the control sample and the test sample with added interferent was calculated.

Unacceptable interference bias was defined as producing a significant error more than 5% of the time.

Significant interfering substances are itemized below:

- Acetaminophen will have no significant effect up to 0.81 mM after which it will increase the lactate reading up to 306µM/mM Tylenol™ (acetaminophen). Because the therapeutic upper limit for acetaminophen is 0.20 mM, interfering levels of acetaminophen should only be encountered in overdose situations

- Iodide will decrease the lactate reading up to -3.3 mM/mM of Iodide for an Iodide concentration under 0.3 mM. Above 0.3 mM Iodide, the Lactate bias will be a constant -1.0 mM.

- Bromide will have no significant effect up to 25.4 mM after which it will decrease the lactate reading up to 14.6µM/mM Bromide.

- Thiocyanate will have no significant effect up to 2.7 mM after which it will decrease the lactate reading by up to 96.6µM/mM thiocyanate.

- N-acetylcysteine will have no significant effect up to 3.7 mM after which it will decrease the lactate reading by up to 96.3µM/mM N-acetylcysteine. It has been reported that 1 mM N-acetylcysteine is therapeutically unattainable in plasma[9]. The therapeutical level for N-acetylcysteine is 0.3 mM[10].

Ethylene glycol ingestion and metabolism has been shown to produce falsely elevated lactate measurements[8]. Ethylene glycol plus three metabolism products - Glycolic Acid, Glyoxylic Acid and Oxalic Acid - were tested for interference. Ethylene Glycol and Oxalic Acid do not interfere significantly.

- Glycolic Acid will have no significant effect up to 0.87 mM after which it will increase the lactate reading up to 142µM/mM glycolic acid.

- Glyoxylic Acid will have no significant effect up to 0.85 mM after which it will increase the lactate reading up to 373µM/mM glyoxylic acid.

The following levels of exogenous interferences were tested and found to be insignificant: 630µmol/L (12.5 mg/dL) Na ascorbate, 20 mmol/L (588 mg/dL) citrate, 100µmol/L (~2 mg/dL) L-dopa, 9 mmol/L (263 mg/dL) EDTA, 4.84 mmol/L (30 mg/dL) ethylene glycol, 105µmol/L (0.441 mg/dL) Na fluoride, 71µmol/L methyldopa, 2.55 mmol/L oxidized glutathione, 2.55 mmol/L reduced glutathione, 132µmol/L (1.0 mg/dL) hydroxyurea, 292µmol/L (4 mg/dL) Nydrazid™ (isoniazide), 81µmol/L (1.5 mg/dL) K oxalate, 0.037 mmol/L (1.2 mg/dL) quinidine, 2.64 mmol/L (47 mg/dL) propofol, 0.7 mmol/L (334.2 mg/dL) cefotaxime, 0.16 mmol/L (59.4 mg/dL) ampicillin, 1 mmol/L (122.4 mg/dL) sodium perchlorate, 3.7 mmol/L (603.8 mg/dL) N-acetylcysteine, 4.8 µM Zofran™, 0.7 mM metronidazole.

The following levels of endogenous interferences were tested and found to be insignificant: +342µmol/L (+29.0 mg/dL) bilirubin conjugated, +342µmol/L (+20.1 mg/dL) bilirubin unconjugated, +13 mmol/L (+503.1 mg/dL) cholesterol, 2mmol/L (24mg/dL) L-cysteine, +0.8g/dL lipids, pH (+0.4, -0.4), 3% to 10% total protein, 1.4 mM (+ 23.5 mg/dL) Uric Acid. Low hematocrit did not interfere down to a level of 21 % hematocrit and high hematocrit did not interfere up to a level of 61 % hematocrit. Triglycerides did not show significant interference up to a level of 37 mM (3274 mg/dL). pO_2 partial pressures below 20 mmHg (2.67kPa) may decrease lactate values.

E. References

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12.12   Creatinine (Crea)

Creatinine is measured by amperometry[1]. Each creatinine sensor is a three layer enzyme electrode, comprising a first immobilized enzyme creatinine-conversion underlayer coated onto a gold electrode, a second immobilized enzyme creatine-screening layer and a third diffusion barrier layer.

The creatinine electrode underlayer contains the enzymes Creatinine Amidohydrolase, Creatine Amidinohydrolase and Sarcosine Oxidase which convert creatinine to hydrogen peroxide in an enzyme → product cascade,

$$\text{Creatinine} + H_2O \xleftrightarrow{\text{Creatinine Amidohydrolase}} \text{Creatine}$$

$$\text{Creatine} + H_2O \xrightarrow{\text{Creatine Amidinohydrolase}} \text{Sarcosine} + \text{Urea}$$

$$\text{Sarcosine} + O_2 + H_2O \xrightarrow{\text{Sarcosine Oxidase}} \text{Glycine} + \text{Formaldehyde} + H_2O_2$$
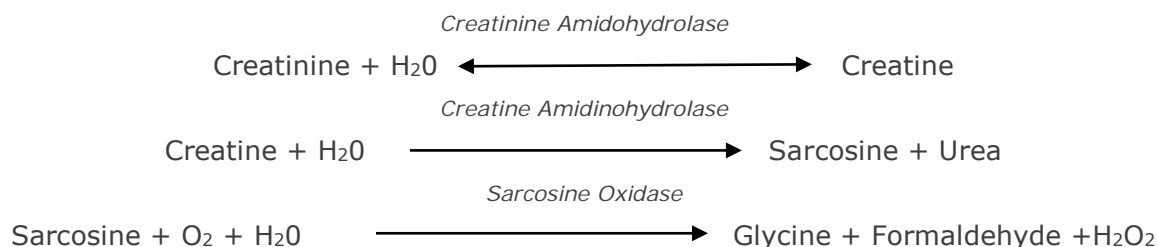
and then uses the underlying gold electrode to detect the enzymatically produced hydrogen peroxide. Peroxide detection is by redox-mediated horseradish-peroxidase (HRP)-catalyzed reduction.

$$H_2O_2 + HRP^{red} \xleftrightarrow{} HRP^{ox}$$

$$H_2O_2 + HRP^{ox} + Red \xleftrightarrow{} HRP^{red} + Ox$$

$$Ox + e^- \xleftrightarrow{} Red$$

The reduction current is proportional to the concentration of creatinine in the test fluid.

12.12.1 Indications for Use

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

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

12.12.2 Contents

Each test card incorporating a Creatinine test contains a sensing electrode with redox mediated enzymatic membrane layers covered with an oxygen permeable diffusion layer, a reference electrode, a counter electrode and a calibrator fluid containing a known concentration of creatinine.

12.12.3 Traceability

The epoc Creatinine test is calibrated to an IDMS-traceable whole blood method and reports plasma equivalent concentrations. Creatinine concentration values assigned to controls and calibrator fluids are traceable to NIST standard SRM 967.

12.12.4 Sample Collection

Refer to 12.2.6 Sample Collection.

12.12.5 Additional Information

Refer to Section 3 "epoc System Operation" in this manual for detailed sample collection and system operating instructions for conducting a blood test.

Refer to Section 9 "Quality Assurance" in this manual for quality control requirements.

12.12.6 Measurement Range

	Measurement Range	Reference Range[2,9]
Creatinine	0.30 – 15.00 mg/dL	0.51 – 1.19 mg/dL
	27 – 1326 μmol/L	45 – 105 μmol/L

12.12.7 Performance Data

Typical performance data summarized below were obtained in-house as well as in healthcare facilities by healthcare professionals trained in the use of the epoc System. Experimental designs conformed to applicable CLSI guidelines.

Applicable standards include: CLSI EP09-A2[3] for method comparison studies, CLSI EP07-A2[4] for interference studies, CLSI EP06-A2[7] for linearity studies, and CLSI EP05-A2[5] for precision studies.

A. Precision Data

Precision (CLSI EP05-A2[5]): Three card lots card lots using at least 25 epoc Readers with replicate measurements were run in-house twice a day for twenty days for each fluid. In the precision data tables below, SD_{WD} denotes within-day standard deviation, SD_{DD} denotes day-to-day standard deviation and SD_T denotes total standard deviation.

Aqueous Control	Units	N	Mean	SD_{WD}	SD_{DD}	SD_T	WD%CV	Total %CV
High Level	mg/dL	241	5.50	0.197	0.112	0.226	3.6%	4.1%
Low Level	mg/dL	239	0.71	0.030	0.017	0.035	4.2%	4.9%

Pooled Whole Blood Precision Data: One hundred twenty seven patient samples were run in duplicate with approximately equal numbers of venous, arterial and capillary samples. Pooled pair-wise precision was estimated over three concentration ranges.

Range	≤2	2 – 10	>10
N	88	44	22
Average Reading, mg/dL	0.74	5.96	13.40
Pair Precision (SD), mg/dL	0.05	0.28	0.67
%CV	6.4%	4.6%	5.0%

Because the SDs presented here are the pooled averages from multiple customer performance verifications, it is expected that, occasionally, SDs from an individual precision study to be higher or lower than these averages. Each site must establish whether the results of their precision studies are clinically acceptable. Alternatively, an f-test can be used to determine whether their precision is statistically equivalent to typical precision values summarized above.

B. Linearity Data

Whole Blood Linearity Study (CLSI EP06-A[7]): This study was performed in-house on multiple whole blood samples with *Creatinine* values spanning the reportable range. Linearity is reported versus theoretical creatinine values based on gravimetric mixtures of high and low creatinine samples (as measured using an in-house standard whole blood creatinine method with IDMS traceability). Three card lots were used in this study.

Test Range	Slope	Intercept	R
0.251 – 15.5 mg/dL	1.00	0.07	0.995

C. Method Comparison Data

Linear regression analysis was performed on the method comparison data in accordance with CLSI EP09-A2[3]. In the method comparison statistics table, N is the number of patient specimens in the data set, Sxx and Syy are the pooled pair-wise imprecision of the comparative and epoc test methods respectively, Syx is the standard error and R is the correlation coefficient.

Venous, arterial and capillary patient samples were compared with an IDMS-traceable serum-based laboratory system.

Crea	Roche Cobas 6000[10]
N	144*
Sxx	0.10
Syy	0.30
Slope	1.03
Intercept	-0.10
Syx	0.45
Xmin	0.30
Xmax	14.80
R	0.995
Mean Bias in eGFR Range of Interest (1.00–1.50 mg/dL)	-0.06

*Patient samples: approximately equal numbers of venous, arterial, and capillary samples

D. Limitations and Interferences

Interference testing[4] was performed in-house on the epoc creatinine sensor. In each of these tests a pooled human serum specimen was aliquoted into two (2) samples. The test sample was spiked by addition of interferent, while the control sample was spiked by the addition of the solvent of the interferent. The creatinine bias between the mean of six (6) replicates on both the control sample and the test sample with added interferent was calculated.

Unacceptable interference bias was defined as producing a significant error more than 5% of the time. The concentration of interfering substance considered as causing no clinically significant interference is defined as a bias (difference between the test and the control sample) of ≤ 0.23 mg/dL for creatinine concentrations ≤2 mg/dL and ≤6.8% for creatinine concentrations >2 mg/dL.

Clinically significant interfering substances are itemized below:

- Creatine will have no significant effect up to 0.10 mmol/L (1.34 mg/dL) after which it will increase the creatinine concentration by up to 2.17 mg/dL creatinine per mmol/L creatine. The reference range of creatine in plasma is 8 – 31 μmol/L (0.1-0.4 mg/dL) in males and 15 – 53 μmol/L (0.2 – 0.7 mg/dL) in females[11].

- Iodide will have no significant effect up to 0.45 mmol/L (5.74 mg/dL) after which it will decrease the creatinine concentration by up to 0.49 mg/dL creatinine per mmol/L iodide.

- N-acetyl cysteine will have no significant effect up to 0.47 mmol/L (7.70 mg/dL) after which it will decrease the creatinine concentration by up to 0.72 mg/dL creatinine per mmol/L N-acetyl cysteine. It has been reported that 1 mM N-acetyl cysteine is therapeutically unattainable in plasma[8]. The therapeutic level for N-acetyl cysteine is 0.3 mM[12].

Ethylene glycol plus three metabolism products - Glycolic Acid, Glyoxylic Acid and Oxalic Acid - were tested for interference. Ethylene glycol, glyoxylic acid, and oxalic acid do not interfere significantly with epoc creatinine.

- Glycolic acid will have no significant effect up to 1.69 mM, after which it will decrease the creatinine reading by up to 5% / 1 mM glycolic acid.

The following levels of exogenous interferences were tested and found to be clinically insignificant: 1.324 mmol/L (20 mg/dL) acetaminophen, 3.62 mmol/L (65.2 mg/dL) acetylsalicylic acid, 342 μmol/L (6.8 mg/dL) Na ascorbate, 3.4 μmol/L (0.1 mg/dL) EDTA, 71 μmol/L (1.7 mg/dL) methyldopa, 2.55 mmol/L (156 mg/dL) oxidized glutathione, 2.55 mmol/L (78 mg/dL) reduced glutathione, 920 μmol/L (6.96 mg/dL) hydroxyurea, 282 μmol/L (4mg/dL) isoniazid (nydrazid), 0.8% (800 mg/dL) intralipid, 3 μmol/L (0.1 mg/dL) dobutamine, 5.87 μmol/L (0.1 mg/dL) dopamine, 86.8 mmol/L (400 mg/dL) ethanol, 105 μmol/L (0.44 mg/dL) fluoride, 133 μmol/L (0.4 mg/dL) formaldehyde, 55 mmol/L (990 mg/dL) glucose, 0.4 mmol/L (5 mg/dL) guaiacol, 3000 U/L heparin, 2.43 mmol/L (50 mg/dL) ibuprofen, 0.1 mmol/L (2.0 mg/dL) L-Dopa, 51.2 μmol/L (1.2 mg/dL) lidocaine, 248 μmol/L (6 mg/dL) thiopental, 2.37 mmol/L (64 mg/dL) tolbutamide, 2.643 mmol/L (120 mg/dL) cefazolin, 1.46 mmol/L (81 mg/dL) ceftriaxone, 4.34 mmol/L (70 mg/dL) salicylate, 6.88 mmol/L (40 mg/dL) thiocyanate, 10 mmol/L (104 mg/dL) β-hydroxybutyrate, 37.5 mmol/L (300 mg/dL) bromide, 20 mmol/L (384 mg/dL) Na citrate, 78.1 μmol/L (6.4 mg/dL) rifampicin, 5 μmol/L (0.7 mg/dL) bacitracin, 30.2 μmol/L (1 mg/dL) ciprofloxacin, 48.6 μmol/L (1.8 mg/dL) levofloxacin, 2.4 μmol/L (0.08 mg/dL) norfloxacin.

The following levels of endogenous interferences were tested and found to be clinically insignificant: +342 μmol/L (+20.1mg/dL) bilirubin unconjugated, +342 μmol/L (+28.8 mg/dL) bilirubin conjugate, 109 mmHg CO_2, 15 mmHg CO_2, +40 mmol/L (+244 mg/dL) bicarbonate , pH >8.0, pH < 6.8, Hct<10PCV, Hct>75PCV, <6% protein, >9% protein, 1.4 mmol/L (23.5 mg/dL) uric acid. 6.6 mmol/L (74 mg/dL) lactate, 131 mmHg O_2, 22 mmHg O_2, 0.25 mmol/L (2.9 mg/dL) proline, 1 μmol/L (0.01 mg/dL) sarcosine, 42.9 mmol/L (258 mg/dL) urea.

E. References

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6. i-STAT 300, Abbott Point of Care Inc., 104 Windsor Center Drive, East Windsor, NJ 08520, "i-STAT" is a registered trademark of Abbott Laboratories.

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12.13 Hematocrit (Hct)

Hematocrit is measured by AC conductometry using two (2) gold electrodes. The conductance of the blood sample in the fluidic path between the two (2) electrodes, after correction for variable plasma conductivity through the measurement of sodium concentration, is inversely proportional to the hematocrit value.

12.13.1 Indications for Use

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

Measurement of Hct distinguishes normal from abnormal states of blood volume, such as anemia and erythrocytosis.

12.13.2 Contents

Each Test Card incorporating an Hct test contains two (2) gold sensing electrodes and a calibrator fluid containing a known concentration of dissolved electrolytes with a known conductivity.

12.13.3 Traceability

Hematocrit values assigned to controls and calibrator fluids are traceable to the standard method for measuring packed cell volume by the microhematocrit method, using whole blood with K_3EDTA anticoagulant, – applicable standard CLSI H07-A3[1].

12.13.4 Sample Collection

Refer to 12.2.6 Sample Collection.

12.13.5 Additional Information

Refer to Section 3 "epoc System Operation" in this manual for detailed sample collection and system operating instructions for conducting a blood test.

Refer to Section 9 "Quality Assurance" in this manual for quality control requirements.

12.13.6 Measurement Range

	Measurement Range	Reference Range[2]
Hct	10 – 75%	38 – 51%
	0.10 – 0.75	0.38 – 0.51 L/L

12.13.7 Performance Data

Typical performance data summarized below were obtained in-house as well as in healthcare facilities by healthcare professionals trained in the use of the epoc System. Experimental designs conformed to applicable CLSI guidelines.

Applicable standards include: CLSI EP09-A2[3] for method comparison studies, CLSI EP07-A2[4] for interference studies and CLSI EP05-A2[7] for precision studies.

A. Precision Data

Twenty replicates of each of two levels of commercial controls were analyzed at each of 20 different sites. The precision study at each site employed from two (2) to eight (8) epoc Readers, and multiple lots of epoc Test cards were included across all of the sites. The pooled SD and averaged means are presented below:

Aqueous Control	Units	Mean	SD	%CV
High Level	% PCV	43.9	0.7	1.6
Low Level	% PCV	22.7	0.5	2.2

Because the SDs presented here are the pooled averages from multiple customer performance verifications, it is expected that, occasionally, SDs from an individual precision study to be higher or lower than these averages. Each site must establish whether the results of their precision studies are clinically acceptable. Alternatively, an f-test can be used to determine whether their precision is statistically equivalent to typical precision values summarized above.

B. Linearity Data

This study was performed in-house on multiple whole blood samples with hematocrit level spanning the reportable range. Linearity is reported versus an in-house standard spun hematocrit method.

	Test Range	Units	Slope	Intercept	R
Hct	0 – 75	% PCV	1.005	-0.58	0.9995

C. Clinical Sites Method Comparison Data

Linear regression analysis was performed on the method comparison data in accordance with CLSI EP09-A2[3]. In the method comparison statistics table, N is the number of Patient specimens in the data set, Sxx and Syy are the pooled pair-wise imprecision of the comparative and epoc test methods respectively, Syx is the standard error and R is the correlation coefficient.

Clinical Site Method Comparison 1: In one hospital study the epoc System was compared with the i-STAT 300[5] in the lab (two test occasions), and then at three (3) point-of-care sites.

Method Comparison Summary Statistics: whole blood

X: i-STAT 300 test

Y: epoc test

Hct	Lab 1	Lab 2	POC 1	POC 2	POC 3	All
N	34	23	35	28	22	142
Sxx	0.49	0.66	0.46	0.67	0.69	0.58
Syy	0.69	0.42	0.65	0.57	0.80	0.64
Intercept	-1.5	1.3	0.0	-0.4	-0.4	-1.1
Slope	1.086	1.006	1.034	1.027	1.051	1.066
Syx	1.28	1.17	1.05	1.48	1.82	1.36
Xmin	19	24	28	23	24	19
Xmax	73	57	41	39	60	73
R	0.995	0.990	0.964	0.955	0.976	0.987
Mean Bias (%CV)						1.7

Clinical Site Method Comparison 2: In another hospital study, the epoc System was compared with the Radiometer ABL 735[6] in the lab. (The ABL 735 hematocrit value was calculated from the measured hemoglobin.)

Method Comparison Summary Statistics: whole blood

X: Radiometer ABL 735

Y: epoc test

Hct	N	Sxx	Syy	Intercept	Slope	Syx	Xmin	Xmax	R	Mean Bias (%CV)
Lab	77	1.42	1.16	-2.3	1.006	2.84	21	63	0.964	-1.6

D. Limitations and Interferences

Blood samples must be well mixed in order to obtain accurate hematocrit results. The best way to ensure this is to test the sample immediately after collection. For samples where testing delays of greater than one minute occur, cells should be thoroughly re-mixed by rolling the sample between the hands for several rotations in both directions.

Note: Thin diameter collection devices (for example, 1cc syringes or epoc Care-Fill Capillary Tubes) may be difficult to re-mix. Therefore, it is recommended that testing from these devices not be delayed. Refer to 12.2.6 Sample Collection.

Interference testing[4] was performed in-house on the epoc hematocrit sensor. In each of these tests a whole blood specimen was aliquoted into two samples. The test sample was spiked by addition of interferent, while the control sample was spiked by the addition of the solvent of the interferent. The hematocrit bias between the mean of six replicates on both the control sample and the test sample with added interferent was calculated.

Note: Automated hematology analyzers may underestimate or overestimate hematocrit values due to the differing osmotic effects on RBC in the isotonic buffer matrix, compared to their native plasma matrix[8].

Clinically significant interfering substances are itemized below:

- Total protein content will affect the hematocrit results as follows: an increase (decrease) of 1 g/dL of total protein will increase (decrease) the hematocrit value by approximately 1% PCV. Total protein levels vary with the clinical populations[2]. Low total protein values may be found in neonates, burned Patients, Patients receiving large volumes of IV fluids, and Patients undergoing cardiopulmonary bypass (CPB) and extra-corporeal membrane oxygenation (ECMO). For the case of hemodilution, the user should activate the hemodilution correction factor or "HCF" in the epoc Host (see Section 6 "epoc Host" and Section 7 "epoc Host Administration" in this manual for details). The HCF corrects hematocrit for low protein in blood samples known to be diluted with fluids that do not contain protein. There is no HCF applied for Hct over 42%. It is recommended that each practice verify the use of the HCF algorithm as well as the time interval that the HCF should be selected during the recovery period.

Hemodilution correction factor (HCF)
Final Hct = Hemotocrit without HCF + HCF
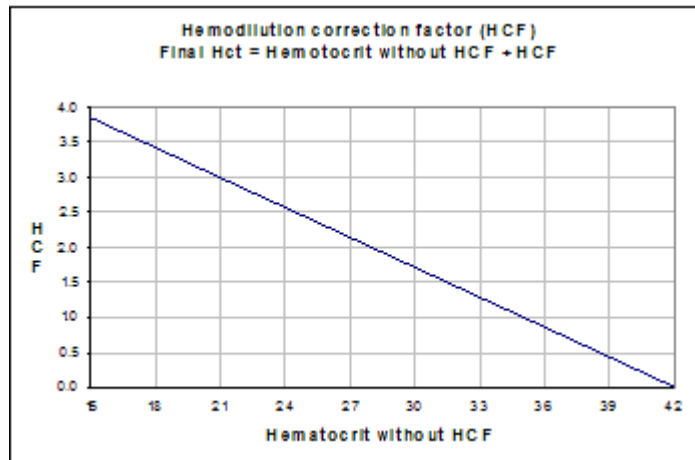
- A significant increase in white blood cell count may increase the hematocrit result.
- Abnormally high lipids may increase hematocrit results.

The following levels of exogenous interferences were tested and found to be clinically insignificant: 447 mg/dL ethanol, 1 mmol/L sodium pentothal, 4.3 mmol/L acetyl salicylate, 0.4 mmol/L ascorbate, 4.3 mmol/L salicylate, 1 mmol/L iodide, 2.2 mmol/L ibuprofen, 4 mmol/L lithium, 19 mmol/L bromide, 2.64 mmol/L propofol, 0.7 mmol/L cefotaxime, 0.16 mmol/L ampicillin, 1 mmol/L sodium perchlorate, 4.8 µM Zofran™, 2.5 mM N-acetylcysteine, 0.7 mM metronidazole.

The following levels of endogenous interferences were tested and found to be clinically insignificant: 0.8g/dL lipids, 9.1 mmol/L cholesterol, 20 mmol/L β-hydroxybutyrate, 2mmol/L (24mg/dL) L-cysteine, 0.26 mmol/L bilirubin, +2 mmol/L phosphate.

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5. i-STAT 300, Abbott Point of Care Inc., 104 Windsor Center Drive, East Windsor, NJ 08520, "i-STAT" is a registered trademark of Abbott Laboratories.

6. Radiometer ABL 735, Radiometer Medical ApS, Åkandevej 21, DK-2700 Brønshøj, Denmark, "Radiometer" and "ABL" are registered trademarks of Radiometer Medical ApS.

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12.14 Calculated Values

Note: Except where noted, calculated values are only available when the measured parameters from which they are derived are displayed.

12.14.1 Calculated Bicarbonate (cHCO$_3$-), Calculated Total Carbon Dioxide (cTCO$_2$), Base Excess (BE)[1]

*Note: Alternate analyte acronyms for **cHCO₃-** are **HCO₃-act** or **HCO₃-**.*

Calculated bicarbonate: LOG cHCO$_3$- = pH + LOG pCO$_2$ − 7.608

Calculated TCO$_2$: cTCO$_2$ = cHCO$_3$- + 0.0307 x pCO$_2$

Base Excess (extra cellular fluid): BE(ecf) = cHCO$_3$- − 24.8 + 16.2 x (pH − 7.4)

Base Excess (blood): BE(b) = (1 − 0.014 x cHgb) x (cHCO$_3$- − 24.8 + (1.43 x cHgb + 7.7) x (pH − 7.4)) *

Applicable standards: CLSI C46-A2[1]. In above equations, units are mmHg for pCO$_2$ and g/dL for cHgb.

* cHgb is obtained from measured Hematocrit value, even if Hematocrit and cHgb are not displayed.

Measurement Range

	Units of Measure	Measurement Range	Reference Range[8-10]	
			Arterial	Venous
cHCO₃-	mmol/L	1 − 85	21 − 28	22 − 29
	mEq/L			
cTCO₂	mmol/L	1 − 85	22 − 29	23 − 30
	mEq/L			
BE(ecf)	mmol/L	-30 − +30	-2 − +3	-2 − +3
	mEq/L			
BE(b)	mmol/L	-30 − +30	-2 − +3	-2 − +3
	mEq/L			

12.14.2 Calculated Oxygen Saturation (cSO$_2$)[2]

*Note: Alternate analyte acronym for **cSO₂** is **O2SAT**.*

cSO$_2$ = 100(X^3 + 150X) / (X^3 + 150X + 23400)

X = pO$_2$ x 10$^{(0.48(pH-7.4)-0.0013(cHCO_3-25))}$

Measurement Range

	Measurement Range	Reference Range, Arterial
cSO₂	0 − 100%	94 − 98%

Because oxygen saturation also depends on the effects of 2,3 diphosphoglycerate and dysfunctional hemoglobins (carboxy-, met–, and sulfhemoglobin) in blood, the above equation does not account for variations in these values, the oxygen saturation that is reported should only be used as an estimate of the actual value[1,3,11]. Shifts in the oxyhemoglobin dissociation curve have also been recorded in cases of uremic and diabetic coma, as well as pernicious anemia[10]. Clinically significant errors can result from incorporation of such an estimated value for oxygen saturation in further calculations, such

as shunt fraction, or by assuming the value obtained is equivalent with fractional oxyhemoglobin.

Oxygen saturation is a useful predictor of the amount of oxygen that is available for tissue perfusion. Some causes for decreased values of cSO_2 include low pO_2 or impaired ability of hemoglobin to carry oxygen.

12.14.3 Anion Gap (AGap)[8]

Anion Gap: AGap = (Na+) - (Cl- + cHCO$_3$-)

Anion Gap, K: AGapK = (Na+ + K+) - (Cl- + cHCO$_3$-)

Applicable reference: Tietz 2nd ed.[8].

Measurement Range

	Units of Measure	Measurement Range	Reference Range
AGap	mmol/L	-14-+95	7-16
	mEq/L		
AGapK	mmol/L	-10-+99	10-20
	mEq/L		

12.14.4 Estimated Glomerular Filtration Rate (eGFR)[4,5]

Estimated Glomerular Filtration Rate (IDMS-traceable MDRD type):

$$eGFR = 175 \times (Crea^{-1.154}) \times (Age^{-0.203}) \times (0.742 \text{ if female, 1 if male})$$

Estimated Glomerular Filtration Rate, *if African American* (IDMS-traceable MDRD type):

$$eGFR\text{-}a = 175 \times (Crea^{-1.154}) \times (Age^{-0.203}) \times (0.742 \text{ if female, 1 if male}) \times 1.212$$

Crea concentration is in units of mg/dL. Age (years) and gender (male or female) are user inputs. eGFR, eGFR-a are both reported on the epoc System. eGFR, eGFR-a values are not reported if Age is less that 18 years old or greater than 120 years old.

Measurement Range

	Measurement Range	Reference Range
eGFR	2 – 60 or >60 mL/min/1.73m^2 *	†
eGFR-a	2 – 60 or >60 mL/min/1.73m^2 *	†

* Numeric values will be reported for values between 2-60 mL/min/1.73 m^2. Values >60 will be reported as > 60 mL/min/1.73 m^2. This range is based on the specific National Kidney Disease Education Program (NKDEP) recommendation for reporting eGFR values[4].

*eGFR > 60 does not exclude the possibility of mild renal disease. Further laboratory testing may be necessary to distinguish normal renal function from mild renal disease.

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

12.14.5 Calculated Hemoglobin (cHgb)[6,7]

Hemoglobin concentration is calculated from the measured hematocrit according to the relation:

cHgb (g/dL) = Hct (decimal fraction) x 34

The relation above assumes a normal Mean Corpuscular Hemoglobin Concentration, MCHC of 34%[6,7].

Measurement Range

	Measurement Range	**Reference Range**
cHgb	3.3 – 25 g/dL	12 – 17 g/dL
	2.0 – 15.5 mmol/L	7.4 – 10.6 mmol/L
	33 – 250 g/L	120 – 170 g/L

12.14.6 Alveolar Oxygen (A), Arterial Alveolar Oxygen Tension Gradient (A-a), Arterial Alveolar Oxygen Tension Ratio (a/A)

*Note: Alternate acronym for **A** is **$pO_2(A)$**.*

*Note: Alternate acronyms for **A-a** are **$pO_2(A-a)$** and **$AaDO_2$**. Also referred to as Arterial Alveolar Oxygen Tension Difference.*

*Note: Alternate acronym for **a/A** is **$pO_2(a/A)$**.*

Entering a patient temperature is required for corresponding temperature-corrected parameters: A(T), A-a(T), a/A(T).

Note: These calculations require the sample type selection of Arterial or Capillary. If these sample types are not selected, these parameters will not be displayed.

Note: If FiO2 is not entered, these parameters will not be displayed.

These six parameters are calculated as follows.

$$A = FiO_2 \times (pAmb\text{-}pH_2O) - pCO_2 \times (1/RQ\text{-}FiO_2(1/RQ\text{-}1))$$

$$A(T) = FiO_2 \times (pAmb\text{-}pH_2O(T)) - pCO_2(T) \times (1/RQ\text{-}FiO_2(1/RQ\text{-}1))$$

$$A\text{-}a = A - pO_2$$

$$A\text{-}a(T) = A(T) - pO_2(T)$$

$$a/A = pO_2 / A$$

$$a/A(T) = pO_2(T) / A(T)$$

where:

RQ = Respiratory Quotient, input parameter (range 0.01-2.00). If RQ is not entered, 0.86 is used.

FiO_2 = Fraction of inspired O_2, input parameter (range 21-100, %). If FiO_2 is not entered, these parameters will not be displayed.

pH_2O = 6.275 kPa

$pH_2O(T) = 6.275 \times 10^{((T-37)(0.0236-0.000096(T-37)))}$ kPa, temperature units are °C.

pAmb = ambient barometric pressure (measured by epoc Reader) kPa

T = Patient Temperature, input parameter.

Measurement Range

	Measurement Range	Reference Range
A, A(T)	5-800 mmHg	†
	0.67-106.64 kPa	†
A−a, A−a(T)	1-800 mmHg	†
	0.13-106.64 kPa	†
a/A, a/A(T)	0-100 %	†
	0-1	†

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

12.14.7 References

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    http://www.nkdep.nih.gov/labprofessionals/equations_and_GFR.htm

    Refer to: Laboratory Professionals > Estimating and Reporting GFR > Equations and GFR Calculators>IDMS-traceable MDRD Study Equation

    Also, refer to: http://nkdep.nih.gov/lab-evaluation/gfr/reporting.shtml.

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13   epoc® Reader and Host Specifications

13.1 epoc Reader

LENGTH	215 mm [8.46 in]
WIDTH	85 mm [3.35 in]
HEIGHT	50 mm [2 in]
WEIGHT	< 500 g [< 1.1 lb]
OPERATION	AC adapter or battery
DC INPUT	5 volts, 3 amps
OPERATION ON BATTERY	Up to 50 Tests
STANDBY BATTERY TIME	10.5 hours with fully charged Battery

Note: "Standby" means "Tests not being run, Reader is connected to Host via Bluetooth®."

TIME TO RECHARGE	<4 hours
RECHARGE DURING USE	Yes
BATTERY ACCESSORY	Battery door (cover) is available for replacement. Supplied with a screw, in a plastic bag.
SAFETY CERTIFICATION	IEC-61010-1 – Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General Requirements IEC-61010-2-81 – Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes IEC-61010-2-101 – Part 2:-101: Particular requirements for In Vitro Diagnostic (IVD) medical equipment
CERTIFICATION MARKS	c CSA us – CSA compliance CE Mark – Certification Mark for European Union MIC – Japanese Radio Law Certification KC Mark – Certification Mark for South Korea
COMPLIANCE	Australian EMI Compliance RoHS2 Directive 2011/65/EU and REACH
OPERATING TEMPERATURE	15º – 30º C [59 - 86º F]
SHIPPING/STORAGE TEMPERATURE	-20º – 45º C [-4 - 113º F]
OPERATING/SHIPPING/ STORAGE HUMIDITY	Up to 85% relative humidity, non-condensing at 30ºC (86ºF)
OPERATING/SHIPPING/ STORAGE BAROMETRIC PRESSURE	400 – 825 mmHg [53.33-110 kPa]

Note: When operating between 2000m (equivalent to 604 mmHg or 81 kPa) and 5000m (equivalent to 400 mmHg or 53.33 kPa) altitude, use only with the following components:

- *Host[2] (Zebra MC55A0)*
- *AC Adapter Protek Power, Model PMP15M-10*

Otherwise, maximum operating altitude is up to 2000 m (equivalent to 604 mmHg or 81 kPa).

SENSOR ELECTRONICS	amperometric, potentiometric, conductimetric
TEST TIME	45 seconds after sample introduction (approximately)
WATER INGRESS	IPX0

13.2 epoc Reader Components

AC ADAPTER(S)	SL Power Electronics, Model MW172KA05
	Globtek Inc., Model GTM41060-1505
	Protek Power, Model PMP15M-10
	AC input: 100-240 Vac, .5 amps, 50-60 Hz DC output: 5 volts, 3 amps Continuous Operation, Class 2
	Safety: IEC 60601-1, CSA/UL 601
	EMC: IEC60601-1-2

Note: Only the PMP15M-10 is allowed for Barometric Pressure 400–825 mmHg [53.33-110kPa] (5000m altitude maximum). Other AC Adapters listed above are for 2000m altitude maximum.

BATTERY	Ultralife™ Lithium Ion Rechargeable Battery, UBP103450A
EMBEDDED BARCODE READER	Opticon LB SAM12 visible red LED Barcode Scanning Module configured to decode Code 128 barcodes located on Test Cards
THERMAL CONTROL	Reader calibrated to 37.0° ±0.15° C [98.6° ±0.3°F]
LED INDICATORS	Amber – Battery Status Indicator Green/Red – Test Status Indicator Green – Power Indicator
BLUETOOTH MODULE (EZURIO BISM2 or BISMS02BI-01)	Radio: R&TTE EN300 328-2 V1.1.1, EN301 489-1 V1.3.1 EMC Emissions: FCC 15B Class B, EN55022 Class B EMC Immunity: EN 55024, EN 60950-1 Part 1 Medical: EN 60601-1-2 Operating Frequency: 2.400- 2.485 GHz Power Output: 0.0021 Watts FCC ID: PI403B
USB PORT	For maintenance purposes only by Epocal authorized personnel.

13.3 epoc Host (Socket)

Note: The epoc System includes either Host (Socket) or Host^2 (Zebra, former Motorola), depending on the region. Please refer to the applicable subsection.

HARDWARE	Mobile Computer, Socket SoMo™ 650
SOFTWARE	Microsoft® Windows® Mobile (Version 5.0 Premium) Operating System, SP4 or Microsoft Windows Mobile (Version 6.0) Operating System, SP7 or higher. epoc Host Application Software
PROCESSOR	Intel® PXA270 @ 624MHz
MEMORY	128MB SDRAM, 256MB NAND FLASH
DISPLAY	3.5" LCD touch screen
LENGTH	127 mm [5.0 in]
WIDTH	74.6 mm [2.94 in]
HEIGHT	20.6 mm [0.81 in]
WEIGHT	178.8 g [6.3 oz]
LITHIUM ION RECHARGEABLE BATTERY	3.7v 1200 mAh (standard) Model SoMo-650-1200 (Socket Communications Inc. # HC1601-756) or 3.7v 2600 mAh (extended) Model SoMo-650-2600 (Socket Communications Inc. # HC1602-757)
OPERATION ON BATTERY	Typical use, up to 40 (standard) or up to 90(extended) Tests (Dependent on battery and use)
TIME TO RECHARGE	<3 hours (standard) or <5 hours (extended)
BLUETOOTH	V2.0 + EDR Class 2 Range: Up to 10m (Data Rate: 3Mbit/s) Maximum output power: 2.5mW (4dBm) Nominal output power: 1mW (0dBm) Minimum output power: 0.25 mW (-6dBm)
BLUETOOTH SECURITY	128-bit encryption with PIN authentication.
WIRELESS LOCAL AREA NETWORK	IEEE™ 802.11 b/g Range: Up to 30m (Data Rate: 1/2/5.5/6/9/11/12/18/24/36/48/54 Mbps) Frequency Range: Country dependent (chan. 1-14); 2.412 to 2.484GHz Output Power: 14.5 dBm (OFDM); 16 dBm (CCK)
WI-FI SECURITY	WEP (64/128): Open and Shared WPA (TKIP): Pre-shared key and Enterprise WPA2 (AES): Pre-shared key and Enterprise EAP (802.1x): PEAPv0/MSCHAPv2, PEAPv1/GTC, LEAP, FAST, TLS, and TTLS CCKM based Fast Roaming
SD CARDS	Only 1 GB or 2 GB SD Cards may be used for upgrading Socket Hosts.

BARCODE SCANNER	1D laser scanner (Socket Mobile Compact Flash Scan Card, CFSC-5P) Barcode Formats: UPC-A; UPC-E; UPC-E1; EAN-8; EAN-13; Bookland-EAN; Code-128; UCC EAN-128; ISBT-1281; Code-39; Trioptic Code-39; Code-39 Full ASCII Conversion; Code-93; Interleaved 2 of 5; Discrete 2 of 5; Codabar; MSI

CERTIFICATION / COMPLIANCE
- FCC: Part 15, Class B
- Industry Canada
- RoHS and WEEE compliant
- EMI / RFI
- Bluetooth Certification (BQB test)
- Microsoft Windows Mobile 5.0 Logo Test Certification
- EU/International: EN301 489-1, -17
- EN61000-4-2: 1995, ESD ±8kV air/±4kV contact
- EN61000-4-3: 1997, radiated immunity eV/m
- EN61000-4-4: 1995, EFT ±0.55kV
- EN61000-4-5: 1995, Surge ±0.5kV
- EN61000-4-6: 1
- CE: EN
- Electrical Safety EN60950, UL, CSA
- Wi-Fi Alliance Certification
- USB IF Test

OPERATING TEMPERATURE	0-50° C [32-122° F]
BAROMETRIC PRESSURE	604 – 825 mmHg [81-110kPa] (2000m altitude maximum)
OPERATING HUMIDITY	95% relative humidity, non-condensing
WATER INGRESS	IPX0

13.4 epoc Host Accessories (for Socket)

AC ADAPTERS (OPTIONAL)	1. PIE Electronics (H K) Limited, Model AD3230
	   Input: 100-240Vac, 50/60Hz, 500mA
	   Output: 5Vdc, 3000mA
	   IEC60950-1 compliant, CSA, UL, TUV
	
	2. Phihong Technology Co., Model PSA15R-050P
	   Input: 100-240Vac, 50/60Hz, 500mA
	   Output: 5Vdc, 3000mA
	   IEC60950-1 compliant, CSA, UL, TUV

BARCODE SCANNER (INCLUDED WITH EPOC HOST)	Socket Communications, Model CFSC5P Class 2 Laser - IEC 60825-1 compliant 3.3Vdc, 4mA standby (typical), 90mA scanning (typical)

13.5 epoc Host^2 (Zebra)

Note: *The epoc System includes either Host (Socket) or Host^2 (Zebra, former Motorola), depending on the region. Please refer to the applicable subsection.*

HARDWARE	Mobile Computer, MC55A0-HC
SOFTWARE	Microsoft Windows Mobile 6.5 Classic
PROCESSOR:	Marvell™ PXA 320 @ 806 MHz processor
MEMORY:	256 MB RAM; 1 GB Flash
DISPLAY:	PenTile™ 3.5 inch Color VGA, super bright 650+ NITS
LENGTH	147 mm [5.78 in]
WIDTH	77 mm [3.03 in]
HEIGHT	27 mm [1.06 in]
WEIGHT	359 g [12.5 oz]
LITHIUM ION RECHARGEABLE BATTERY	Rechargeable Lithium Ion 3.7V, 3600 mAh Smart Battery
OPERATION ON BATTERY	Typical use, up to 70 Tests (dependent on battery and use)
TIME TO RECHARGE	<5 hours
BLUETOOTH	Class II, v 2.1 EDR Range: Up to 10m (Data Rate: 3Mbit/s) Maximum output power: 2.5mW (4dBm) Nominal output power: 1mW (0dBm) Minimum output power: 0.25 mW (-6dBm)
BLUETOOTH SECURITY:	128-bit encryption with PIN authentication
WIRELESS LOCAL AREA NETWORK	Tri-mode IEEE™ 802.11a/b/g Range: Up to 30m (Data Rates: 1, 2, 5.5, 6, 9, 11, 12, 18, 24, 36, 48, and 54 Mbps) Frequency Range: Chan 8-165 (5040 – 5825 MHz), Chan 1-13 (2412-2472 MHz), Chan 14 (2484 MHz) Japan only, actual operating channels/frequencies depend on regulatory rules and certification agency Security: WPA2, WEP (40 or 128 bit), TKIP, TLS, TTLS, (MS-CHAP), TTLS, (MS-CHAP v2), TTLS, (CHAP), TTLS-MD5, TTLS-PAP, PEAP-TLS, PEAP (MS-CHAP v2), AES, LEAP, CCXv4, certified; FIPS 140-2 certified Output Power: 14.5 dBm (typical)

WI-FI SECURITY:	WEP (40/128):	Open and Shared
	WPA (TKIP):	Pre-shared key and Enterprise
	WPA2 (AES):	Pre-shared key and Enterprise
	EAP (802.1x):	TLS, TTLS (MS-CHAP), TTLS (MS-CHAP v2), TTLS (CHAP), TTLS-MD5, TTLS-PAP, PEAP-TLS, PEAP (MS-CHAP v2), LEAP, FAST
	Certification:	CC Xv4 certified, FIPS 140-2 certified (NIST FIPS 140-2 Certificate #1210)

BARCODE SCANNER: 2D Imager (SE4500-DL)

Barcode Formats:

1D barcodes: UPC-A, UPC-E, UPC-E1, EAN-8, EAN-13, Bookland EAN, Code-128, UCC EAN-128, Code-39 Full ASCII Conversion, Code-39, Trioptic Code-39, ISBT-1281, Code-93, Interleaved 2 of 5, Discrete 2 of 5, Codabar, MSI

2D barcodes: PDF417, MICROPDF, MACROPDF, MaxiCode, DataMatrix, QRCode, MACROMICROPDF, Composite AB, Composite, TLC39, AZTEC, MICROQR

CERTIFICATION / COMPLIANCE

Electrical Safety: Certified to UL/cUL 60950-1, IE C/EN60950-1
Environmental: RoHS-compliant
WLAN and Bluetooth (PAN)
USA: FCC Part 15.247, 15.407
Canada: RSS-210, RSS 310
EU: EN 300 328, EN 300 440-2, EN 301 893
Japan: ARI B STD-T33, ARI B STD-T66, ARI B, STD-T70 & T71
Australia: AS/NZS 4268

RF Exposure:
USA: FCC Part 2, FCC OET Bulletin 65, Supplement C
Canada: RSS-102
EU: EN 50392
Australia: Radio communications Standard 2003
EMI/RFI North America: FCC Part 15, Class B
Canada: ICES 003 Class B
EU: EN55022 Class B, EN 301 489-1, EN 301 489-17, EN 301 489-19, EN 60601-1-2
Laser Safety IE C/Class 2/FDA ll in accordance with IE C60825-1/EN 60825-1

RoHS2 Directive 2011/65/EU and REACH

OPERATING TEMPERATURE -10°C -50° C [14°F -122° F]

BAROMETRIC PRESSURE 400 – 825 mmHg [53.33 -110kPa] (5000m altitude maximum)

OPERATING HUMIDITY 95% relative humidity, non-condensing

WATER INGRESS IP64

13.6 epoc System Accessories

DESKTOP CRADLES (OPTIONAL)

1. Zebra Single Slot Cradle, Model #CRD5501-1000XR (for Host[2] only)
2. Portsmith Technologies Ethernet Cradle, for MC67, MC65, and MC55 Series, Model #PSCMC67UE (for Host[2] only)

Note: The original cradle for connecting epoc Host[2] to epoc Reader must be removed before inserting it in a desktop cradle.

Note: Inserting the epoc Host[2] into the desktop cradle may trigger the barcode scanner. Never look directly into the laser light. Laser light may be harmful to eyesight if viewed directly.

PRINTERS (OPTIONAL)

Note: Supported character sets are shown in parentheses.

1. EPSON TM-T88IV. Supports printing in English (ASCII), French (1252), German (1252), Spanish (1252), Italian (1252), Finnish (1252), Norwegian (1252), Swedish (1252), Dutch (1252), Danish (1252), Portuguese (1252).
2. EPSON TM-P60. Supports printing in English (ASCII), French (1252), German (1252), Spanish (1252), Italian (1252), Finnish (1252), Norwegian (1252), Swedish (1252), Dutch (1252), Danish (1252), Portuguese (1252).
3. Zebra MZ320/iMZ320 thermal printer. Supports printing in English (ASCII), French (1252), German (1252), Spanish (1252), Italian (1252), Finnish (1252), Norwegian (1252), Swedish (1252), Dutch (1252), Danish (1252), Portuguese (1252).
4. SANEI BLM-80BT. Supports printing in English (ASCII), French (1252), Spanish (1252), Italian (1252), German (1252), Japanese (Shift-JIS), Greek (1253), Romanian (1250), Dutch (1252), Portuguese (1252), Norwegian (1252), Swedish (1252), Danish (1252), Finnish (1252), Turkish (857), Estonian (1252), Polish (852), Hungarian (1250), Czech (1250).
5. DATECS DPP350. Supports printing in English (ASCII), French (1252), Spanish (1252), Italian (1252), German (1252), Greek (1253), Romanian (1250), Dutch (1252), Portuguese (1252), Norwegian (1252), Swedish (1252), Danish (1252), Finnish (1252), Turkish (857), Estonian (1252), Polish (852), Hungarian (1250), Czech (1250).
6. Martel LLP1880B-391 Unicode™ printer. Supports printing in English (UTF-8), French (UTF-8), Spanish (UTF-8), Italian (UTF-8), German (UTF-8), Greek (UTF-8), Romanian (UTF-8), Dutch (UTF-8), Portuguese (UTF-8), Norwegian (UTF-8), Swedish (UTF-8), Danish (UTF-8), Finnish (UTF-8), Turkish (UTF-8), Estonian (UTF-8), Polish (UTF-8), Hungarian (UTF-8), Czech (UTF-8), Simplified Chinese (UTF-8).
7. Zebra ZQ110 standard. Supports printing in English (ASCII), French (1252), Spanish (1252), Italian (1252), German (1252), Greek (1253), Romanian (1250), Dutch (1252), Portuguese (1252), Norwegian (1252), Swedish (1252), Danish (1252), Finnish (1252), Turkish (857), Estonian (1252), Polish (1250), Hungarian (1250), Czech (1250),
8. Zebra ZQ110 Chinese. Supports GB18030, Simplified Chinese characters only.
9. Citizen CMP-20BT. Supports printing in Japanese (Shift-JIS) and English (ASCII).

To obtain status, follow the steps below in accordance with the printer type:

Epson TM-P60 (Wi-Fi and BT models): Press and hold **Power** and **Feed** buttons together. Once the printer turns on, release both buttons. The printer will print out the status page.

Zebra MZ320: Press and hold the **Feed** button. Press and release the **Power** button while keeping the **Feed** button pressed. When printing starts, release the **Feed** button. The printer will print a line of interlocking "x" characters to ensure all elements of the print head are working, print out the version of software loaded in the printer and then print two reports.

Sanei BLM-80BT, DATECS DPP350: Press and hold the **Line Feed** button. While pressing the **Line Feed** button, press the **Power** button until Status LED turns green. When the printer beeps once, release the **Line Feed** button. The printer will print out the status page.

Citizen CMP-20BT: Press and hold the **Feed** button, then release. Press and hold **Power** button until all LEDs flash once, then release. The printer will print the first portion of the status test (which include the BT address and other status). Press the **Feed** button again to complete the status test. _Note_: this printer has 1 Power LED, 1 Error LED and 3 Battery level LEDs.

Martel LLP1880B-391: Press and hold the **Power/Feed** button for 2 seconds, then release. it. _Note_: This printer has only one button. The printer will print the first portion of the status test and pause for a second. Then the rest of the status test is printed. To complete, press the **Power/Feed** button to power off. Otherwise, Hosts can't print to it.

Zebra ZQ110: Press and hold the **Feed** button. Press and hold the **Power** button until the first LED turn on, then release. Release the **Feed** button. The printer will print the first portion of the status test (which include the BT address and other status). Press and hold the **Power** button until all LEDs turn off, to power off the printer. Otherwise, press the **Feed** button again to complete the remainder of the status test.

13.7 epoc System Compliance

EUROPEAN UNION	IVD Directive (98-79-EC), EMC Directive (2004/108/EC), Low Voltage Directive (2006/95/EC), WEEE Directive (2002-96-EC)
COMPLIANCE MARK	CE
EMC PRODUCT STANDARDS	IEC 61326-1 – Electrical equipment for measurement, control and laboratory use – EMC Requirements. Generic requirements. IEC 61326-2-6 – Electrical equipment for measurement, control and laboratory use – EMC requirements. Particular requirements for In Vitro Diagnostic (IVD) medical equipment

14 Troubleshooting and Error Messages

14.1 General

This section provides information to diagnose and correct basic epoc® System operating problems. Most problems encountered can be resolved by reviewing the epoc Host Application Messages in this section.

⚠️ Do not attempt to open the Reader, Host or tamper with epoc Test Cards. With the exception of the Li battery and battery door, the epoc System has no User serviceable parts or adjustments.

⚠️ If System fails to function as intended, first attempt recommended solutions in this section or contact your System Administrator for assistance. If problem cannot be resolved, then contact Technical Services and/or local distributor to arrange for repair of the device.

14.2 Out-of-Range Results on the Test Card for Liquid Quality Control or Calibration Verification

From epoc Host, disconnect from Reader and then reconnect. If wireless connection is successful <u>and</u> Electronic QC passes, verify the following (below) and then repeat the test.

1. Use of correct Control or Calibration Verification Value Assignment Datasheet.
2. Use by Date of Controls has not been exceeded.
3. The Controls have been handled correctly: see Instructions for Use.
4. 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.

14.3 Failed Reader Electronic QC

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 Reader connects successfully (and therefore passes electronic QC) it is acceptable for use. If problem is not resolved, then contact Technical Services.

14.4 Failed Thermal QA

Perform Reader Thermal QA only after Reader has remained in same location and temperature with no airflow (i.e. within box or cabinet) for a minimum of two (2) hours.

Reader must remain "OFF" for at least 30 minutes prior to Thermal QA because heating from circuits inside Reader will cause temperature variations.

If a Reader fails Thermal QA, this may indicate that three (3) Temperature Sensors inside Reader are not at same temperature. This can occur if Reader is not fully equilibrated to environment after being turned "OFF."

Turn "ON" Reader. Repeat Thermal QA one time. Reader is acceptable for use if Thermal QA passes on second attempt.

If Thermal QA fails when repeated, then contact Technical Services.

14.5 epoc Host Application Messages

Messages are organized by the location in the epoc Host Application where the Message may be encountered. For each message, the description indicates reason why message occurred and an appropriate response is provided.

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, then first contact your System Administrator for assistance and then your Technical Services.

14.5.1   Login Page

Message#1:	**"Enter user ID and password."**
Description:	epoc Host requires a User ID and possibly Password to access System.
Response:	Verify correct User ID and Password were entered without spaces or other hidden characters. Passwords are case sensitive. Enter information again. If still not able to Login, then contact System Administrator to retrieve correct User ID and Password.

--- Login Page---

Message#2:	**"Critical Error: Unable to read startup files. Please contact your system administrator."**
Description:	Host Application is unable to read User ID and Password file due to corrupt or missing file. A pre-Login Error Message is displayed and remains on Screen. The User cannot leave this Error Page.
Response:	Ask System Administrator to contact Technical Services.

--- Login Page---

Message#3:	**"Critical Error: Missing required Host files. Contact administrator."**
Description:	If the Application detects that any required files are missing, a pre-login Error Message is displayed and remains on Screen. It is not possible to exit this Error Page.
Response:	Ask System Administrator to contact Technical Services.

--- Login Page---

Message#4: **"Invalid User ID or Password. Please try again." "Error"**

Description: Either User ID or Password entered are incorrect. Passwords are case sensitive.

Response: Verify that valid User ID and Password are used for login without spaces or other hidden characters. Carefully enter information again. If still not able to Login, then contact the System Administrator to retrieve correct User ID and Password. If no account is set up then contact System Administrator to create Account. System Administrator can determine whether to provide valid User ID and Password, valid User ID only, or any User ID for Login.

--- Login Page---

Message#5: **"User account locked. Contact administrator." "Error"**

Description: After three (3) unsuccessful Login attempts in succession, User Account is locked until Administrator re-enables account.

Response: To unlock account when an EDM is not present, the Administrator should log in, selects Tools > Admin Options > User Account Page > Modify User > Account Status > Enabled. To unlock the account when an EDM is present, any User can log in and perform synchronization, provided that User is not also locked through the EDM. If the account is locked in the EDM, an Administrator must change the account status through the EDM before synchronization is done.

--- Login Page---

Message#6: **"User account temporarily locked. Try again in five minutes." "Error"**

Description: After three (3) unsuccessful login attempts in succession, Administrator Account is temporarily locked for five (5) minutes from last login attempt.

Response: Administrator must wait five (5) minutes before attempting to log in with valid User ID and Password. If Administrator has forgotten Password, they may contact Technical Services, who will provide Administrator with Emergency Password that will work for that day. Administrator can then change Password on their account using emergency Password for login.

--- Login Page---

Message#7: **"User account expired. Contact administrator." "Error"**

Description: User Account has expired based upon the expiry date entered for account by Administrator.

Response: To reactivate account when there no EDM is present, Administrator logs in, selects Tools > Admin Options > User Account Page > Modify User > Account Expiry. Account is reactivated by changing expiry date to future date using Calendar accessed by tapping Date field. To reactivate account when EDM is present, EDM Administrator must change account expiration Date on EDM, and then any User can log into the Host and perform synchronization to update with new account expiration date.

--- Login Page---

Message#8: **"Incorrect date and time detected. To continue, enter correct date and time."**

Description: When User logs in, and Application determines that Date and Time have been moved back since last time Host was running, Host attempts to get the current Date and Time from EDM, if EDM is configured. If EDM is not configured, or Host is unable to retrieve Date and Time from EDM, a window is displayed for User to select current Date and Time.

Response: The User must set correct current Date and Time and press "Continue" Button.

--- Login Page---

Message#9:	**"Invalid date." "Error"**
Description:	User attempted to set Date and Time to a Date that was before last known Date of User activity.
Response:	User must set Date to be on or after the Date of last known User activity, which would be default Date that was in the date time picker. To set Date before this, User must wait till they are logged in and use "Tools" then "Set Date/Time."

14.5.2   Start Up

Message#1:	**"Critical Error: Data files corrupted. Contact administrator."**
Description:	Message is displayed when the host is unable to read the test data file and its backup .
Response:	Ask System Administrator to contact Technical Services.

--- Start Up---

Message#2:	**"Critical Error: Test configuration files corrupted. Contact administrator."**
Description:	Message is displayed when the host is unable to read the test configuration file and its backup .
Response:	Ask System Administrator to contact Technical Services.

--- Start Up---

14.5.3   Main Reader Tab

Message#1:	**"Readers not detected. Ensure Readers are turned on and within range then try again"**
Description:	The Application did not discover any epoc Readers. Reader(s) may be turned "OFF", out of range, or there may be a communication problem with Reader or Host.
Response:	Make sure that required epoc Readers are within range and turned "ON." Attempt discovery again by tapping Reader Discovery Icon at the top right of Screen. If epoc Readers are not found, switch epoc Readers in question "OFF" and then "ON" again. Attempt Reader discovery again. If epoc Readers are still not found, switch Host "OFF" and then "ON" again. Attempt Reader discovery again. If this does not resolve discovery problem, reset Host and log into epoc Host again. Attempt reset and discovery sequence twice if necessary.

--------------------------------------- Main Reader Tab--

Message#2:	**"Select a reader to run test." "Error"**
Description:	The menu is displayed by pressing down on empty space on Screen. **Run blood test** or **Run QA test** are selected from the menu.
Response:	Press on a Reader Icon to bring up menu to run a test on Reader.

--------------------------------------- Main Reader Tab--

Message#3:	**"Select a reader to view status." "Error"**
Description:	The menu is displayed by pressing down on empty space on Screen. **Status** is selected from menu.
Response:	Press on a Reader Icon to bring up the menu to check Reader status.

--------------------------------------- Main Reader Tab--

Message#4:	**"Select a reader to page." "Error"**
Description:	The menu is displayed by pressing down on empty space on Screen. **Page** is selected from menu.
Response:	Press on a Reader Icon to bring up menu to **Page** Reader.

--------------------------------------- Main Reader Tab--

Message#5: **"Select a reader to run Thermal QA." "Error"**

Description: The menu is displayed by pressing down on empty space on the Screen. "Thermal QA" is selected from the menu.

Response: Press on a Reader Icon to bring up the menu to perform a thermal QA test on the Reader.

-- Main Reader Tab--

Message#6: **"Testing already in progress!" "Error"**

Description: User selects "Run Blood Test" or "Run QA Test" on a Reader that is already connected for testing.

Response: Double tap on Reader Icon to go to Reader Tab or tap Reader Tab on Screen.

-- Main Reader Tab--

Message#7: **"Unable to connect to Reader..." "Error."**

Description: The Application is unable to connect to selected epoc Reader. Reader can only connect to one epoc Host and may already be connected to another Host. Reader(s) may also be turned "OFF", out of range, or there may be a communication problem in the Reader or Host.

Response: Verify that Reader is not connected to another epoc Host. If used by another Host, wait until test is complete. Other epoc Host can close Reader connection by tapping red "X" on Reader Tab. If other epoc Host is not available, turn "OFF" Reader and turn "ON" again to disconnect from other Host. Initiate discovery again by tapping Reader Discovery Icon at top right of Screen. Once discovered, attempt menu option again.

If Reader is discovered, but still not able to connect, make sure that required Reader is within range. Initiate discovery again by tapping Reader Discovery Icon at top right of Screen. Once discovered, attempt menu option again.

If Reader is not discovered, reset Host and log into epoc Host Application again. Attempt reset and discovery sequence twice if necessary.

-- Main Reader Tab--

Message#8: **"Unable to obtain status. Try again later"**

Description: Application was able to connect to selected epoc Reader, but Reader did not respond to requests for status information.

Response: User must close Reader status window, turn epoc Reader "OFF", then "ON" and try again.

-- Main Reader Tab--

Message#9: **"Disconnect from the reader before starting configuration."**

Description: The Administrator attempts to configure a Reader that is already connected.

Response: Wait until the current test is completed or test will be cancelled when disconnecting Reader. Disconnect Reader by going to that Reader Tab and pressing red "X" in top right corner. Once Reader Tab is closed, Administrator can proceed with **Configure** option.

-- Main Reader Tab--

Message#10: **"Configuration tab already visible."**

Description: Administrator attempts to configure Reader whose Configuration Screen is already displayed.

Response: Administrator can go to Reader Configuration Screen by clicking Tab labeled **Configure <serial number>**.

-- Main Reader Tab--

Message#11: **"Reader <name> not responding."**

Description: When performing a thermal QA test, epoc Host is able to connect to Reader, but Reader does not respond.

Response: Make sure that required Readers are within range and turned "ON." Attempt discovery again by tapping Reader Discovery Icon at top right of Screen. Attempt Thermal QA again. If Reader is not found, switch Reader in question "OFF" and then "ON" again. Attempt Reader discovery again.

-- Main Reader Tab--

Message#12: **"Unable to search for Readers. Turn the Host OFF then ON and try again." "Error"**

Description: An error was returned by Host Bluetooth® functionality when attempting to discover Readers.

Response: Wait five (5) seconds and attempt discovery again. If message is displayed again, turn the Host "OFF" and then "ON" and attempt discovery again. If error persists, reset Host, log in and try again.

-- Main Reader Tab--

Message#13: "Insufficient memory to run another test. Contact administrator" **"Error"**

Description: When Operator attempts to connect to Reader, epoc Host determines that there may not be enough memory for additional Test Results.

Response: Contact System Administrator to free up memory in epoc Host.

-- Main Reader Tab--

Message#14: **"Close all Reader screens before searching for Readers." "Error"**

Description: When the Host program is connected to a Reader, initiating a discovery of other epoc Readers is blocked.

Response: Close all connections before attempting a rediscovery. If a test is in progress, wait until the test is completed before closing the connection to that Reader.

-- Main Reader Tab--

Message#15: **"Close all Reader screens before exiting."**

Description: Administrator is unable to exit epoc Host Application when one or more Readers are still connected.

Response: Close all Reader connections before exiting Application. Go to each Reader Tab and tap on red "X" to close Reader connection. Exit again.

-- Main Reader Tab--

Message#16: **"Close all Reader screens before logging out."**

Description: User is unable to log out of epoc Host Application when one or more Readers are still connected.

Response: Close all Reader connections before exiting the program. Go to each Reader Tab and tap on red "X" to close the Reader connection. Log out again.

-- Main Reader Tab--

Message#17: **"Close all Reader screens before changing date and time." "Error."**

Description: Administrator attempts to change date and time by using **Tools** and then **Set Date/Time** while Reader Screens are open. Since test time is an important part of Test Record, changing Date and Time is blocked while Reader Screens are open.

Response: Close all Reader Screens and then attempt to set Date and Time again.

-- Main Reader Tab--

Message#18: **"Close all Reader screens before synchronizing." "Error."**

Description: User attempts to synchronize with EDM by using **Tools** and then **Sync with EDM** or by pressing the **Sync with EDM** Button (second from right on Main Reader Screen) while Reader Screens are open.

Response: Close all Reader Screens and then attempt to synchronize with EDM again.

-------------------------------------- Main Reader Tab--------------------------------------

Message#19: **"Close all Reader screens before changing administrative options." "Error."**

Description: Administrator attempts to change administrative options while Reader Screens are open.

Response: Close all Reader Screens and then attempt to change administrative options again.

-------------------------------------- Main Reader Tab--------------------------------------

Message#20: **"Close all Reader screens before changing personal options." "Error."**

Description: User attempts to change their personal options while Reader Screens are open.

Response: Close all Reader Screens and then attempt change personal options again.

-------------------------------------- Main Reader Tab--------------------------------------

Message#21: **"Close all Reader screens before changing EDM options." "Error."**

Description: Administrator attempts to change EDM options while Reader Screens are open.

Response: Close all Reader Screens and then attempt to change EDM options again.

-------------------------------------- Main Reader Tab--------------------------------------

Message#22: **"Close all Reader screens before changing card options." "Error."**

Description: Administrator attempts to change card options while Reader Screens are open.

Response: Close all Reader Screens and then attempt to change card options again.

-------------------------------------- Main Reader Tab--------------------------------------

Message#23: **"Close all Reader screens before upgrading Host." "Error."**

Description: Administrator selected **Tools**, then **Perform upgrade** while there were Reader Configuration Tabs open.

Response: Close all Reader Configuration Tabs and then select **Tools** and **Perform upgrade** again and select one of the upgrade methods.

-------------------------------------- Main Reader Tab--------------------------------------

Message#24: **"Upgrade file not found on SD card." "Error"**

Description: After selecting **Tools**, then **Perform upgrade** then **From SD Card**, epoc Host could not find an upgrade file on SD Card.

Response: Place SD Card containing upgrade files from Epocal into SD Slot atop epoc Host and try again. If SD Card is in epoc Host, remove then re-insert it and try again. If Error Message persists, contact Technical Services.

-------------------------------------- Main Reader Tab--------------------------------------

14.5.4 Reader Tab

Message#1: **"Unable to communicate with reader." "Closing Connection"**

Description: At any time before test starts, epoc Host is unable to communicate with epoc Reader.

Response: Close Reader Tab, turn the Reader "OFF" and "ON", perform a rediscovery and connect to Reader again. If this does not resolve problem, reset Host, log in and try again.

---Reader Tab---

Message#2: **"Reader <name> not compatible with current Host. Contact administrator." "Closing Connection"**

Description: epoc Host has determined that epoc Reader software is out of date.

Response: Reader's software requires an upgrade. Ask System Administrator to contact Technical Services.

---Reader Tab---

Message#3:	**"Reader Failure: Reader stopped responding." "Remove test card, turn reader off and on, reconnect, insert new card and repeat test "**
Description:	epoc Host waits for 30 seconds for a message and if not received Host times out. This occurs during test and at Reader Configuration stage.
Response:	Close Reader Tab. Ensure epoc Reader is within range and turned "ON." Switch epoc Reader in question "OFF" and then "ON" again. Reconnect to Reader and perform test again. If connection fails, repeat procedure one more time.

---Reader Tab---

Message#4:	**"Battery low. Recharge Reader." "Closing connection"**
Description:	Reader has less than 5% battery power remaining. Remaining charge may not be enough to complete a test.
Response:	Close Reader Screen, plug A/C Adapter into Reader and wait until Reader has enough battery charge to complete a test or operate A/C Adapter plugged in. Reconnect to Reader.

---Reader Tab---

Message#5:	**"Electronic QC failure." "Turn Reader OFF and ON, and reconnect"**
Description:	Electronic QC is performed by Reader every time epoc Host connects to it. If Reader repeatedly fails Electronic QC, then this indicates it is not fit for use. It is not possible to use a Reader that has failed Electronic QC. This may indicate contamination inside the Reader in card contact area.
Response:	Confirm failure. Close Reader Screen, turn Reader "OFF" and "ON" and try to connect to Reader again. If Reader connects successfully, it is ok to use. If this does not resolve problem, contact Technical Services.

---Reader Tab---

Message#6:	**"Remove test card to begin a new test"**
Description:	Test card was inserted into Reader before it was ready to accept card or card was already in Reader before epoc Host connected to Reader.
Response:	Remove card in Reader and begin new test.

---Reader Tab---

Message#7:	**"Critical reader error." "Closing connection"**
Description:	epoc Host has determined that there is a critical error in Reader's Configuration.
Response:	Ask System Administrator to contact Technical Services.

---Reader Tab---

Message#8:	**"Ambient temperature too low to use Reader." "Closing connection"**
Description:	Ambient temperature is too low for epoc Reader to function properly.
Response:	Move Reader to a location where Ambient Temperature is within the limits described in this Manual. Allow Reader enough time to adjust to new temperature. If Actual Ambient Temperature is within specified limits, report problem to System Administrator to contact Technical Services.

---Reader Tab---

Message#9:	**"Ambient temperature too high to use Reader." "Closing connection"**
Description:	Ambient Temperature is too high for epoc Reader to function properly.
Response:	Move Reader to a location where Ambient Temperature is within the limits described in this Manual. Allow Reader enough time to adjust to new temperature. If Actual Ambient Temperature is within specified limits, report problem to System Administrator to contact Technical Services.

---Reader Tab---

Message#10: **"Ambient pressure too low to use Reader." "Closing connection"**

Description: Ambient Pressure is too low for the epoc Reader to function properly.

Response: Move Reader to a location where Atmospheric Pressure is within the limits described in this Manual. Allow Reader enough time to adjust to new environment. If Actual Atmospheric Pressure is within specified limits, report problem to System Administrator to contact Technical Services.

---Reader Tab---

Message#11: **"Ambient pressure too high to use Reader." "Closing connection"**

Description: Ambient Pressure is too high for the epoc Reader to function properly.

Response: Move Reader to a location where Atmospheric Pressure is within the limits described in this Manual. Allow Reader enough time to adjust to new environment. If Actual Atmospheric Pressure is within specified limits, report problem to System Administrator to contact Technical Services.

---Reader Tab---

Message#12: **"Ambient pressure sensor failed QC." "Closing connection"**

Description: Ambient Pressure Sensor QC did not pass.

Response: User should close Reader Tab, turn Reader "OFF" and "ON" and then try again. If problem persists, Administrator must contact Technical Services.

---Reader Tab---

Message#13: **"Reader error. Turn Reader OFF and ON." "Closing connection"**

Description: epoc Reader has sent an error to epoc Host during Configuration.

Response: Close Reader Tab, turn Reader "OFF" and "ON." Perform discovery and try again.

---Reader Tab---

Message#14: **"Fluid detected in test card." "Remove and insert a different card"**

Description: Fluid was detected in the Test Card before calibration cycle has started.

Response: Insert new Test Card into Reader. Discard old Test Card.

Message is triggered when fluid is detected immediately upon insertion of card into the reader. Card may have been previously used or sample was injected before card was inserted into the reader.

Note: Examine the card to check whether fluid is present in the measurement region (see Section 4.1 of the epoc System Manual). If failure occurs on the same Reader with multiple cards and no fluid is present in cards, then the failure may be due to internal Reader failure. Contact Technical Services to send Reader for servicing.

---Reader Tab---

Message#15: **"Unable to read barcode. Remove and insert the card again"**

Description: epoc Reader is unable to read Barcode on Test Card.

Response: Remove card and insert again with swift, smooth motion. If unsuccessful after multiple attempts, use new Test Card.

---Reader Tab---

Message#16: **"Invalid barcode. Check test card for damage."**

Description: epoc Reader read Barcode on Test Card, but it appears to be invalid.

Response: Remove card, check that Barcode is not damaged. If Barcode is damaged, use another Test Card. If Barcode appears to be undamaged, insert again with swift, smooth motion. If unsuccessful after multiple attempts, use new Test Card.

---Reader Tab---

Message#17: **"Invalid card manufacture date. Check Host date."**

Description: epoc Reader read barcode on Test Card, but Date of Manufacture of the card appears to be ahead of current Date on epoc Host, making it impossible to determine if card is expired or not.

Response: Check current Date of epoc Host in Reader Tab. If Date appears to be incorrect, Administrator must log in to correct Date. Date and Time can also be corrected by performing EDM synchronization. If Date and Time are still wrong after EDM synchronization, EDM Administrator needs to check Date and Time on computer that hosts EDM. If Date appears to be correct, remove card, check that Barcode is not damaged. If Barcode is damaged, use new Test Card. If Barcode appears to be undamaged, insert with a swift, smooth motion. If unsuccessful after multiple attempts, use new Test Card.

---Reader Tab---

Message#18: **"Expired test card. Insert new test card"**

Description: Test Card has expired. Current Date is after "Use By" Date on Test Card.

Response: Use Test Card that has not expired. "Use By" Date can be checked on card and package labeling. Remove expired Test Cards from general use.

---Reader Tab---

Message#19: **"Warning! Expired test card. Results will not be shown."**

Description: Expired Test Card is inserted into Reader after epoc Host is configured to allow running of expired cards. Message serves as warning to remind Operator that Test Card is expired and Test Results that pass QC will have values suppressed.

Response: Test results are not valid and can only be used for training purposes.

---Reader Tab---

Message#20: **"No more than 4 tests at one time."**

Description: epoc Host is already running four (4) tests and Test Card is inserted into fifth Reader.

Response: Wait until one of the tests is completed and then re-insert Test Card. Only four (4) tests can run simultaneously on one epoc Host.

---Reader Tab---

Message#21: **"Test card not properly inserted. Remove and insert card again"**

Description: Test Card was not fully inserted into epoc Reader. Card must be removed and inserted fully so that it locks into place.

Response: Remove card and fully insert again into epoc Reader to begin test.

---Reader Tab---

Message#22: **"iQC Failure: Calibration fluid not detected." "Insert new card and repeat test."**

Description: Calibration Fluid is not detected in card within first five (5) seconds after inserting Test Card. Test stops.

Response: Remove card and insert new Test Card to begin another test.

---Reader Tab---

Message#23: **"iQC Failure: Sensor check." "Insert new card and repeat test."**

Description: During test, but before sample is introduced, epoc Host performs continuous monitoring to make sure quality control checks are passing on Sensors. If these checks fail, test fails.

Response: Remove Test Card and insert a new Test Card to begin another test.

---Reader Tab---

Message #24: **"iQC Failure: Fluidics check." "Insert new card and repeat test."**

Description: During test, but before sample is introduced epoc Host performs continuous monitoring to make sure quality control checks are passing on Fluidics Channel. If these checks fail, test fails.

Response: Remove Test Card and insert new Test Card to begin another test.

---Reader Tab---

Message #25: **"iQC Failure: Humidity check." "Insert new card and repeat test."**

Description: During test, but before sample is introduced epoc Host performs a check to make sure readings from Test Card are consistent with readings expected from a card stored in dry conditions. If check fails, test fails.

Response: Remove Test Card and insert new Test Card to begin another test. Wait for calibration to end before injecting sample.

---Reader Tab---

Message #26: **"iQC Failure: Thermal check." "Use another reader"**

Description: Heaters quality control, run throughout test, has failed. Test fails.

Response: Use different Reader as it is likely that current Reader is in environment that prevents heaters from functioning properly. If Reader is well equilibrated within environmental limits described in this Manual, and this message persists on Reader, contact Technical Services.

---Reader Tab---

Message #27: **"iQC Failure: Fast sample injection." "Insert new card, repeat test and reduce injection speed"**

Description: Test sample is injected too quickly (<0.2 sec). Test fails.

Response: Remove Test Card and insert new Test Card to begin another test. Inject test sample a little slower.

---Reader Tab---

Message #28: **"iQC Failure: Insufficient sample detected." "Insert new card, repeat test and ensure full injection"**

Description: The Reader detected the beginning of sample injection, but the sample had not arrived in its entirety 3.4 seconds after the sample injection had begun. The test fails.

Response: Remove the Test Card and insert a new Test Card to begin another test. Ensure that the sample is fully injected within 3.4 seconds from the start of sample injection.

---Reader Tab---

Message #29: **"iQC Failure: Sample Delivery." "Insert new card, repeat test and ensure smooth, steady injection"**

Description: Irregularities were detected with sample injection. Test fails.

Response: Remove Test Card and insert new Test Card to begin another test. Ensure that Syringe or Capillary Tube makes proper seal with Test Card and inject in a smooth, steady motion. Avoid injecting air into Test Card.

---Reader Tab---

Message #30: **"Timeout: Sample not introduced in time." "Insert new card, repeat test and introduce sample within time limit"**

Description: Test sample is not introduced into Test Card within allotted time. Test fails.

Response: Remove Test Card and insert new Test Card to begin another test and introduce sample within 7.5 minute time window after calibration ends.

---Reader Tab---

Message#31: **"To view results: - Enter sample type. Press SAVE when done"**

Description: Test has finished running, but no Sample Type was selected on Test Information Page. Test Results are unavailable.

Response: Go to Test Information Page and select a Sample Type, then press Save Button.

Error may be accompanied by other errors in list form (Messages #31-#35).

--Reader Tab---

Message#32: **"To view results: - Enter Patient ID. Press SAVE when done"**

Description: Valid Patient ID has not been entered for Blood Test. Test results are unavailable.

Response: Enter valid Patient ID (with correct number of characters as specified by System Administrator) and tap Save Icon. Patient ID must be entered before Reader Tab is closed or another card is inserted into Reader otherwise Test Results will not be stored with Test Record.

Error may be accompanied by other errors in list form (Messages #31-#35).

--Reader Tab---

Message#33: **"To view results: - Enter Lot Number. Press SAVE when done"**

Description: Valid Lot Number has not been entered for QA Test. Test results are unavailable.

Response: Enter valid Lot Number (any string of characters) and tap Save Icon. Lot Number must be entered before Reader Tab is closed or another card is inserted into Reader otherwise Test Results will not be stored with Test Record.

Error may be accompanied by other errors in list form (Messages #31-#35).

--Reader Tab---

Message#34: **"To view results: - Enter Test Selection. Press SAVE when done"**

Description: Test has finished running, but no Analytes have been selected on Test Selection Page. Test Results are unavailable.

Response: Go to Test Selection Page and select at least one Analyte, then press Save Button.

Error may be accompanied by other errors in list form (Messages #31-#35).

--Reader Tab---

Message#35: **"To view results: - Enter Hemodilution Setting. Press SAVE when done"**

Description: Test has finished running, but hemodilution Application has not been selected on Test Information Page. Test Results are unavailable.

Response: Go to Test Information Page and enter whether hemodilution should be applied to results, then press Save Button.

Error may be accompanied by other errors in list form (Messages #31-#35).

--Reader Tab---

Message#36: **"Reader Failure: General error." "Remove card, turn reader off and on, reconnect, insert new card and repeat test"**

Description: If, during calibration, Host detects general error with epoc Reader, test will fail.

Response: Close Reader Tab, turn Reader "OFF" and "ON" again. Reconnect and insert another Test Card to begin new test.

--Reader Tab---

Message#37: **"Connection Failure: Connection to Reader lost"**

Description: Bluetooth connection between epoc Host and epoc Reader no longer exists.

Response: Make sure Reader is always in range, and always turned "ON." Reconnect to Reader by pressing reconnection Button that appears on Reader Screen (when connection is lost) tot the right of Patient ID/Lot Number Entry Box or by closing Reader Screen using red "X" in top right corner and pressing on Reader Icon and selecting "Run blood test" (or "Run QA test").

--Reader Tab---

Message#38: **"Critical results not documented. Continue?." "Yes." "No." "Attention!"**

Description: Test has finished running, there are Critical Results, and User attempts to close test by pressing red "x" without first entering valid critical value handling.

Response: User must close Error Message Box and, if desired, click on Critical Value Handling Button on the Results Table. User must select action from Dropdown list. If User selects "Notify physician", "Notify RN", or "Other" from Dropdown list, then something must be entered into Notify Text Box.

--Reader Tab--

Message#39: **"Critical handling date/time precedes test date/time." "Error"**

Description: User has attempted to enter a Date and Time for Critical Value Handling that is before Date and Time of test.

Response: User must close Error Message Box and modify Date and Time of the Critical Handling to reflect Time after Time of test.

--Reader Tab--

Message#40: **"Test cannot be modified after printing. Continue?" "Yes" "No." "Attention!"**

Description: User has attempted to print test from Reader Screen

Response: User must select **Yes** to save test before printing or **No** to cancel printing of test.

--Reader Tab--

Message#41: **"Unsaved entries will be LOST. Continue?." "Yes." "No." "Attention!"**

Description: User has attempted to close test while there are still unsaved data entries.

Response: User must press **Yes to** close the test, or no to go back to the test

--Reader Tab--

Message#42: **"User action: Card removed from reader." "Insert new card and repeat test"**

Description: User has forcibly removed card from Reader during test.

Response: User can insert a new card and repeat test. Removing card from epoc Reader by force during test may damage epoc Reader and require repair.

--Reader Tab--

Message#43: **"Test card removed. Insert test card to begin test"**

Description: Test Card is removed after test is completed. epoc Host prompts Operator to insert new Test Card to begin another test.

Response: Insert another Test Card to begin new test or tap red "X" to close Reader Tab and Reader connection.

--Reader Tab--

Message#44: **"Battery low. Recharge Host." "Closing connection"**

Description: Host has less than 10% battery power remaining. Remaining charge may not be enough to complete a test.

Response: Close Reader Screen, plug A/C Adapter into Host and wait until Host has enough battery charge to complete a test or operate A/C Adapter plugged in. Reconnect to Reader.

--Reader Tab--

Message#45: **"iQC Failure: Early sample." "Insert new card and repeat test."**

Description: During calibration, the Host detected an early injection.

Response: Remove Test Card and insert new Test Card to begin another test. Make sure calibration is completed before injecting sample.

--Reader Tab--

Message#46: **"iQC Failure: Resistance check." "Insert new card and repeat test."**

Description: During test, but before sample is introduced epoc Host performs continuous monitoring to make sure quality control checks are passing on Fluidics Channel. If one of these checks fails in a way that indicates there may be a problem with the fluidics sensor itself, this message is shown.

Response: Remove Test Card and insert new Test Card to begin another test. If this problem persists, contact Technical Services.

---Reader Tab---

Message#47: **"Test Card not supported."**

Description: epoc Reader read barcode on test card, and epoc Host determined the type of test card identified by the barcode is not supported.

Response: The type of test card identified does not match the software running on epoc Host. Update software or contact Technical Services for further information.

---Reader Tab---

14.5.5   Administrator Options

Message#1: **"Saving raw data increases memory usage and may affect system performance." "Warning"**

Description: Message warns Administrator that checking **Save raw data** Checkbox dramatically increases amount of memory used to store this information in epoc Host and slows down Application.

Response: Tap **OK** to exit message. Set **Save raw data to "Always"** Checkbox only when asked to collect data to troubleshoot epoc System performance problems. This data is only retrievable by Epocal authorized personnel.

---Administrator Options---

Message#2: **"Tests run with expired cards are for training purposes only. Results will not be displayed." "Warning"**

Description: Message warns Administrator that checking **Allow use of expired cards** Checkbox is permitted for training purposes only. When Checkbox is checked, Test Results are not saved.

Response: Tap **OK** to exit message. Do not leave Box checked for any reason other than training purposes. Uncheck box when training is completed.

---Administrator Options---

Message#3: **"User ID already exists." "Error"**

Description: Administrator attempts to add new User with User ID that already exists.

Response: Tap **OK** to exit message. Edit **User ID** field so it is unique from those already in use. Tap **Add** Button to add new User.

---Administrator Options---

Message#4 **"Please complete all fields." "Error"**

Description: Administrator attempts to add a new User or Printer when one or more fields on the Page are empty.

Response: Tap **OK** to exit message. Add missing information in empty field(s). Tap **Add** Button to add new User or Printer.

---Administrator Options---

Message#5: **"Password must be at least 4 characters." "Error"**

Description: Administrator adds User but Password field has less than four (4) characters when Administrator taps **Add** Button.

Response: Tap **OK** to exit this message. Change Password in Password field to four (4) characters or more. Tap **Add** Button to add User.

---Administrator Options---

Message#6: **"Changes will be lost? Continue." "Warning"**

Description: Administrator makes some changes to options, but does not save them.

Response: Tap **Yes** to cancel changes and or tap **No** to keep modifying options.

--Administrator Options-------------------------------------

Message#7: **"Do you wish to delete raw data files?"**

Description: The Administrator presses **Purge** Button in Administrator options.

Response: The Administrator may press **Yes** to delete all raw data files on epoc Host (this could take several minutes if there are many files), or press **No** to go back to the administrative options window.

--Administrator Options-------------------------------------

Message#8: **"User id must be at least 4 in length." "Error"**

Description: Administrator adds User but User Id field has less than four (4) characters when Administrator taps **Add** Button.

Response: Tap **OK** to exit this message. Change User Id in User Id field to four (4) characters or more. Tap **Add** Button to add User.

--Administrator Options-------------------------------------

Message#9: **"'Action when closing test' cannot 'None' if background synchronization is enabled." "Error"**

Description: Administrator has enabled background synchronization but has set "Action when closing test" to "None". Such a configuration could result in a full synchronization becoming a rare event since test records will be sent in the background. In order to ensure that full synchronization is performed periodically, "Action when closing test" must be set to "Synchronize" or "Sync and Logout (one test mode)" if background synchronization is enabled.

Response: Tap **OK** to exit this message. Change "Action when closing test" to "Sync" or "Sync and Logout (one test mode)". Alternatively, background synchronization may be disabled.

14.5.6   Card Options 1

Message#1: **"This will change units for all future tests." "Warning"**

Description: Message is displayed first time Administrator makes changes to Units of Measurement after entering Administration Options Pages. Message cautions Administrator that changing Units of Measurement changes Units of Measurement for all future Test Results. Units of Measurement are also changed on the Reference Ranges Page without converting the low and high limits to the new Units of Measurement.

Response: Tap "OK" to exit message. Carefully consider impact of changing Units of Measurement before making any changes.

--Card Options 1--

Message#2: **"This will change reference and critical ranges for all future tests." "Warning"**

Description: Message is displayed first time the Administrator makes changes to the Reference Ranges after entering Administration Options Pages. Message cautions Administrator that changing high / low limits changes Reference Range Limits for all future Test Results.

Response: Tap "OK" to exit message. Carefully consider impact of changing Reference Range Limits before making any changes.

--Card Options 1--

Message#3: **"The <low or high> <Blood or QA> - <Type of range> reference range for <analyte> cannot be <lower or higher> than the reportable range of <converted if units changed> <units> (<original reportable low or high> <default units if units changed>." "Range Error"**

Description: Message is displayed if Administrator makes changes to Reference Ranges high / low Limits or to the Units of Measurement that results in Analyte Range to extend beyond the Reportable Range.

Response: Tap "OK" to exit message. Correct invalid range value and tap **Save** Button to save all changes.

---Card Options 1---

Message#4: **"The <low or high> <Blood or QA> - <Type of range> <reference or critical> range for <analyte> is invalid." "Error"**

Description: Invalid characters are entered for specified reference or Critical Ranges Page.

Response: Tap "OK" to exit message. Correct invalid range value (using numbers and decimal points only) and tap **Save** Button to save all changes.

---Card Options 1---

Message#5: **"The low <Blood or QA> - <Type of range> <reference or critical> range for <analyte> is higher than the high range." "Error"**

Description: Specified low range value is higher than its high counterpart. Either low end of range must be edited to be lower than high range, or high end of range must be edited to make it higher than low end.

Response: Tap "OK" to exit message. Correct invalid range value and tap **Save** Button to save all changes.

---Card Options 1---

Message#6: **"At least one test must be enabled by default" "Error."**

Description: Boxes for selecting which test will be enabled on Test Card are all turned off.

Response: Administrator should press **OK** to exit message, then select at least one test to enable on Test Card, then press **Save** Button to save card options.

---Card Options 1---

Message#7: **"Changes will be lost. Continue?" "Warning"**

Description: Administrator makes some changes to options, but does not save them.

Response: Tap **Yes** to cancel changes and or tap **No** to keep modifying options.

---Card Options 1---

14.5.7   Card Options 2

Message#1: **"At least one base excess display must be selected." "Error."**

Description: Boxes that allow Administrator to select which type of Base Excess will be displayed are both turned "OFF."

Response: The Administrator should press **OK** to exit message, then select at least one Base Excess to display with Test Record, then press **Save** Button to save card options.

---Card Options 2---

Message#2:   **"Changes will be lost. Continue?" "Warning"**

Description: Administrator makes some changes to options, but does not save them.

Response: Tap **Yes** to cancel changes and or tap **No** to keep modifying options.

---Card Options 2---

14.5.8   EDM Options

Message#1:   **"EDM connection failed"**

Description: Message is displayed if connection attempt fails when Administrator attempts to test EDM connection through EDM options window.

Response: Administrator must check Wireless connectivity of epoc Host, and then check that EDM is running at specified address and then try again.

---EDM Options---

Message#2:   **"Changes will be lost? Continue." "Warning"**

Description: Administrator makes some changes to options, but does not save them.

Response: Tap **Yes** to cancel changes and or tap **No** to keep modifying options.

---EDM Options---

Message#3:   **"Invalid EDM IP address"**

Description: IP Address entered by Administrator does not match xxx.xxx.xxx.xxx mask.

Response: Administrator must enter a valid IP Address matching xxx.xxx.xxx.xxx mask. Contact Network Administrator for a valid IP Address.

---EDM Options---

Message#4:   **"Invalid EDM port number"**

Description: IP Port Number entered by Administrator is out of range or has illegal characters.

Response: Administrator must enter valid Port Number. Valid Port Number has numeric value in 0-65535 range.

---EDM Options---

14.5.9   Reader Configuration Screen

Message#1:   **"Unable to update Reader configuration"**

Description: After tapping **Send configuration to Reader** Button on Reader Configuration Page, Reader rejects new configuration information.

Response: Contact Technical Services.

----------------------------------Reader Configuration Screen----------------------------------

Message#2:   **"Reader <name> not responding"**

Description: epoc Reader is no longer communicating wirelessly with epoc Host.

Response: Close Reader connection by pressing red "X" on Reader Tab. Make sure that Reader is in range, turned "ON" and not in use by another epoc Host. Press **Reader Discovery** Icon from Main Reader Tab. Once discovered, continue with Reader configuration by tapping "Configure" from the Reader menu.

If unsuccessful, turn the Reader "OFF" and "ON" again. Discover Readers again and attempt to configure again.

----------------------------------Reader Configuration Screen----------------------------------

Message#3:   **"Disconnect from Reader before starting configuration."**

Description: Administrator attempted to bring up Reader Configuration Screen while Reader Screen was open or while epoc Host was connected to Reader.

Response: Administrator must open up Reader Configuration Screen when Host is no longer connected to Reader.

----------------------------------Reader Configuration Screen----------------------------------

Message#4: **"Upgrade not available"**

Description: Administrator attempted to upgrade epoc Reader when no upgrade was necessary.

Response: Administrator must close Reader Configuration Screen.

-----------------------------------Reader Configuration Screen----------------------------------

14.5.10 Personal Configuration

Message#1: **"Invalid password." "Error"**

Description: Old Password does not match Password on file. Password cannot be changed.

Response: Tap **OK** to exit message. Correct Password in **Old Password** field to match current Password. If Operator has forgotten their Password, they must contact System Administrator to reset Password. If Administrator has forgotten Password, they need to contact Technical Services for temporary Password, which allows Administrator to reset Administrator Password.

--Personal Configuration--------------------------------------

Message#2: **"Passwords do not match." "Error"**

Description: New Password needs to be entered twice when changing Password. Error Message indicates that new Password and verification Password do not match.

Response: Tap **OK** to exit message. Delete Passwords in **New Password** and **Verify** fields. Carefully enter same new Password in both fields.

--Personal Configuration--------------------------------------

Message#3: **"Account not found for user ID <user id that was used to log in>"**

Description: Authentication level required to Login is set to **None**. User with no account is logged in and attempts to change personal options.

Response: Tap **OK** to exit message. User account needs to be set up by Administrator before editing User Name and Password.

--Personal Configuration--------------------------------------

Message#4: **"Changes will be lost? Continue." "Warning"**

Description: Administrator makes some changes to options, but does not save them.

Response: Tap **Yes** to cancel changes and or tap **No** to keep modifying options.

--Personal Configuration--------------------------------------

14.5.11 Previous Test Results

Message#1: **"Deleting test record. Continue?" "Yes." "No." "Warning."**

Description: Administrator is able to delete test from device to free up memory space in epoc Host. Message is displayed to warn Administrator that Test Record will be permanently deleted.

Response: Tap **Yes** to remove Test Record. Tap **No** to retain Test Record.

--Previous Test Results--

Message#2: **"No results were stored for this test."**

Description: Test Record is selected for viewing that has no Test Results stored on epoc Host for viewing. Test records with no results include those tests that fail prior to completion of test, Test Results without Patient ID or other required entry information (Sample Type, etc). The reason for not storing results is displayed below message.

Response: None

--Previous Test Results--

Message#3: **"Unable to open test record." "Error"**

Description: Test Record is selected for viewing has no Test Record stored on epoc Host. Situation can only occur due to tampering with epoc Host.

Response: None

--Previous Test Results--

Message#4: **"All <filtered> tests will be permanently removed. Continue?" "Yes." "No." "Warning."**

Description: Administrator is able to remove all tests currently displayed in the results lookup table. Message is displayed to warn Administrator that all Test Records currently shown will be permanently deleted.

Response: Tap **Yes** to remove Test Records. Tap **No** to retain Test Records.

14.5.12 EDM Synchronization

Message#1: **"Unable to connect to EDM"**

Description: epoc Host was unable to open an IP connection to IP address of EDM.

Response: User must check that epoc Host is connected to wireless network and has access to EDM. Look for **Wireless Networking** Icon in taskbar. If there is no wireless networking, System Administrator must set up wireless networking. If there is connection, Administrator must log in and check that IP Address and IP Port Number of EDM are correct.

--EDM Synchronization--

Message#2: **"Connection to EDM lost. Try again later"**

Description: epoc Host lost connection to EDM during synchronization.

Response: User must check that epoc Host is connected to wireless network and has access to EDM. Look for **Wireless Networking** Icon in taskbar. If there is no wireless networking, System Administrator must set up wireless networking. If there is connection, Administrator must check that EDM is still running.

--EDM Synchronization--

14.5.13 Print to Compatible Printer Device

Message#1: **"Unable to print test record"**

Wi-Fi Printer:

Description: epoc Host was unable to open an IP connection to the IP address of the printer.

Response: Administrator must also check that epoc Host is connected to same wireless network as Printer. Look for **Wireless Networking** Icon in taskbar. If there is no wireless networking, System Administrator must set up wireless networking. If there is connection, Administrator must log in and check that IP Address and IP Port Number of epoc Host and Printer are correct.

Bluetooth Printer:

Description: epoc Host was unable to open Bluetooth connection to Printer.

Response: Administrator must log in and check that Bluetooth address of Printer is set correctly in System.

14.6 epoc Host Screen Alignment

On a rare occasion, the Host will not respond accurately to stylus taps. In this case, exit the Host by tapping **Tools**, then **Exit** from the menu.

For Host (Socket):

On the "Today" screen, click **Start**, then select **Settings**. Under **Settings**, find the **Screen** icon.

On the **Screen** page, select **Portrait** and click **Align Screen.**

Align the screen by clicking on each of the cross targets firmly and accurately. When done, you will return to the **Screen** page. Click **OK** to exit.
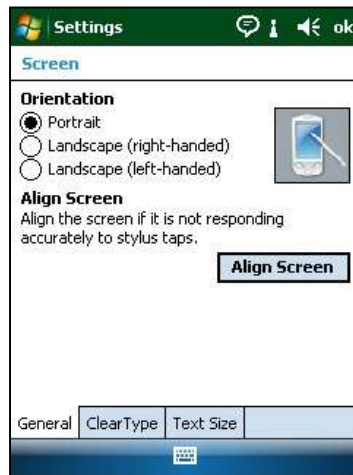
For Host[2] (Zebra):

On the "Today" screen, click **Start**, select **Settings**, then **System**, then **Screen**.

On the **Screen** page, select **Portrait** and click **Align Screen.**

Align the screen by clicking on each of the cross targets firmly and accurately. When done, you will return to the **Screen** page. Click **OK** to exit.

15 Glossary
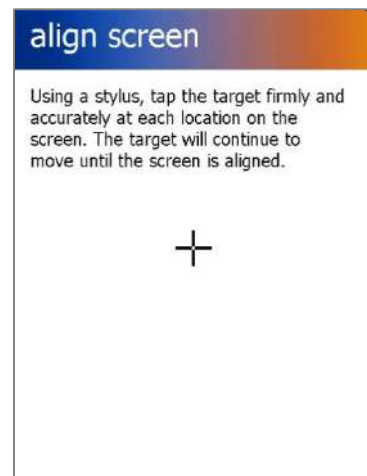
15.1 Symbols

Interpretation of Symbols from epoc® System labeling:

Symbol	Description	Symbol	Description
	Warning, Biological Risks		Manufacturer
	Warning, Biohazard		Date of Manufacture YYYY-MM
	Warning, Radiation of Laser Apparatus		Separate Collection for Disposal of Electrical / Electronic Equipment
	Caution, Consult Accompanying Documents	EC REP	European Union Authorized Representative
	Consult Instructions For Use	IVD	In Vitro Diagnostic Medical Device
	Single Use Only. Do Not Reuse	LOT	Batch or Lot Code
	Do Not Touch	REF	Model and/or Catalog Number
	Temperature limitation	SN	Serial Number
	Use By YYYY-MM-DD or YYYY-MM		Non-ionizing Radiation
N15360	C-Tick Symbol and Supplier Code for Australian EMI Compliance		MIC Symbol for Japanese Radio Law Certification
	KC Mark – Certification Mark for South Korea		Direct Current
Σ/25	Number of cards in box		CSA Mark – CSA compliance
Rx ONLY	Prescription only	CE	CE Mark – Certification Mark for European Union

15.2 Terminology and Abbreviations

Interpretation of Terms and Abbreviations from epoc System labeling:

A	Alveolar Oxygen
A-a	Arterial Alveolar Oxygen Tension Gradient
a/A	Arterial Alveolar Oxygen Tension Ratio
Agap	Anion gap
AC	Alternating Current
Analyte	Substance being measured
Authentication	Verification of User's identity or User's access eligibility
Barcode	Printed code consisting of a series of vertical bars that vary in width
Barcode scanner	Electronic device for reading barcodes printed on various surfaces
BE	Base Excess
BGEM	Blood Gas, Electrolyte and Metabolite
BT	Bluetooth®
Ca++, iCa	Ionized Calcium
Calibration mode	Process that establishes measurement references
Cl-	Chloride
cnc	Could not calculate (test result)
Connect	Establish a wireless communication link
Crea	Creatinine
CSA	Canadian Standards Association
CLIA	Clinical Laboratory Improvement Amendments
CLSI	Clinical and Laboratory Standards Institute (Formerly NCCLS)
CV	Coefficient of Variation, i.e. standard deviation divided by mean
DC	Direct Current
Discovery mode	Process of locating wireless devices
EDTA	Ethylenediaminetetracetic acid
eGFR	Estimated Glomerular Filtration Rate
Electrode	Conductor used to make electrical contact
EMC	Electromagnetic compatibility
Expired	Past "Use By" date
FCC	Federal Communications Commission
FiO$_2$	Fraction of inspired oxygen, percent concentration of oxygen in a gas
Glu	Glucose
GND	Ground
HCO$_3$-	Bicarbonate ion
Hct	Hematocrit
Hgb	Hemoglobin
Hematocrit	Percent of whole blood that is comprised of red blood cells
Hemolysis	Rupture of red blood cells with release of hemoglobin

Heparin	Substance used to liquefy the blood and slow the blood clotting process
Host	Dedicated use Mobile Computer – epoc Host
ID	Identification
IEC	International Electro-technical Commission
iQC	Internal quality control
K+	Potassium ion
K$_2$	di Potassium
K$_2$EDTA	di Potassium EDTA
K$_3$EDTA	tri Potassium EDTA
Lac	Lactate
LAN	Local area network
LED	Light emitting diode
MCHC	Mean cell hemoglobin concentration
Na+	Sodium ion
Na$_2$EDTA	di Sodium EDTA
NIST	National Institute of Standards and Technology
PCV	Packed cell volume
*p*CO$_2$	Partial pressure of carbon dioxide
pH	Hydrogen ion concentration to a given standard
PIN	Personal identification number
POC	Point of care
*p*O$_2$	Partial pressure of oxygen
PVB	PolyVinylButyral
QA	Quality assurance
QC	Quality control
Raw test data	Pre-analytical test parameters and measurements
Reader	Test card reader – epoc Reader
Reference range	Optimal range of test results for patients
Sensor	Device transforming a chemical signal into an electrical signal
SN	Serial number
sO$_2$	Oxygen saturation
TCO$_2$	Total carbon dioxide
Test Card	epoc BGEM Test Card
Test mode	Process of analyzing a blood sample to produce measured results
Thermal control	System that maintains the sensors at a desired temperature
USB	Universal serial bus
UV	Ultraviolet

epoc® Host Quick Start Guide

epoc BLOOD ANALYSIS

This quick start guide provides first time setup instructions for the epoc Host. For complete user instructions, please refer to the epoc System Manual.

epoc Host Components

The figure below shows the epoc Host's primary components.

Barcode Scanner

Status Indicators
Left - Wi-Fi & Bluetooth
Right - Battery

Stylus

Power button

Barcode Scanner button
(Silver, on side edge)

Barcode Scanner button
(Silver, on side edge)

Cradle Blade

Prior to use . . .

Step 1: Install the epoc Host battery

Your new epoc Host comes with the rechargeable battery uninstalled. It is located in the same plastic bag as the Host. Take the battery out of the plastic bag and install it in the Host prior to first use as per instructions below for **Version B** cradles.

When the battery is installed, reassemble the Host. Then, charge the battery as described in **Step 2**.

NOTE: When replacing the battery (with either cradle), only replace with the battery designated for use.

NOTE: Always dispose of the battery in accordance with local regulations. Never place the battery in municipal waste.

Removing the Cradle (to access SD Slot and / or replace Battery)

To remove the **Version A** cradle (with black rubber back):

1. Turn off epoc Host.

2. Fold back corners of Rubber Cover to expose two (2) attachment Screws.

3. Remove two (2) Screws using correct Screwdriver.

4. Slide Scanner Bracket forward and up to release Barcode Scanner. Pull Barcode Scanner from Slot.

5. Lift Host up and out to remove from Cradle.

6. SD slot is beneath the Barcode Scanner. If needed, carefully pull Barcode Scanner from its slot to gain access.

7. Use the Stylus to release Battery Cover.

8. Remove Battery Cover from back of Host.

9. Remove Battery.

10. Replacement Battery information is found in Section 13 of the epoc System Manual.

11. Replace Battery Cover and fasten securely.

12. Re-assemble Host into Cradle. Carefully align Host with Cradle Connector. Insert Barcode Scanner through Rubber Collar. Slide Scanner Bracket tightly in place. Fasten two (2) attachment Screws.
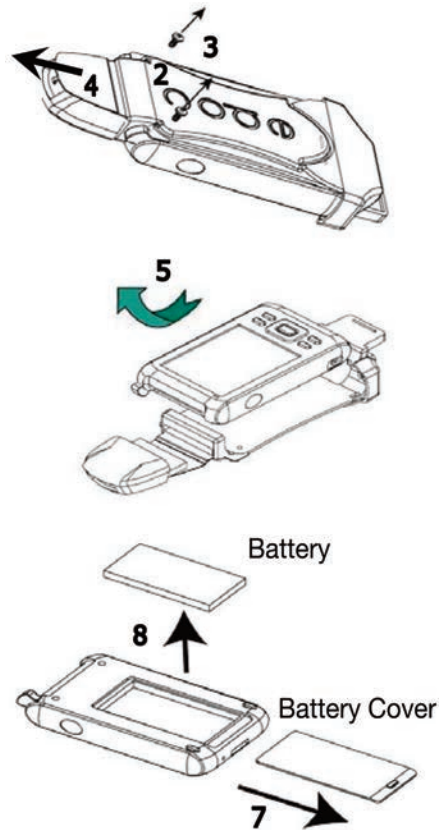
To remove the **Version B** cradle (plastic back, one piece):

1. Turn off epoc Host.

2. Undo two (2) Screws using correct Screwdriver so they remain captive in plastic housing.

3. Unclip Cradle from Barcode Scanner and lift Host up and out to remove from Cradle.

4. SD slot is beneath the Barcode Scanner. If needed, carefully pull Barcode Scanner from its slot to gain access.

5. Use the Stylus to release Battery Cover.

6. Remove Battery Cover from back of Host.

7. Remove Battery.

8. Replacement Battery information is found in Section 13 of the epoc System Manual.

9. Replace Battery Cover and fasten securely.

10. Insert Barcode Scanner in Host. Re-assemble Host into Cradle. Carefully align Host with Cradle Connector. Fasten two (2) attachment Screws.
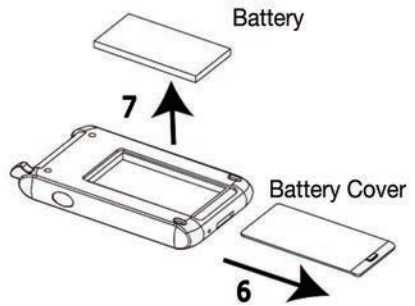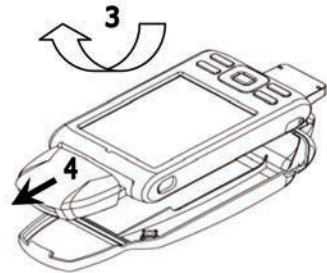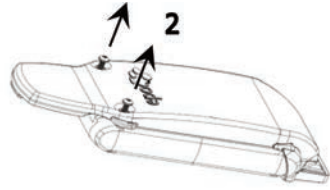
Step 2: Charge the epoc Host

Before using the epoc Host, charge its battery as follows:

1. Connect the epoc Reader power supply to the power jack on the back of the Reader.

2. Insert the epoc Host into the Reader's pivot slot as shown below. The initial charge will take approximately eight hours.

   - A **RED** battery indicator shows that the epoc Host is charging.
   - A **GREEN** battery indicator shows that the epoc Host is fully charged.

Resetting the epoc Host

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

NOTE: Always verify that date and time are correct after performing a Hard Reset.

The **Soft Reset** button is recessed in the bottom of the epoc Host. To perform a Soft Reset, insert the stylus into the opening on the bottom of the Host Cradle. The Soft Reset Button may be used to restart the Host application if the epoc Host stops functioning and/or responding.

If the Soft Reset Button does not respond, then at the same time, press the top two (2) Buttons and the Soft Reset Button (as shown) to perform a **Hard Reset**.

Hard reset buttons

Soft reset button access
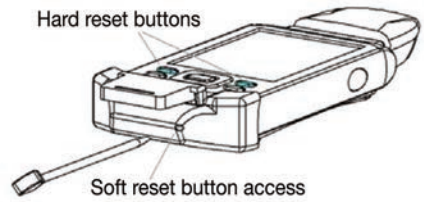
NOTE: For facilities not using the epoc Enterprise Data Management System, skip steps 3 and 4.

Step 3: Connect to your Wi-Fi Network

NOTE: It may be necessary to contact your facility's Information Technology department to obtain the proper Wireless connection and security settings.

1. Run Wi-Fi Companion.

- Turn on the epoc Host by pressing the power button.

- At the login screen, enter the word "**administrator**" into the User ID and Password fields.

To scan, aim the Barcode Scanner at the barcode and press the **Barcode Button.**

administrator

NOTE: Set date and time if prompted.

- Exit the epoc Host application by tapping "**Tools**", then "**Exit**" from the menu.
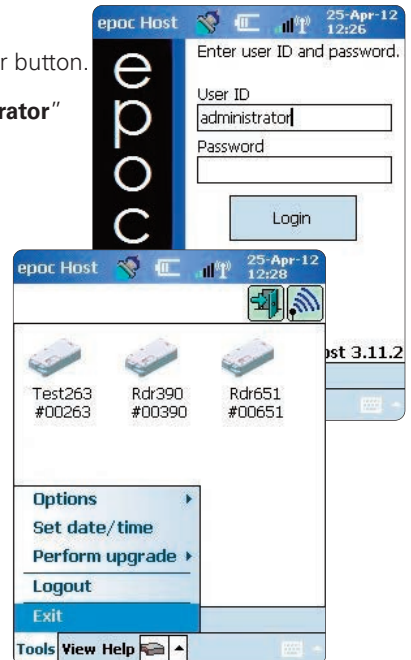
- Tap ✓ to turn on the Wi-Fi radio and configure the Wireless network profile.

- Tap .
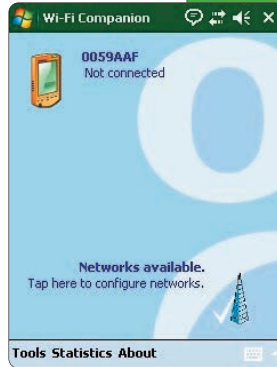
2. Configure Wi-Fi.
NOTE: Screenshots are examples only.

- Tap "**New**".

- Enter correct Network Name (SSID), then tap "**Next**".
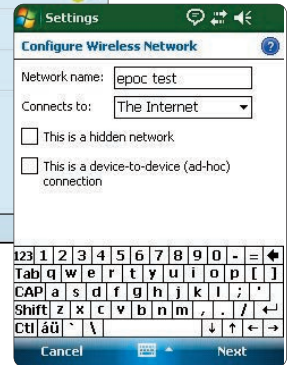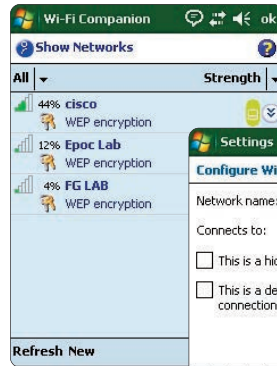
- Select correct network security settings, then tap "**Next**".

- Tap "**Finish**". The epoc Host will return to the list of available networks.
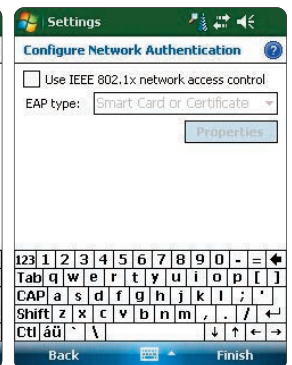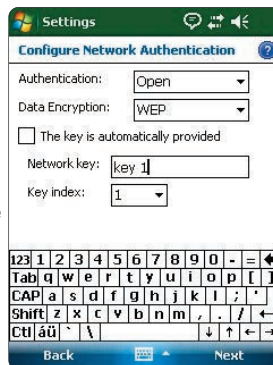
3. Confirm Wi-Fi connection.

• Tap "**OK**" in the upper right
  hand corner to confirm a
  successful Wi-Fi connection.

NOTE: The screen will display a
      successful Wi-Fi connection.

4. Reset the epoc Host.

• Perform a soft reset by inserting
  the stylus in the hole on the bottom
  side of the epoc Host.

Step 4: Connect to the EDM

1. Configure EDM options

• Turn on the epoc Host by pressing the power button.

• At the login screen, enter the word "**administrator**"
  into the User ID and Password fields.

To scan, aim the Barcode Scanner at the
barcode and press the **Barcode Button.**

administrator
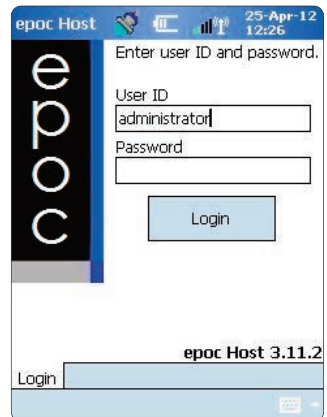
- Select "**Tools**" then "**EDM options**" from the dropdown menu.

- Set "**EDM present?**" to **Yes**.

- Enter the correct EDM address (name) and Port Number.

- Tap Save 💾 .
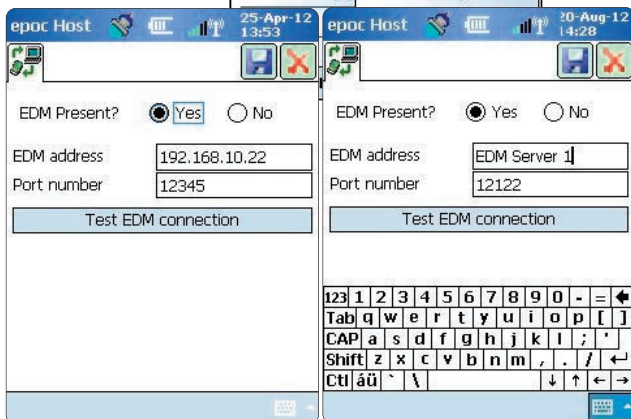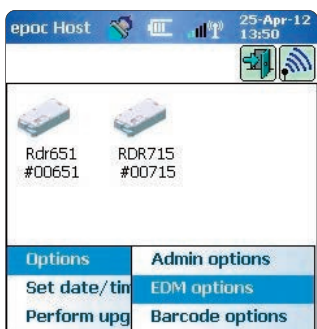
2. Confirm EDM Connection

- Tap the "Test EDM connection" button to confirm a successful EDM connection.
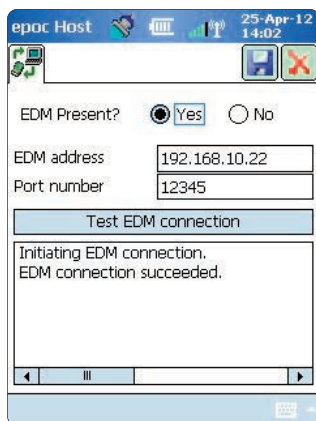
The epoc Host is now ready for use.

NOTE: Consult the epoc System Manual for instructions on how to update the epoc Host software.

NOTE: Before placing this unit into service, consult your facility's internal quality control procedures and regulatory requirements.

epoc® Host² Quick Start Guide

epoc BLOOD ANALYSIS

📖 This quick start guide provides first time setup instructions and other useful instructions for the epoc Host² (Motorola MC55A0). For complete user instructions, please refer to the epoc System Manual.

epoc Host² Components

Barcode Scan LED
- 🟥 Barcode scanning active
- 🟩 Successful scan/capture (blinking)

Charging/Battery LED
- 🟧 Battery fully charged
- 🟧 Battery charging (blinking)
- 🟧 Charging error (fast blink)

Barcode Scanner

Radio Status LED
(NOT USED!)

Scan Button
(on side)

Scan Button(s)

epoc System v3.8.0 by Epocal Inc.

OK

Details
Sensor config 15.6
Host version 3.8.11
Host name 11075521400811
Host battery Charging
Reader firmware 2.2.5.7
Host SN 11075521400811
Memory level 97% free
MAC Address ???????
EDM address 0.0.0.0
Port number 0
SSID ------
Host IP address 0.0.0.0

Test count | Blood | QA
All | 0 | 0
Unsent | 0 | 0
Not accepted | 0 |

Touch Screen

Keypad

Power Button

Cradle Blade

epoc Host[2] Numeric Keypad

- **Power** button turns device on and off. Holding the **Power** button for 5 seconds will reset the device.

- **Scan** key *(and Scan Buttons on sides of Host)* activates the barcode scanner.

- Alphanumeric keys default to numeric values. Pressing the **Toggle** key allows entry of alpha characters. *(Key is illuminated and orange symbol appears on display when active).* Pressing the **Toggle** key again returns key functions to numeric values.

- **Tab** and **Enter** keys navigate to the next editable field.

- **Backspace** key (BKSP) deletes entered characters.

Note: Shaded keys are not active

Scan   **Toggle Key**
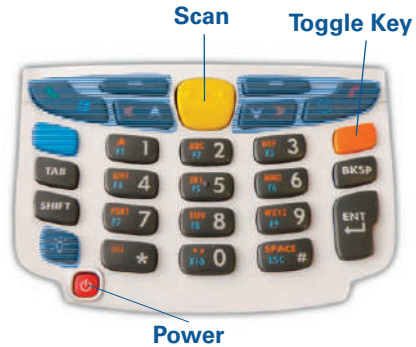
Power

Prior to use . . .

Step 1: Charge the epoc Host[2]

Before using the epoc Host[2], charge its battery as follows:

1. Connect the epoc Reader power supply to the power jack on the back of the Reader.

2. Insert the epoc Host[2] into the epoc Reader's pivot slot as shown. The initial charge will take approximately eight hours.

- A blinking Amber battery LED shows that the epoc Host[2] is charging.

- A solid Amber battery LED shows that the epoc Host[2] is fully charged.

2

For facilities not using epoc Enterprise Data Management System, skip Steps 2 and 3.

Step 2: Connect to your Wi-Fi Network

NOTE: Please read Step 2 in its entirety before starting. It may be necessary to contact your facility's Information Technology department to obtain the proper Wireless connection and security settings.

1. **Run Motorola Wireless Fusion.**

   - Turn on the epoc Host[2] by pressing the **Power** button. ⏻

   - At the login screen, scan or enter the word "**administrator**" into the User ID and Password fields.

     To scan, aim the Barcode Scanner at the barcode and press the **Scan** key**.**

   - Exit the epoc Host[2] application by tapping "**Tools**", then "**Exit**" from the menu.

For networks that broadcast their SSID:

   - Tap the "**Fusion**" on-screen icon and select "**Find WLANS**" from the menu.

   - Tap and hold desired WLAN and select "**Create Profile**" from the menu.

   - Proceed to **Configure the Wi-Fi Network Profile** as described on the next page, starting with the 3rd bullet. Typically, your settings will be already entered.

For networks that DO NOT broadcast their SSID:

   - Tap the "**Fusion**" on-screen icon and select "**Manage Profiles**" from the menu.

   - Proceed to **Configure the Wi-Fi Network Profile** as described on the next page. You will need to enter your settings manually.

3
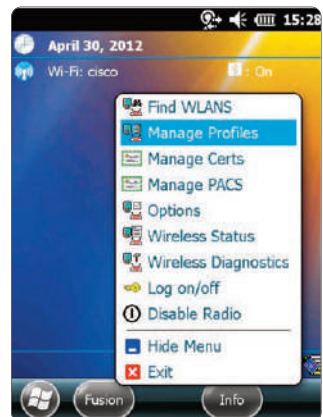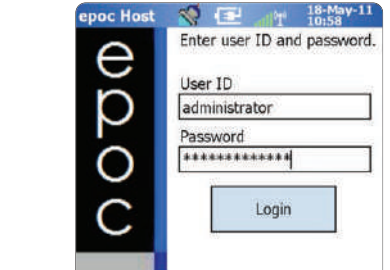
Configure the Wi-Fi Network Profile

- Tap and hold the screen to bring up the menu; then tap on "**Add**".

- Enter correct Profile Name and Network Name (ESSID), and then tap "**Next**".

- Continue entering the correct network security settings on the screens that follow (Screenshots 2-8) by tapping "**Next**", then "**Save"**.

NOTE: Screenshots are examples only.

1 of 8
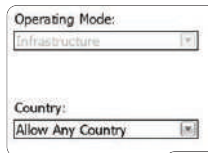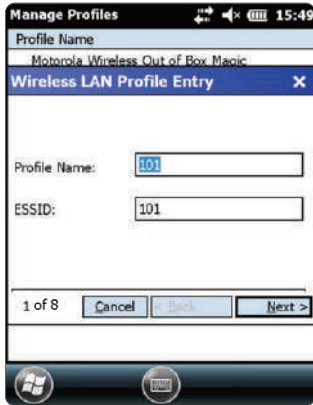
2 of 8
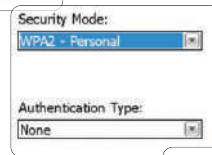
3 of 8
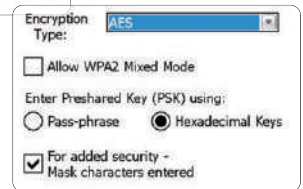
4 of 8
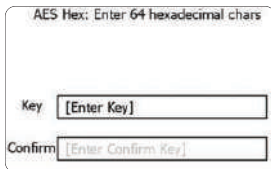
5 of 8
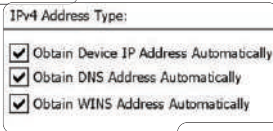
6 of 8
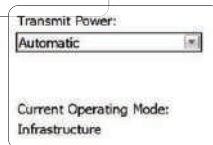
7 of 8

8 of 8

• When finished, tap and hold on the network name, then tap "**Connect**".

• Tap "**OK**" on bottom of the screen to return to the "Today" screen..

• If required, tap on the "**Fusion**" icon and select "**Options**" to configure the appropriate wireless network options.

NOTE: On some networks, it may be required to disable 802.11d in "Regulatory" options.
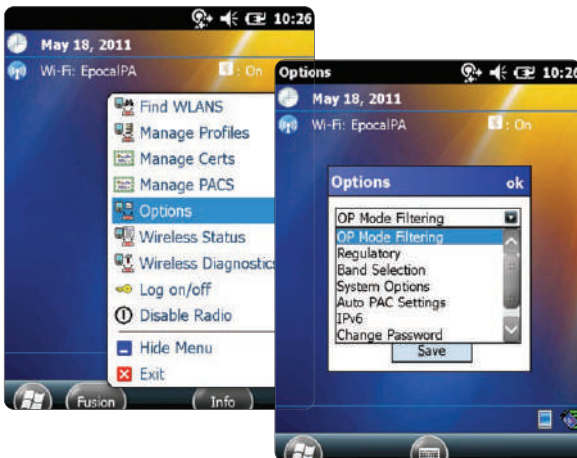
2. **Reset the epoc Host [2].**

• Perform a warm reset by holding down the power button 🔴 for 5 seconds.

Step 3: Connect to the epoc Enterprise Data Manager (EDM)

1. Configure EDM options

- Turn on the epoc Host[2] by pressing the **Power** button. ⏻
- At the login screen, scan or enter the word "**administrator**" into the **User ID** and **Password** fields. (Set date and time if prompted)

To scan, aim the Barcode Scanner at the barcode and press the **Scan** key.

administrator

- Select "**Tools**" then "**Options**", then "**EDM Options**" from the menu.

- Set "**EDM Present?**" to "**Yes**", and enter the correct EDM address and port number, then tap the disk symbol. 💾
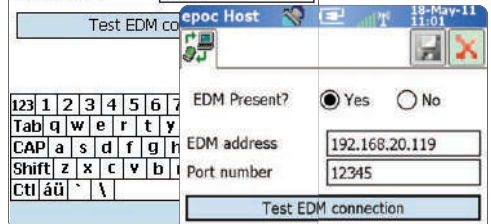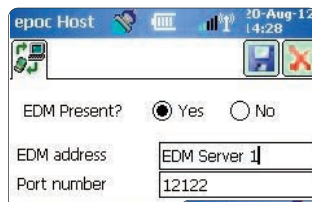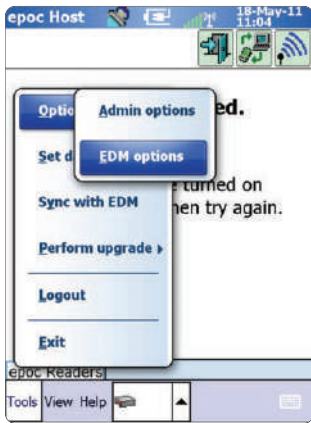
2. Confirm EDM Connection

- Tap the "**Test EDM connection**" button to confirm a successful EDM connection.
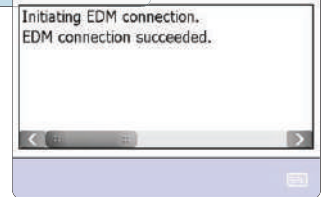
The epoc Host[2] is now ready for use.

NOTE: Refer to the epoc System Manual for instructions on updating the epoc Host Software.

NOTE: Before placing this unit into service, consult your facility's internal quality control procedures and regulatory requirements.

Resetting the epoc Host[2]

There are two reset functions – warm reset and cold reset. In the rare event that the epoc Host[2] stops responding or is not functioning properly, perform a warm reset. If the epoc Host[2] still does not respond, perform a cold reset. Data will **not** be lost with either procedure, which takes approximately one minute.

- Perform a *warm reset* by holding down the power button ⏻ for 5 seconds.

- Perform a *cold reset* by simultaneously holding down the power button, the "**1**" key, and the "**9**" key, and then release.

Installing the Cradle

In the event that the cradle becomes separated from the epoc Host[2], position the cradle as shown, and press the two together until both cradle locking tabs snap into the pockets on the side of the Host.

How to install or replace the microSD Card on the epoc Host[2]

The SD card slot is located on the back of the epoc Host[2] under the battery compartment.

NOTE: It is not necessary to remove the plastic cradle.

1. Press and release the **Power** button to suspend the epoc Host[2]. ⏻

2. Use your finger or stylus to slide the battery latch to the right releasing the battery. The battery ejects slightly.

3. Lift the battery from the device.

4. Lift the rubber access door and slide SIM card holder door to unlock.

5. Lift SIM card holder door (if it exists), then lift the microSD card holder door.

6. If removing microSD card, simply remove the microSD card from holder.

7. Insert the microSD card, with gold bars facing out, into the card holder door ensuring that the card slides into the holding tabs on each side of the door.

8. Then close microSD card door and slide SIM card holder door to lock position.

9. Close rubber access door.

10. Insert the battery; bottom first, into the battery compartment in the back of the epoc Host[2] .

11. Press the battery down into the battery compartment until the battery release latch snaps into place.
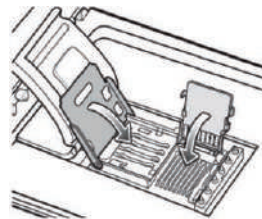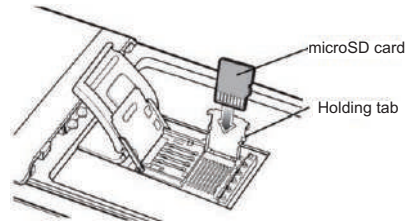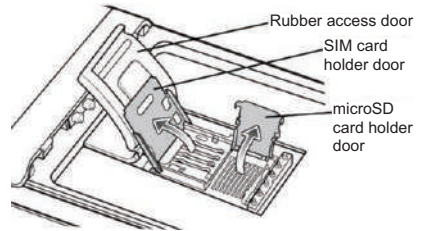
NOTE: To upgrade the epoc Host[2] software from an SD card, refer to the epoc System Manual.

epoc® Reader Quick Start Guide

This guide provides first time setup instructions for the epoc Reader. For complete user instructions, please refer to the epoc System Manual.

Package Contents

- epoc Reader
- AC Adapter power supply
- Sheet of labels
- Sheet of clear label overlays

epoc Reader Components

The figure below shows the Reader's primary components and status light indicators.
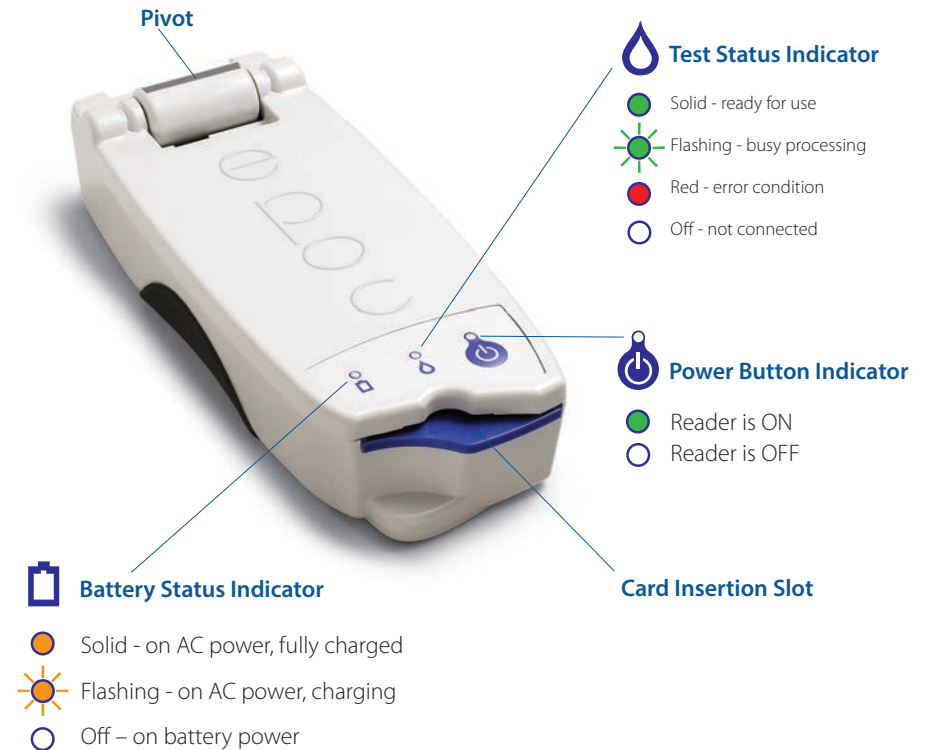
Pivot

Test Status Indicator

- Solid - ready for use
- Flashing - busy processing
- Red - error condition
- Off - not connected

Power Button Indicator

- Reader is ON
- Reader is OFF

Battery Status Indicator

- Solid - on AC power, fully charged
- Flashing - on AC power, charging
- Off – on battery power

Card Insertion Slot

Prior to use . . .

Step 1: Charge

Before using the epoc Reader, charge its battery as follows:

1. Make sure the Reader is OFF. If the Power Button Indicator is green, press and hold the power button for at least three seconds to turn the Reader off.

2. Plug the AC Adapter into a wall socket.

3. Plug the AC Adapter into the power jack on the back of the Reader.

   • The amber battery status indicator will start blinking

   • When the battery has been fully charged, the amber battery status indicator will stop blinking

   Note: Initial charge will take approximately four hours.

AC Adapter

Power jack
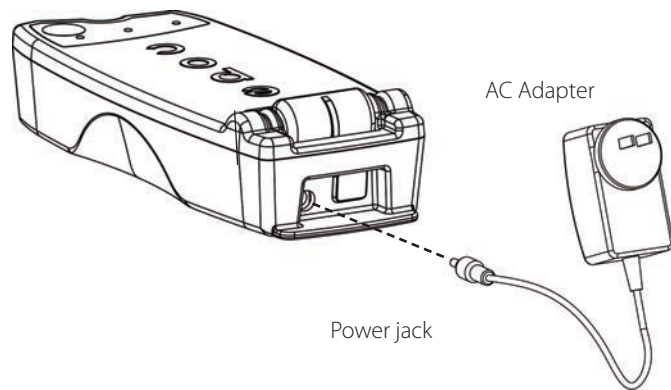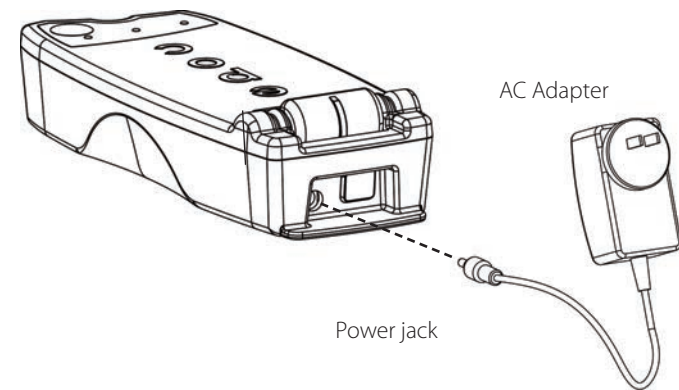
Step 2: Label

Label the epoc Reader to help easily identify it from other Readers in your facility. Use the included labels, and place the clear overlay over the label to increase its durability.

Note: Before placing this unit into service, consult your facility's internal quality control procedures and regulatory requirements.

epoc® Care-Fill™ Capillary Tubes

For in vitro diagnostic use

Intended Use

epoc Care-Fill Capillary Tubes are for use with the epoc Blood Analysis System and are used for the collection and dispensing of capillary blood samples with the epoc Test Cards.

Product Description

epoc Care-Fill Capillary Tubes are Mylar™ wrapped glass capillary tubes. The capillary tubes feature a custom adapter specifically designed to perform with the epoc Test Card. Each capillary tube is marked with a single blue band and contains a white porous plug positioned at the 90µL mark.

In the event of accidental breakage, the Mylar puncture-resistant wrapping minimizes risks associated with glass capillaries by containing both the glass and blood sample.

Product Specifications

Packaging:	10 capillary tubes per box, 5 boxes per package
Storage:	2–30 ˚C
Shelf Life:	See label for expiration date
Volume:	90 µL
Anticoagulant:	Approximately 65 IU/mL calcium balanced lithium heparin

Ordering Information

Catalog Number:	AT-0006-00-00
Description:	epoc Care-Fill Capillary Tubes

Safety and Regulatory

Practice recommended "Universal Precautions" when using this device. Use gloves, gowns, eye protection, and other personal protective equipment as necessary to protect from exposure to bloodborne pathogens. Discard after use by disposing in sharps and biohazard disposal containers according to the policies and procedures of your facility.

In 2006, a joint advisory letter was released by the FDA, NIOSH and OSHA addressing the potential risks to safety posed by the use of plain glass capillary tubes[1]. This letter has been referenced by laboratory accreditation and inspection agencies to promote discontinuing the use of plain glass capillary tubes for specimen collection due to safety reasons[2]. Optional ways of reducing risks are suggested, such as the use of non-glass capillary tubes or glass capillary tubes wrapped in puncture resistant film[1,2]. The use of Mylar-wrapped epoc Care-Fill Capillary Tubes is in compliance with current regulatory standards.

1. Burlington, D. et al. Glass Capillary Tubes: Joint Safety Advisory About Potential Risks, Center for Disease Control and Prevention. Feb 1999 USDHHS. 1 June 2006

2. Laboratory General Checklist. College of American Pathologists. 6 April 2006: Gen.71032, page 110. 1 June 2006

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51003903-07

Instructions for Use

Follow the policies and procedures for capillary blood collection used in your facility.

Remove one epoc Care-Fill Tube from the box. When handling the capillary tube, hold only by the blue band. Do not remove, re-position, depress or hold the capillary tube by the plunger. Do not remove the adapter. The adapter can be repositioned for ease of handling and to ensure the white porous plug remains visible during specimen collection.

PLUG   ADAPTER   BLUE BAND   PLUNGER
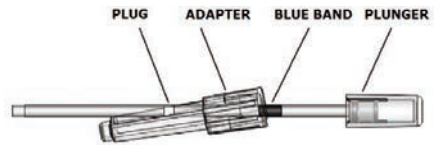
1. Collect patient sample

    a. Hold the capillary tube horizontally, pointing towards the puncture site and contact the blood drop.

    b. Maintain the horizontal position and continue filling the capillary tube until the blood sample contacts the porous plug.

    NOTE: The collected sample should be free of bubbles. Wetting the porous plug prevents sample spillage when the capillary tube is held with tip down.

2. Prepare tube for sample introduction

    a. Hold the tube by the blue band, pointing the tip of the capillary tube upwards.

    b. Slide the adapter towards the tip of the capillary tube, and insert the capillary tube tip into the adapter.

    c. Affix the adapter to the capillary tube by gently pushing the capillary tube into the adapter until it is secured in the adapter.

3. Introduce patient sample

    a. Hold the capillary tube vertically by the large end of the adapter, insert it into the test card sample port, and rotate the adapter 1/4 turn to ensure a good seal.

    b. Maintain hold of the adapter and use the fingers of your other hand to push the plunger completely down in a single motion.

    c. Continue to hold the plunger completely down while waiting for the Reader to beep.

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

Precautions

- Do not squeeze or "milk" the puncture site excessively as it may result in sample hemolysis*.

- Do not use the epoc Care-Fill Capillary Tube if an air bubble has been trapped in the sample.

- Do not use the sample if it appears to be clotted.

- Do not use the sample if the epoc Care-Fill Capillary Tube breaks.

- Use only one epoc Care-Fill Capillary Tube per epoc Test Card.

Recommendations

- The choice of the lancet should be adequate to supply a sample size of 90µL.

- Wipe away the first drop of blood to avoid contamination with tissue fluids.

- While collecting blood, gently apply intermittent pressure to the tissue surrounding the puncture* with your free hand.

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

- Roll tube between fingers to mix blood if dispensing is delayed.

* Source: Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard- Fifth Edition, CLSI H4-A5, Vol 24, No 21, 2004.

For more information, go to www.epocal.com.

epoc® Blood Analysis System

User Guide: Enhanced QA Features for the epoc® System

Enhanced QA features for the epoc® System provide the following benefits.

1. Improved QA workflow using electronic Value Assignment Datasheets or eVADs.
2. Improved QA compliance using QA schedules and lockout.

To take advantage of these new features, the following software is required.

- epoc Host software version **3.22.4** and higher
- epoc Reader firmware version **2.2.12.1** and higher
- epoc Enterprise Data Manager (EDM) software version **2.12** and higher

Note: *Although it is safe to continue patient and QA testing, attempting to run a test without the proper epoc Reader firmware will result in a warning message.*

Electronic Value Assignment Datasheets (eVADs)

The Enhanced QA feature set improves QA testing workflow by using electronic Value Assignment Datasheets (eVADs). An eVAD file is a single file stored on the epoc Host that contains all current ranges and expiration dates for all valid quality control (QC) fluids, calibration verification (CV) fluids, and sensor configuration versions.

When using eVADs while performing QC or CV testing, epoc Host users can simply scan the liquid control lot barcode from the printed Value Assignment Datasheet (VAD) and run the QC or CV test. When results are ready, QA ranges are applied automatically (based on lot and sensor configuration) and the epoc Host will indicate whether or not the QA test has passed or failed.

The following images show examples of QC tests that passed (Fig. 1) or failed (Fig. 2), and the results (Fig. 3).

Fig. 1.

Fig. 2.

Fig. 3.

STEP 1: Obtain the latest eVAD File

Electronic Value Assignment Datasheets (eVAD) and printable Value Assignment Datasheets (VADs) are available on the Customer Resource Center website for the epoc System.

1. Go to www.alere-epoc.com and click on Customer Resource Center to find a link to the Electronic Value Assignment Datasheet (eVAD) page.
2. Follow the instructions (Fig. 4) to download the eVAD file to your desktop.
3. Check the eVAD file name to make sure the correct eVAD file was downloaded (see section "How to check the eVAD file name" below).
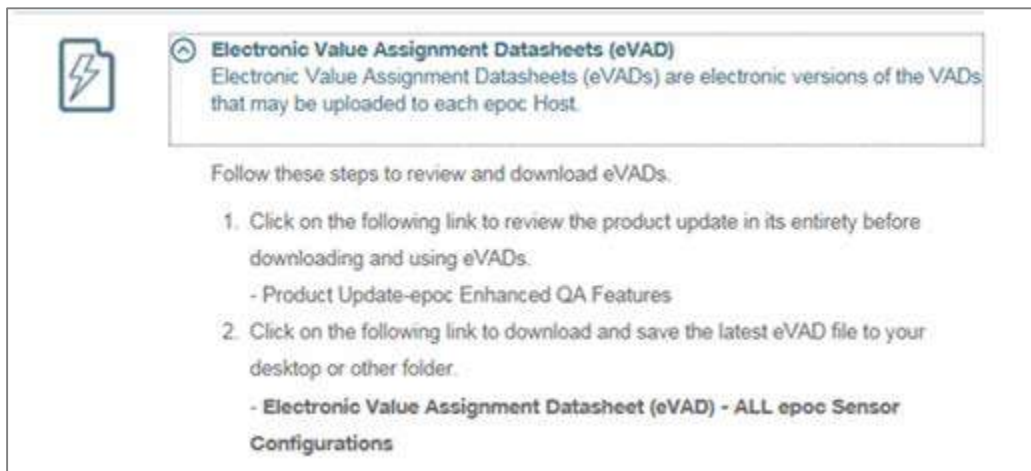
Fig. 4.

Before proceeding, make sure you have the correct eVAD update file. The eVAD file name has the following format: **epocYYDDD.eVAD** and it appears in the header of each printable datasheet (circled in Fig. 5).
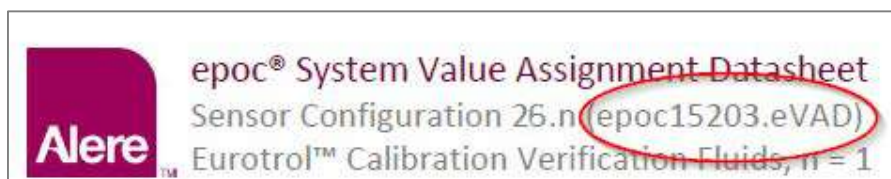
Fig. 5.

STEP 2: Load the eVAD File into the EDM

To load an updated eVAD file on the EDM, go to **Settings → Host Settings → eVAD update** (Fig. 6) and the eVAD update page will open (Fig. 7):
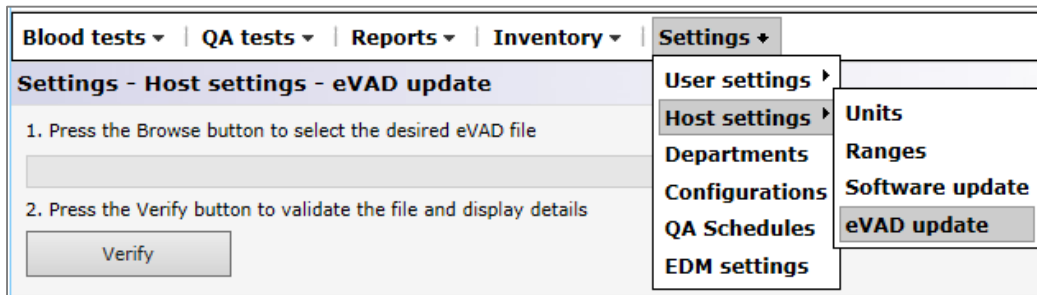
Fig. 6.
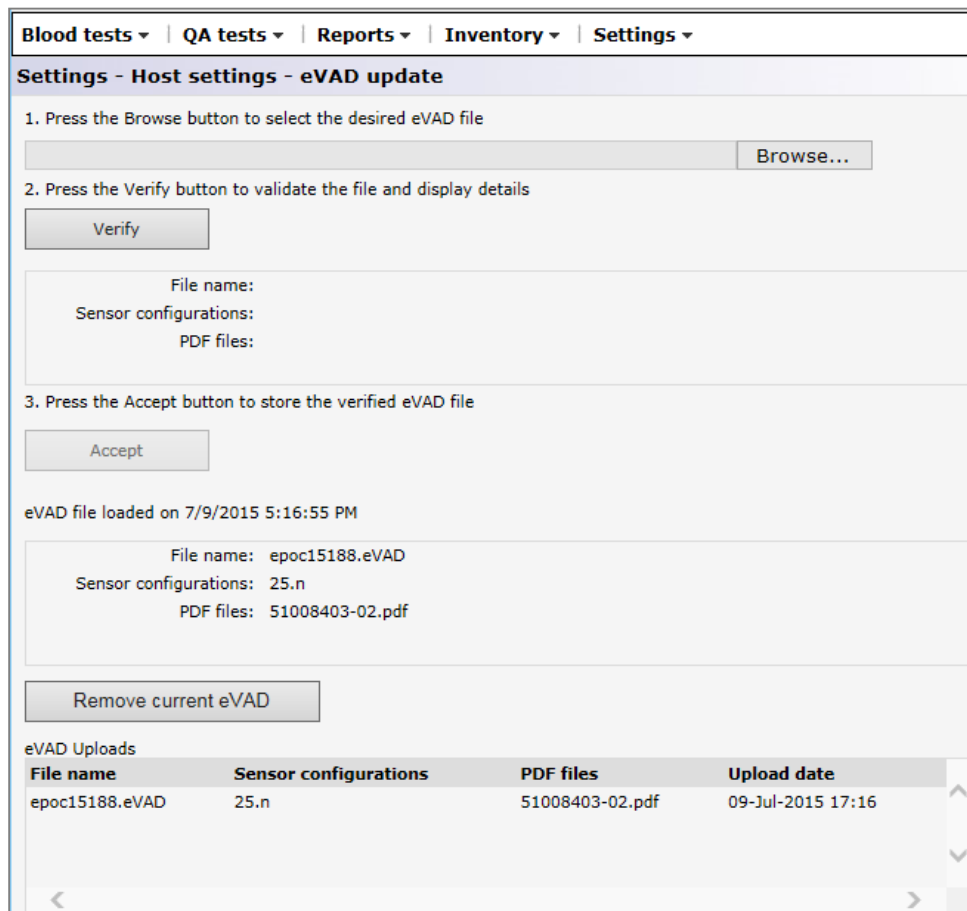
Fig. 7.

Follow the steps as indicated in the **eVAD update** page (Fig. 7 above).

1) Press the **Browse** button and find the valid eVAD file (format: epocXXXXX.eVAD).

2) Press the **Verify** button (Fig. 8) to validate the eVAD file and display details (circled in Fig. 9) including the eVAD filename, Sensor Configuration version, and the PDF file name associated with the eVAD file used.

Note: The names of the drive, folder, and update file are examples only. Make sure the most up-to-date eVAD file is being used.
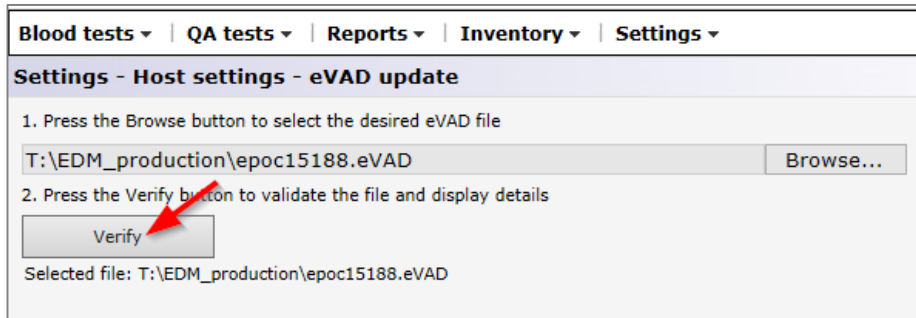
Fig. 8.

3) Press the **Accept** button (Fig. 9) to store the verified eVAD file.
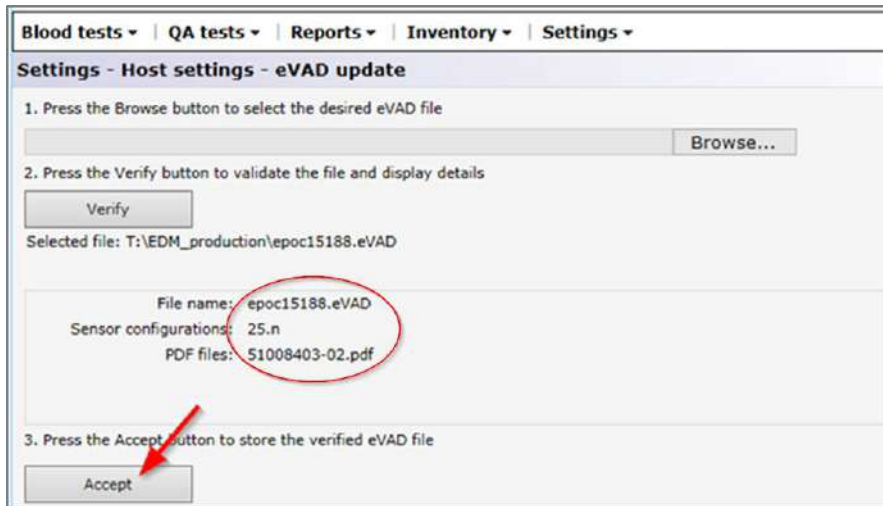
Fig. 9.

STEP 3: Synchronize each epoc Host

Each epoc Host must now be synchronized with the EDM to receive the newly loaded eVAD.

After synchronizing each epoc Host with the EDM system, verify the eVAD version by going to the epoc Host's **Help→ About** screen (circled in Fig. 10). This revision number must match the header of the latest printed VAD (circled in Fig. 11).

Fig. 10.
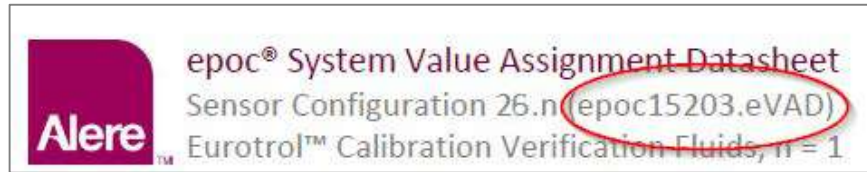
Fig. 11.

Removing an eVAD file from use.

If needed, the eVAD file may be removed from use. Press **Remove current eVAD** and select **OK** (Fig. 12).
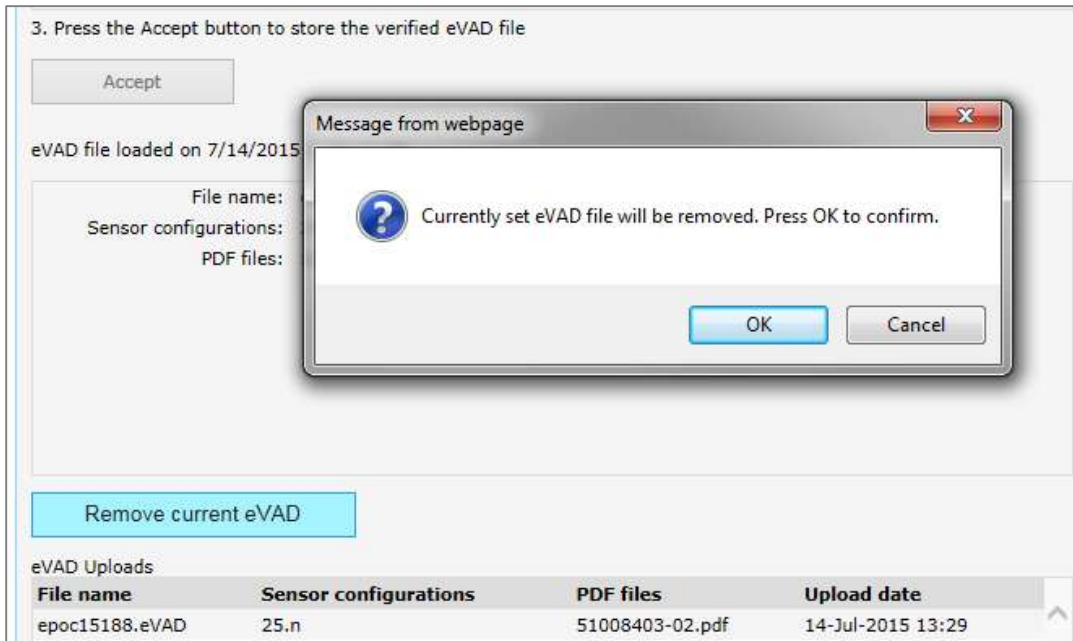
Fig. 12.

eVAD file loaded on 7/14/2015 1:29:12 PM

File name:
Sensor configurations:
PDF files:

Remove current eVAD
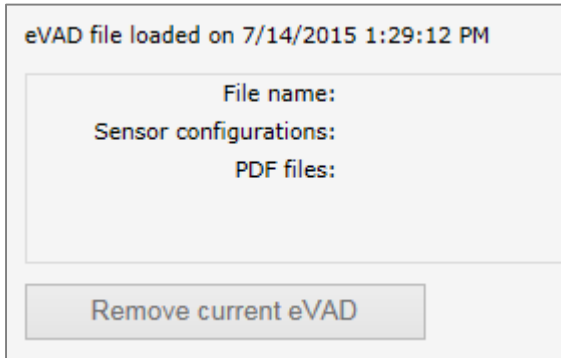
Fig. 13.

You will see that the fields are blank again and the **Remove current eVAD** button is greyed out (Fig. 13).

Each epoc Host must now be synchronized with the EDM, and the eVAD will be removed from use.

How to Run a QA Test Using an eVAD File

1. Start a QA test by selecting the **Run QA test** option, or switch to QA test while running a blood test (Fig.14).

| Fig. 14. | Fig. 15. | Fig. 16. |

epoc® System Value As
Sensor Configuration 25.
Eurotrol™ Calibration Ve

LOT 183-B433

CV1:183-1-B428

		X	R, n = 1
pH		7.012	6.952 - 7.072
pCO2	mmHg	69.9	61.5 - 78.3
	kPa	9.32	8.20 - 10.44
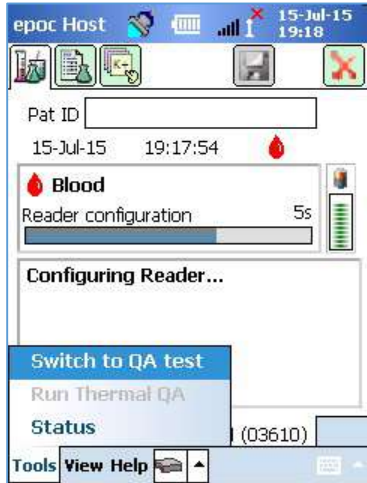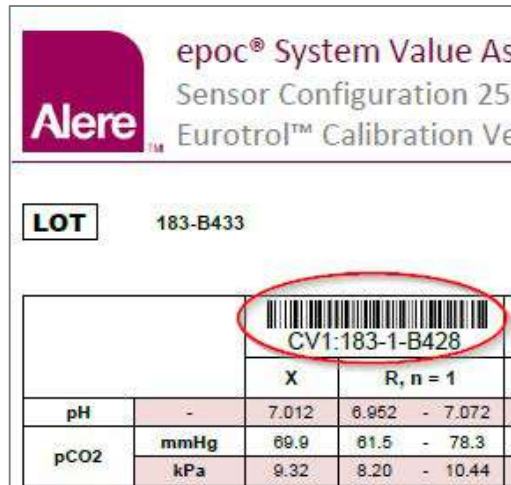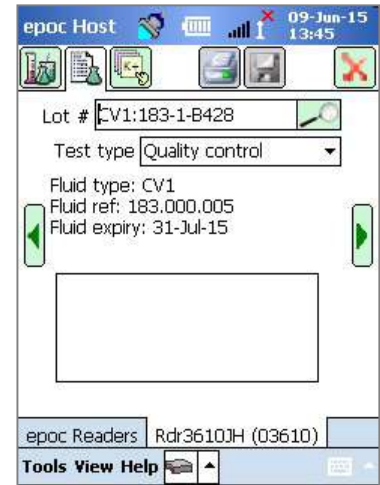
2. Scan QA fluid information:

   a. Find the fluid you want to run in the printed VAD (circled in Fig. 15; Lot # shown is an example only).

   b. Scan the appropriate VAD barcode into the Lot # field. The screen will automatically switch to the middle tab (Fig. 16) where the QA Fluid information will be shown.

3. Select a test type from the dropdown menu (Fig. 17).
Test types include:

    a. Quality Control

    b. Calibration Verification

    c. Proficiency

    d. Other

Note: QA schedules are set and maintained separately for Quality Control and Calibration Verification test types.
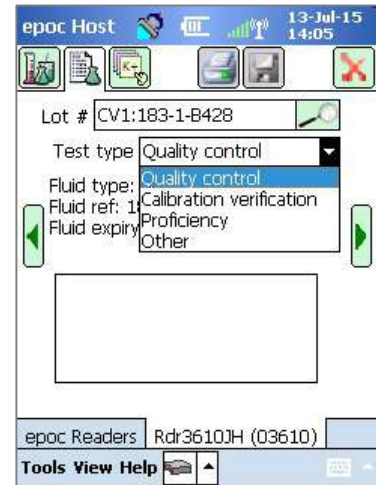
Fig. 17.

4. Select the desired analytes for the QA test.

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. (Figs. 18, 19).
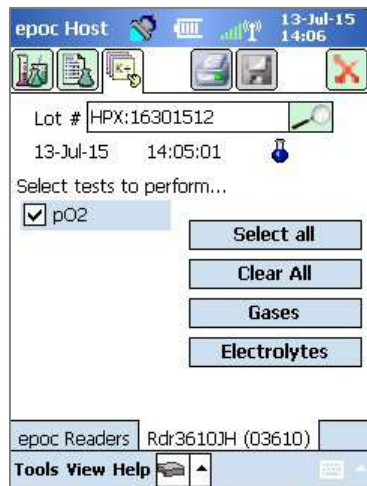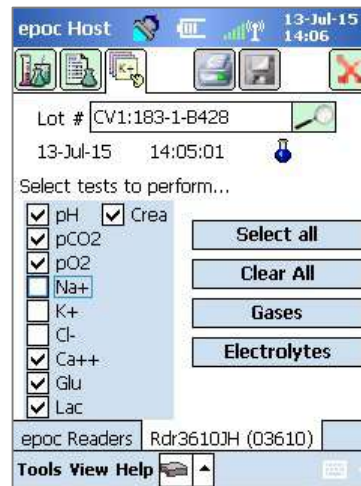
Fig. 18.   Fig. 19.

5. View the test results

When the QA test is completed, the screen will display **Pass** (Fig. 20) or **Fail** (Fig. 21). Tap on the green bar to see the complete results (Fig. 22).

Note: If the scanned fluid lot # is not found in the eVAD file, the Pass or Fail indication will be not be displayed.
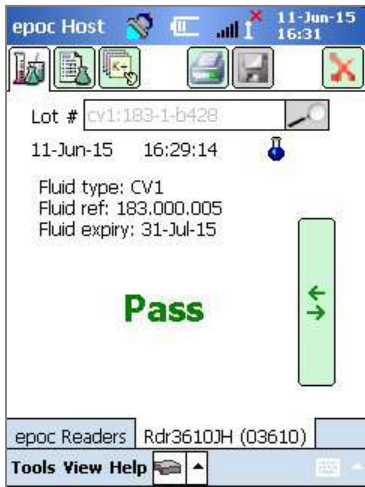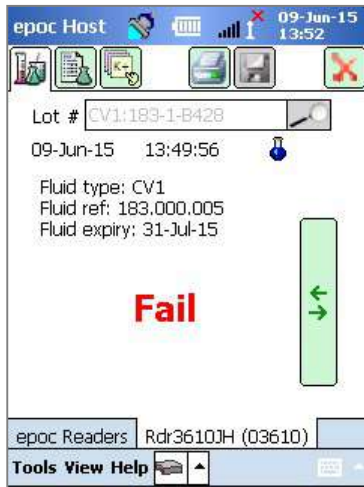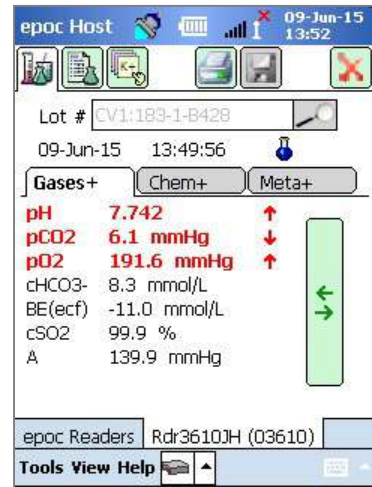
Fig. 20.   Fig. 21.   Fig. 22.

Using the soft keyboard to enter Lot #

Although scanning the Lot # barcode from a printed VAD is recommended, you may also use the soft keyboard and a stylus to type in the information into the Lot # field. **When** using the soft keyboard, you must enter the fluid level and number exactly as it appears in the VAD printouts, with a colon and no space, for example:

CV1:183-1-B428, L1:179-1-B445, HPX:16301512, HA:195-2-B427

When you are finished typing the Lot #, tapping the lookup icon will bring you to the middle tab (Fig. 23).

Unknown fluid type

If you scan or enter the barcode, and the epoc Host cannot find it in the eVAD file, the middle tab of your test information screen will show "Unknown" in all fluid fields (Fig. 23).

When this happens, do the following:

1. Check that the barcode in the printed VAD is not damaged.

2. Check that the Lot # field on the epoc Host matches exactly the Lot # in the printed VAD.

3. Check that the eVAD file installed on the epoc Host matches the printout by going to **Help→About** to verify the eVAD revision number (circled in Fig. 24). Compare this number with the header of the latest printed-out VAD (circled in Fig. 25).
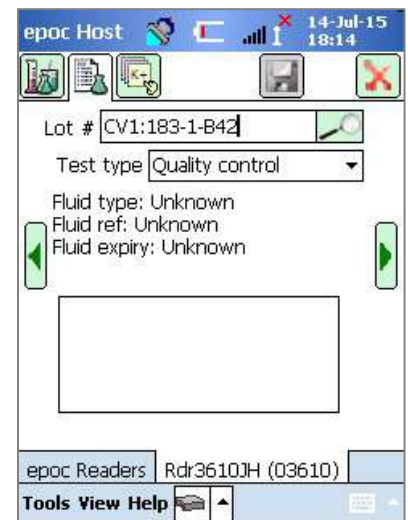
Fig. 23.

Fig. 24.
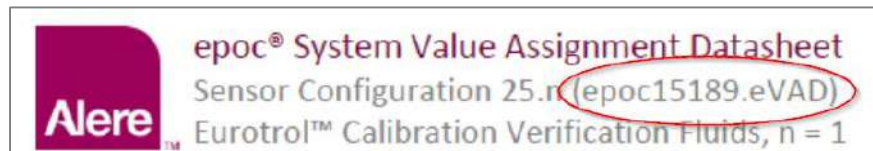
Fig. 25.

How to Configure QA Schedules and Lockout Using EDM

EDM 2.12 and higher can be used to configure and enforce periodic QA schedules and lockout in accordance with your institution's policies and procedures. QA Schedules provide the following capabilities:

- Three verification types that can help enforce QA schedules during blood testing: Lock, Ask, and Disabled. These settings determine whether to simply inform the user that the device's QC schedule has expired (and ask if they want to proceed) or strictly lock the device so blood testing cannot continue until the proper QC requirements are met.

- QA Schedules can be configured to require a certain number of QC fluid levels or specific QC fluid levels in order to help meet the compliance requirements of your institution.

- Each department can have its own QA Schedule to help enforce compliance through device QC lockout on a periodic schedule (fixed, hourly, weekly, monthly, etc.)

Important: *All required QA testing must be completed before enabling QA Schedules.*

If you enable QA schedules before QA testing is complete, the Readers may be locked out unexpectedly.

To configure QA schedules, go to **Settings → QA Schedules**. One QA schedule may be established for each type of QA test: **Quality Control, Calibration Verification, Electronic QC,** and **Thermal QA** (Fig. 26).

Fig. 26.

There are a number of options available to configure each QA schedule to meet the needs of your institution: by verification type, schedule period, or required fluids.

Verification Type

Verification type determines the behavior of the system when the QA schedule period has expired. There are 3 verification types.

1) Lock

If a QA schedule is set to **Lock**, when the QA schedule period has expired, the system will be locked out preventing operators from running blood tests until proper QA testing is completed.

*Note: Electronic QC is always set to **Lock**, and cannot be changed (Fig. 27).*

Quality control	Verification type	⦿ Lock ○ Ask ○ Disabled			
Calibration verification	Schedule period	⦿ Fixed	Every (1-8)	8	Hours ▾
Electronic QC					
Thermal QA					

Fig. 27.

2) Ask

If a QA schedule is set to **Ask**, and the QA schedule period has expired, the system will warn users that the QA schedule period has expired and ask if they would like to proceed with the test.

3) Disabled

If a QA schedule is set to **Disabled**, no schedules are applied.

Schedule period

A schedule period can be set to determine the frequency with which QA tests must be run. There are 3 options for setting a schedule period.

1) Fixed

The schedule period will be set to a fixed time period, e.g. every 30 days (Fig. 28).

Schedule period	⦿ Fixed	Every	(1-365)	30	Days ▾

Fig. 28.

2) Weekly

The schedule period will expire on the specific day of the week at a specific time, e.g. every Tuesday at 07:00 (Fig. 29).

Schedule period	○ Fixed	Every	(1-365)	30	Days ▾
	⦿ Weekly	Every	Tuesday ▾	At	07:00 ▾

Fig. 29.

3) Monthly

There are two options with monthly schedules. The schedule period can be set to expire on a specific day of the month, e.g. the first day of the month at 07:00 (Fig. 30).

Fig. 30.

Alternately, the schedule period can be set to expire on a specific week of the month, e.g. every first Monday of the month at 07:00 (Fig. 31).

Fig. 31.

4) Bi-Annual

Note: A bi-annual (twice a year) QA scheduling option is available for customers using EDM 2.13 and higher.

A month pair, six months apart, can be selected from the dropdown menu. A specific day of the month or a specific week of the month may be selected, like in the monthly option.

Fig. 32.

Grace period

The Grace period can be set when the verification type is **Lock.** The Grace period begins when the QA schedule period has expired. During the Grace period, users can still run tests, but a warning will be displayed, and the user will be asked whether or not to continue with the test. The Grace period must be shorter than the schedule period (Fig. 33).

Grace period	(0-8760)	24	Hours ∨

Fig. 33.

Warning period

The Warning period can be set when the verification type is **Lock** or **Ask**. The warning period is the period of time before the QA schedule period expires. During the Warning period, the users will receive reminders that QA is expiring. The Warning period must be shorter than the schedule period (Fig. 34).

Warning period	(0-8760)	24	Hours ∨

Fig. 34.

Required fluids

The fluid requirements that must be run to satisfy the QA schedule can be set in the Required fluids section. The required fluids can be set for either **Number of Levels** or **Specific Levels**.

1) Number of Levels

A minimum number of levels is specified. With this method, every enabled analyte must have the minimum number of successful fluid levels passed within the schedule period (Fig. 35).

Required fluids	⦿ Number of levels	1 ∨

Fig. 35.

2) Specific Levels

Specific levels are specified to be run in the schedule period. When this method is specified, the system will require that all analytes have passed tests for each selected fluid within the schedule period (Fig. 36).

Required fluids		
	○ Number of levels	1 ▾
	● Specific levels	☑ CV1/L1 ☐ CV2/L2 ☐ CV3/L3 ☐ CV4 ☐ CV5
		☑ H1 ☐ H2/HA ☐ H3/HC ☐ H4/HB ☐ H5
		☑ HPB ☑ HPX

Fig. 36.

Allow test on expired schedule?

This option is only available when the verification type is set to **Lock**. When this option is set to **Yes** (Fig. 37), Host users will be allowed to run blood tests after the grace period is over. However, only analytes with unexpired QA status will be available.

Allow test on expired schedule?	● Yes ○ No

Fig. 37.

Important: *The verification type for each schedule, corresponding warning period and grace period, as well as change requirements for fluid levels, should be set in accordance with your institutions policies and procedures.*

Assign QA schedule to departments

After configuring a QA Schedule, you must assign this QA schedule to each department where it will be used via **Settings → Departments** (Fig. 38).

Fig. 38.

Then, synchronize these departments' epoc Hosts in order for the new schedule to take effect.

Once QA schedules are configured and assigned to departments in the EDM, you must synchronize each epoc Host for the new schedules to take effect.

When the QA schedules are in effect, blood testing will be allowed only when the system is compliant with the schedules.

QA Schedule Enforcement When Running a Test

There are three possible verification types that can enforce QA schedules during blood testing: **Lock**, **Ask**, and **Disabled**.

1. Lock:

If a QA schedule's verification type is set to **Lock**, and the QA schedule period has expired, the system will be locked out preventing the operator from running blood tests.

- Each QA schedule can be configured with a warning period and/or a grace period.

- The **warning period** is the time before the schedule expires, during which the epoc Host will display a reminder that the schedule will soon expire (Fig. 39)

- The **grace period** allows the user to continue blood testing for a set period of time after the schedule expires.

  o During the grace period, a warning will appear each time a blood test is run, indicating that the schedule is expired (Fig. 40).

  o When the grace period is over, the system will be locked out immediately.
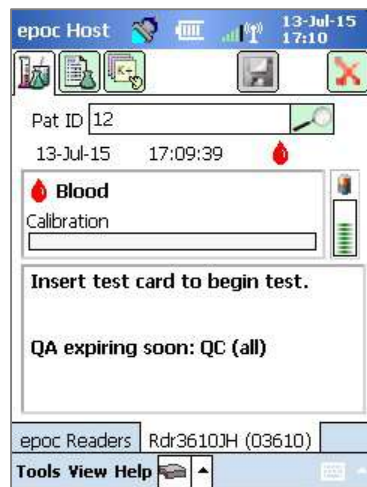
Fig. 39.
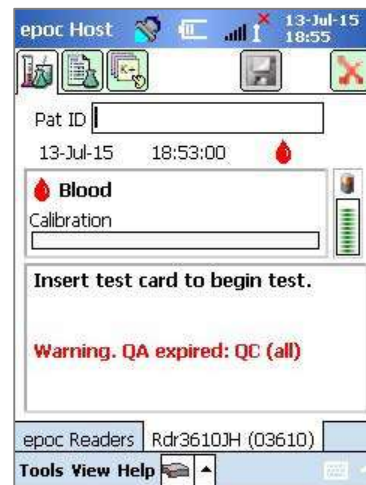
Fig. 40.

- Additionally, after a Test Card is inserted into the epoc Reader, a pop-up message will appear, asking if the user would like to proceed with the test (Fig. 41).

  o Tapping **Yes** will proceed with the test.

  o Tapping **No** will lock out the system (Fig. 42), preventing blood testing until the required QA schedule criteria is met.
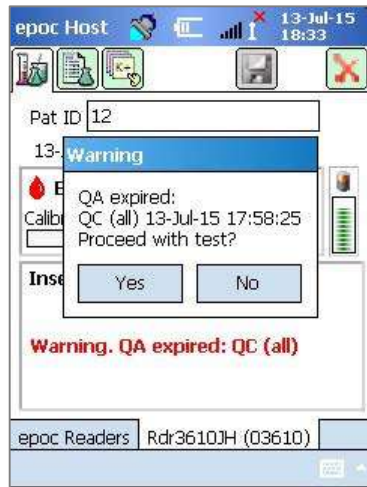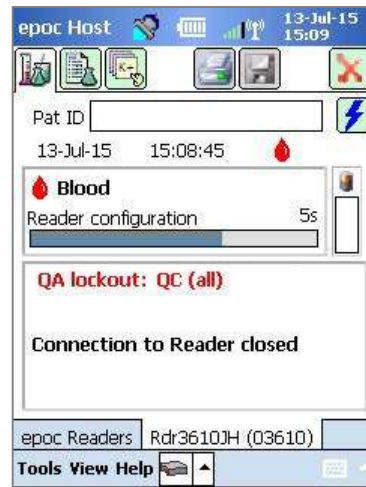

Fig. 41.

Fig. 42.

2. Ask:

If a QA schedule's verification type is set to **Ask**, and the QA schedule period has expired, the system will warn users that the QA schedule period has expired and ask if they would like to proceed with the test.

- A warning will be displayed when the schedule is expired (Fig. 43).

- When the user inserts a Test Card, a pop-up message will appear asking the user if they want to proceed with the test (Fig. 44).

  o If the user taps **No**, the epoc Host will disconnect from the Reader,

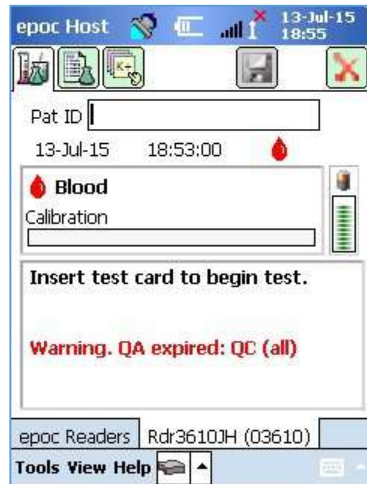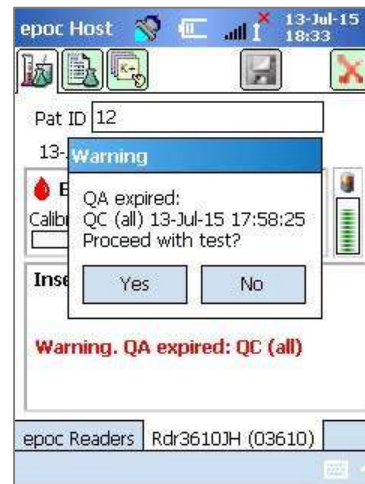 o if the user taps **Yes**, the test will proceed.

Fig. 43.

Fig. 44.

3. Disabled:

If a QA schedule's verification type is set to **Disabled**, no schedules are applied.

How to View and Print QA Information

You can access QA information in several ways:

1. Check the Reader status:

   a. While on the main Reader screen, press and hold the stylus on the Reader icon to open the **Options** Menu.

   b. Select **Status**.

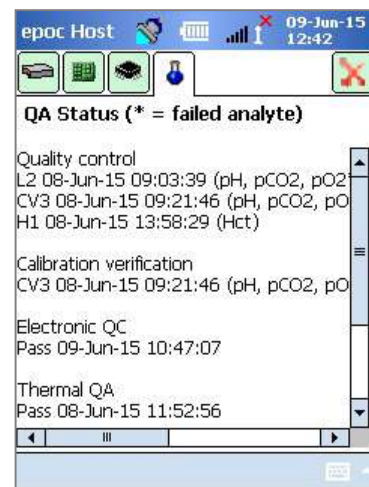   c. Open the fourth tab (Fig. 45) to display the current Reader QA status.

Fig. 45.

2. View blood test results:

   a. Go to the **View Test** option.

   b. Select a test record to view.

   c. Open the fourth tab (Fig. 46) to display the QA status at the time the test was performed.

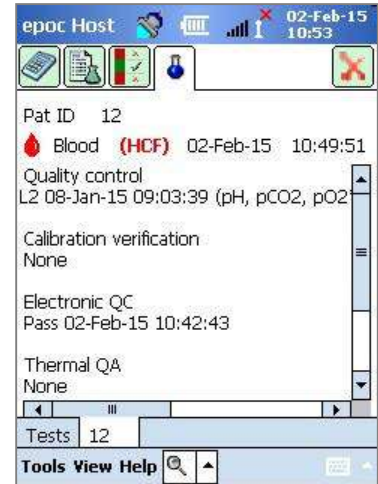This option can be enabled from the EDM **Configurations** screen.

Fig. 46.

3. Print QA information.

When the **Print QA info** option is enabled, all test result printouts will contain all QA information including the QA status at the time the test was performed.

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